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Presidential Documents

Title 3—

The President

Presidential Determination No. 2016–02 of November 13, 2015

Distribution of Department of Defense Funded Humanitarian Assistance in Syria

Memorandum for the Secretary of Defense

By the authority vested in me as President by the Constitution and the laws of the United States, including section 2249a(b)(1)(B) of title 10, United States Code, I hereby:

Determine that section 2249a(a) of title 10, United States Code, would impede the distribution of urgently needed humanitarian assistance in Syria to alleviate the current refugee crisis, as well as other United States Government objectives in the Middle East for stability and humanitarian relief; and

Waive the prohibition in section 2249a(a) of title 10, United States Code, for humanitarian reasons and to the extent necessary to allow the Department of Defense to carry out the purposes of section 2561 of title 10, United States Code, for the distribution of humanitarian assistance into Syria.

You are authorized and directed to publish this determination in the *Federal Register.*

THE WHITE HOUSE,
Washington, November 13, 2015

[FR Doc. 2015–29569
Filed 11–17–15; 8:45 am]
Billing code 5000–04–P

Rules and Regulations

Federal Register

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

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NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2015–0186]

RIN 3150–AJ65

List of Approved Spent Fuel Storage Casks: NAC International, Inc., MAGNASTOR® Cask System; Certificate of Compliance No. 1031, Amendment Nos. 0–3, Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the NAC International, Inc. (NAC), MAGNASTOR® Cask System listing within the ''List of approved spent fuel storage casks'' to include Revision 1 to Amendment Nos. 0 (the initial Certificate), 1, 2, and 3 to Certificate of Compliance (CoC) No. 1031. Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 makes changes to the Technical Specifications (TSs), including correcting a typographical error in two actual boron loadings in TS 4.1.1(a), and revising the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

DATES: The direct final rule is effective February 1, 2016, unless significant adverse comments are received by December 18, 2015. If the direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0186. Address questions about NRC dockets to Carol Gallagher, telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Email comments to: *Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3781; email: *Solomon.Sahle@nrc.gov.*

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0186 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–2015–0186.
- 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, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0186 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should

inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Procedural Background

This rule is limited to the changes contained in Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 and does not include other aspects of the MAGNASTOR® Cask System design. The NRC is using the ''direct final rule'' procedure to issue this amendment because it represents a limited and routine change to an existing CoC that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured. The amendment to the rule will become effective on February 1, 2016. However, if the NRC receives significant adverse comments on this direct final rule by December 18, 2015, the NRC will publish a document that withdraws this action, and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rule section of this issue of the **Federal Register**. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

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

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

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

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

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

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

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, CoC, or TSs.

For detailed instructions on submitting comments, please see the **ADDRESSES** section of this document.

III. Background

Section 218(a) of the Nuclear Waste Policy Act (NWPA) of 1982, as amended, requires that ''the Secretary [of the U.S. Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [U.S. Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the NWPA states, in part, that ''[the Commission] shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule which added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L within 10 CFR part 72 entitled, ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs.

The NRC issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC MAGNASTOR® Cask System design to add Amendment No. 0 to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No.1031. Subsequently on June 15, 2010 (75 FR 33678), the NRC issued a final rule adding Amendment No. 1 to CoC No. 1031 to the list of NRC-approved cask designs in 10 CFR 72.214. Similar final rules were issued on November 14, 2011 (76 FR 70331), and June 25, 2013 (78 FR 37927), to add Amendment Nos. 2 and 3 to CoC No. 1031, respectively, to the list of NRC-approved cask designs in 10 CFR 72.214.

By letter dated June 5, 2014 (ADAMS Accession No. ML14160A856), NAC submitted a technical deficiency report for the calculation error associated with the additional cooling time required for fuel assemblies that contain nonfuel hardware—one issue sought to be addressed by this revision. In its letter, NAC stated that Duke Energy Carolinas, LLC (Duke Energy), hold the only two general licenses (Catawba Nuclear Station and McGuire Nuclear Station) that are loading and storing casks using Amendment No. 2 to CoC No. 1031; and that Zion*Solutions* is the only general licensee currently loading and storing casks using Amendment No. 3 to CoC No. 1031. According to NAC, no casks manufactured under CoC No. 1031, Amendment Nos. 0 and 1, have been purchased by a general licensee. Subsequently, NAC contacted the licensees loading and storing casks Amendment Nos. 2 and 3 to CoC No. 1031 to notify them of the errors and to determine whether any loaded casks did not meet or planned loading would not meet the correct additional cool times.

In its revision request dated January 14, 2015, NAC provided letters from both Duke Energy and Zion*Solutions* discussing the actions Duke Energy and Zion*Solutions* took after being notified of the errors. Duke Energy established administrative controls to ensure that all loaded storage casks will meet the proposed cooling time limits in Table B2–5, which are more conservative than the additional cooling time limits in Table B2–5 of the TSs for Amendment No. 2. Duke Energy evaluated the five already-loaded storage systems to ensure compliance with NAC's proposed Table B2–5 (correct additional cooling times for spent fuel assemblies that contain control components). Duke Energy determined that all five already-loaded systems meet NAC's proposed Table B2–5. Additionally, Duke Energy stated that the five storage casks loaded since Duke Energy implemented administrative controls to ensure compliance with NAC's proposed Table B2–5 also meet both the TSs and NAC's proposed Table B2–5. Duke Energy documented these results within the Duke Energy corrective action program.

Zion*Solutions* initiated a condition report to review the loading records of the 20 already-loaded storage systems and those storage systems that Zion*Solutions* planned to continue loading using this amendment. Zion*Solutions* also established administrative controls to ensure that all loaded storage casks will meet the proposed cooling time limits in NAC's proposed Table B2–5, which are more conservative than the additional cooling time limits in Table B2–5 of the TSs for Amendment No. 3.

IV. Discussion of Changes

By application dated June 20, 2014 (ADAMS Accession No. ML14174B095), as supplemented January 14, 2015 (ADAMS Accession No. ML15016A047), NAC submitted an application for revision to Amendment Nos. 0 (the initial certificate), 1, 2, and 3 to CoC No. 1031, MAGNASTOR® Cask System. Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 makes changes to the TSs, including correcting a typographical error in two actual boron loadings in TS 4.1.1(a), and revising the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

As documented in the Safety Evaluation Reports (SERs) (ADAMS Accession Nos. ML15180A092, ML15180A141, ML15180A220, and ML15180A281), for Revision 1 to Amendment Nos. 0–3 to CoC No. 1031, the NRC staff performed detailed safety evaluations of the proposed CoC revision request. There are no significant changes to cask design requirements in the proposed CoC revision. Considering the specific design requirements for each accident condition, the design of the cask would prevent loss of containment, shielding, and criticality control. If there is no loss of containment, shielding, or criticality control, the environmental impacts would be insignificant. This amendment does not reflect a significant change in design or fabrication of the cask. In addition, any resulting occupational exposure or offsite dose rates from the implementation of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 would remain well within the 10 CFR part 20 limits. Therefore, the proposed CoC changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents.

This direct final rule revises the MAGNASTOR® Cask System listing in 10 CFR 72.214 by adding Revision 1 to Amendment Nos. 0–3 to CoC No. 1031. The amendment consists of the changes previously described, as set forth in the revised CoC and TSs. The revised TSs are identified in the SER.

The revised MAGNASTOR® cask design, when used under the conditions specified in the CoC, the TS, and the NRC's regulations, will meet the requirements of 10 CFR part 72; therefore, adequate protection of public health and safety will continue to be ensured. When this direct final rule becomes effective, persons who hold a general license under 10 CFR 72.210 may load spent nuclear fuel into MAGNASTOR® Cask Systems that meet the criteria of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 under 10 CFR 72.212.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC will revise the MAGNASTOR® Cask System design listed in 10 CFR 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this direct final rule is classified as Compatibility Category ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR. Although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

VII. Plain Writing

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

VIII. Environmental Assessment and Finding of No Significant Environmental Impact

A. The Action

The action is to amend 10 CFR 72.214 to revise the MAGNASTOR® Cask System listing within the ''List of approved spent fuel storage casks'' to include Revision 1 to Amendment Nos. 0–3 to CoC No. 1031. Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact on the basis of this environmental assessment.

B. The Need for the Action

This direct final rule amends the CoC for the MAGNASTOR® Cask System design within the list of approved spent fuel storage casks that power reactor licensees can use to store spent fuel at reactor sites under a general license. Specifically, Revision 1 to Amendment Nos. 0–3 to CoC No. 1031, corrects a typographical error in two actual boron loadings in TS 4.1.1(a), and revises the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

C. Environmental Impacts of the Action

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was initially analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for this amendment tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act.

The NAC MAGNASTOR® Cask System is designed to mitigate the effects of design basis accidents that

could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an Independent Spent Fuel Storage Installation (ISFSI), the type of facility at which a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

Considering the specific design requirements for each accident condition, the design of the cask would prevent loss of containment, shielding, and criticality control. If there is no loss of confinement, shielding, or criticality control, the environmental impacts would be insignificant. This amendment does not reflect a significant change in design or fabrication of the cask. There are no significant changes to cask design requirements in the proposed CoC amendment. In addition, because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of Revision 1 to Amendments Nos. 0–3 to CoC No. 1031 would remain well within the 10 CFR part 20 limits. Therefore, the proposed CoC revision will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. The NRC staff documented its safety findings in the SERs for these revisions.

D. Alternative to the Action

The alternative to this action is to deny approval of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 and end the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent nuclear fuel into MAGNASTOR® Cask Systems in accordance with the changes described in proposed Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 would have to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, interested licensees would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee. Therefore, the environmental impacts would be the same or less than the action.

E. Alternative Use of Resources

Approval of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 would result in no irreversible commitments of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in 10 CFR part 51. Based on the foregoing environmental assessment, the NRC concludes that this direct final rule entitled, ''List of Approved Spent Fuel Storage Casks: NAC International, Inc., MAGNASTOR® Cask System; Certificate of Compliance No. 1031, Amendment Nos. 0–3, Revision 1,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any information collection requirements and, therefore, is not subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and NAC. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if it notifies the NRC in advance, the spent fuel is stored under the conditions specified in the cask's CoC, and the conditions of the general license are met. A list of NRC-approved cask designs is contained in 10 CFR 72.214. The NRC issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC MAGNASTOR® Cask System design to add Amendment No. 0 to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No. 1031. Subsequently on June 15, 2010 (75 FR 33678), the NRC issued a final rule adding Amendment No. 1 to CoC No. 1031 to the list of NRC-approved cask designs in 10 CFR 72.214. Similar final rules were issued on November 14, 2011 (76FR 70331), and June 25, 2013 (78 FR 37927), to add Amendment Nos. 2 and 3 to CoC No. 1031, respectively, to the list of NRC-approved cask designs in 10 CFR 72.214.

On June 20, 2014, as supplemented January 14, 2015, NAC submitted an application to revise the MAGNASTOR® Cask Systems as described in Section IV, ''Discussion of Changes,'' of this document.

The alternative to this action is to withhold approval of Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into the MAGNASTOR® Cask System under the changes described in Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the SERs and the environmental assessment, the direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of the direct final rule are commensurate

with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory, and therefore, this action is recommended.

XII. Backfitting and Issue Finality

The NRC has determined that the backfit rule (10 CFR 72.62) does not apply to this direct final rule. Therefore, a backfit analysis is not required. This direct final rule revises Amendment Nos. 0–3 for CoC No. 1031 for the MAGNASTOR® Cask System, as currently listed in 10 CFR 72.214, ''List of approved spent fuel storage casks.'' Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 corrects a typographical error in two actual boron loadings in TS 4.1.1(a), and revises the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

Although NAC has manufactured casks under existing CoC No. 1031, Amendment Nos. 0–3, that are being revised by this final rule, NAC, as the vendor, is not subject to backfitting protection under 10 CFR 72.62. Moreover, NAC requested these changes and has requested to apply it to the existing casks manufactured under Amendment Nos. 0–3. Therefore, even if the vendor were deemed to be an entity protected from backfitting, this request represents a voluntary change and is not backfitting for the vendor.

Under 10 CFR 72.62, general licensees are entities that are protected from backfitting. However, according to NAC, no general licensees have purchased the systems under CoC No. 1031, Amendment Nos. 0 and 1, which are, in part, the subject of this revision. Therefore, the changes in CoC No. 1031, Amendment Nos. 0 and 1, which are approved in this direct final rule do not fall within the definition of backfitting under 10 CFR 72.62 or 10 CFR 50.109(a)(1), or otherwise represent an inconsistency with the issue finality provisions applicable to combined licenses in 10 CFR part 52 for general licensees.

According to NAC, casks under CoC No. 1031, Amendment Nos. 2 and 3, have been provided to two general licensees (Duke Energy Carolinas, LLC, loaded under CoC No. 1031, Amendment No. 2; and Zion*Solutions* loaded under CoC No. 1031, Amendment No. 3). General licensees are required, pursuant to 10 CFR 72.212, to ensure that each cask conforms to the terms, conditions, and specifications of a CoC, and that each cask can be safely used at the specific site in question. Because the casks delivered under CoC No. 1031, Amendment Nos. 2 and 3, now must be evaluated under 10 CFR 72.212 consistent with Revision 1 to Amendment Nos. 2 and 3 to CoC No. 1031, this change in the evaluation method and criteria constitutes a change in a procedure required to operate an ISFSI and, therefore, would constitute backfitting under 10 CFR 72.62(a)(2).

However, in this instance, NAC has provided documentation from the general licensees voluntarily indicating their lack of objection to Revision 1 to, Amendment Nos. 2 and 3 to CoC No. 1031. Specifically, in this instance, both licensees indicated their intention to upgrade their existing CoC No. 1031, Amendment Nos. 2 and 3, storage fleet to Amendment Nos. 4 or 5 of CoC No. 1031. These later amendments to CoC No. 1031 are consistent with the corrections being made in this revision. Therefore, although the general licensees are entities protected from backfitting, this request represents a voluntary change and is not backfitting. In order to provide general licensees adequate time to implement the revised CoC in the event that they have not upgraded to Amendment Nos. 4 or 5 by the time these revisions become effective, the revised CoC also incorporates a condition that provides general licensees 180 days from the effective date of Revision 1, for each revised certificate, to implement the changes authorized by this revision and to perform the required evaluation.

In addition, the changes in Revision 1 to CoC No. 1031, Amendment Nos. 0–3to CoC No. 1031, do not apply to casks which were manufactured to other amendments of CoC No. 1031, and, therefore, have no effect on current ISFSI licensees using casks which were manufactured to other amendments of CoC No. 1031. For these reasons, NRC approval of Revision 1 to, Amendment Nos. 0–3 to CoC No. 1031, does not constitute backfitting for users of the MAGNASTOR® Cask System which were manufactured to other amendments of CoC No. 1031, under 10 CFR 72.62, 10 CFR 50.109(a)(1), or the issue finality provisions applicable to combined licenses in 10 CFR part 52.

Accordingly, no backfit analysis or additional documentation addressing the issue finality criteria in 10 CFR part 52 has been prepared by the staff.

XIII. Congressional Review Act

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

XIV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No.
Proposed CoC No. 1031, Amendment No. 0, Revision 1	ML15180A230.
Proposed CoC No. 1031 Amendment No. 0, Revision 1, TS Appendix A	ML15180A238.
Proposed CoC No. 1031 Amendment No. 0, Revision 1, TS Appendix B	ML15180A270.
Proposed SER for CoC No. 1031 Amendment No. 0, Revision 1	ML15180A281.
Proposed CoC No. 1031, Amendment No. 1, Revision 1	ML15180A161.
Proposed CoC No. 1031 Amendment No. 1, Revision 1, TS Appendix A	ML15180A164.
Proposed CoC No. 1031 Amendment No. 1, Revision 1, TS Appendix B	ML15180A192.
Proposed SER for CoC No. 1031 Amendment No. 1, Revision 1	ML15180A220.
Proposed CoC No. 1031, Amendment No. 2, Revision 1	ML15180A114.
Proposed CoC No. 1031, Amendment No. 2, Revision 1, TS Appendix A	ML15180A119.
Proposed TS Amendment No. 2, Revision 1, TS Appendix B	ML15180A128.
Proposed SER for CoC No. 1031 Amendment No. 2, Revision 1	ML15180A141.
Proposed CoC No. 1031, Amendment No. 3, Revision 1	ML15180A033.
Proposed CoC No. 1031 Amendment No. 3, Revision 1, TS Appendix A	ML15180A077.
Proposed CoC No. 1031 Amendment No. 3, Revision 1, TS Appendix B	ML15180A087.
Proposed SER for CoC No. 1031 Amendment No. 3, Revision 1	ML15180A092

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking Web site at *http://www.regulations.gov* under Docket ID NRC–2015–0186. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2015–0186); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Hazardous waste, Indians, Intergovernmental relations, Manpower training programs, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH–LEVEL RADIOACTIVE WASTE, AND REACTOR–RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1031 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1031.

Initial Certificate Effective Date: February 4, 2009, superseded by Initial Certificate, Revision 1, on February 1, 2016.

Initial Certificate, Revision 1, Effective Date: February 1, 2016.

Amendment Number 1 Effective Date: August 30, 2010, superseded by Amendment Number 1, Revision 1, on February 1, 2016.

Amendment Number 1, Revision 1, Effective Date: February 1, 2016.

Amendment Number 2 Effective Date: January 30, 2012, superseded by Amendment Number 2, Revision 1, on February 1, 2016.

Amendment Number 2, Revision 1, Effective Date: February 1, 2016.

Amendment Number 3 Effective Date: July 25, 2013, superseded by Amendment Number 3, Revision 1, on February 1, 2016.

Amendment Number 3 Revision 1, Effective Date: February 1, 2016.

Amendment Number 4 Effective Date: April 14, 2015.

Amendment Number 5 Effective Date: June 29, 2015.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the MAGNASTOR® System.

Docket Number: 72–1031.

Certificate Expiration Date: February 4, 2029.

Model Number: MAGNASTOR®.

* * * * *

Dated at Rockville, Maryland, this 5th day of November, 2015.

For the Nuclear Regulatory Commission.

Glenn M. Tracy,

Acting, Executive Director for Operations.

[FR Doc. 2015–29424 Filed 11–17–15; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA–2011–N–0920]

RIN 0910–AG36

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Clarification of Compliance Date for Certain Food Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; clarification of compliance date for certain food establishments.

SUMMARY: The Food and Drug Administration (FDA or we) is clarifying the compliance date that we provided for certain food establishments subject to a final rule that published in the **Federal Register** of September 17, 2015. Among other things, that final rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to establish and implement hazard analysis and risk-based preventive controls for human food. We are taking this action in response to requests for clarification of the compliance date for facilities that manufacture, process, pack, or hold grade ''A'' milk or milk products and that are regulated under the National Conference on Interstate Milk Shipments (NCIMS) system.

DATES: The compliance date under the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (published on September 17, 2015 at 80 FR 55908) for grade ''A'' milk and milk products covered by NCIMS under the PMO is September 17, 2018.

FOR FURTHER INFORMATION CONTACT: Jenny Scott, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2166.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 17, 2015 (80 FR 55908), we published a final rule entitled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food'' (the final human preventive controls rule). Among other things, the final human preventive controls rule amended our regulation for current good manufacturing practice in manufacturing, packing, or holding human food to modernize it, and to add requirements for domestic and foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d) to establish and implement hazard analysis and risk-based preventive controls for human food. In the preamble to the final human preventive controls rule (80 FR 55908), we stated that the rule is effective November 16, 2015, and provided for compliance dates of 1 to 3 years in most cases.

In Comment 214 in the final human preventive controls final rule (80 FR 55908 at 55986 to 55987), we described comments that discuss facilities that comply with the Grade ''A'' PMO and are regulated under the NCIMS system, and we used the term ''PMO facilities'' as an abbreviation for these facilities. As previously discussed (78 FR 3646 at 3662; January 16, 2013), the PMO is a model regulation published and recommended by the U.S. Public Health Service/FDA for voluntary adoption by State dairy regulatory agencies to regulate the production, processing, storage and distribution of Grade ''A'' milk and milk products to help prevent milk-borne disease. Some comments recommended that we make full use of the existing milk safety system of State regulatory oversight for Grade ''A'' milk and milk products provided through the NCIMS and the food safety requirements of the PMO. Some comments asked us to exempt PMO-regulated facilities (or the PMO-regulated part of a PMO facility that also produces food products not covered by the PMO) from the requirements of the rule for hazard analysis and risk-based preventive controls, or to otherwise determine that facilities operating in compliance with the PMO are also in compliance with those requirements. These comments suggested we could, as an interim step if we find it necessary, stay the application of these requirements to PMO-regulated facilities and work with the NCIMS cooperative program to enact any modifications to the PMO as may be needed to warrant an exemption or comparability determination. In response to these comments, we established a compliance date of September 17, 2018, for ''PMO facilities'' (see Response 214, 80 FR 55908 at 55987 to 55988).

II. Clarification of the Compliance Date for Facilities Regulated Under the NCIMS System

On September 10, 2015, the Office of the Federal Register made a pre-publication copy of the final human preventive controls rule available to the public through its procedures for advance display (Ref. 1). Since September 10, 2015, we have provided opportunities for stakeholders to ask questions about the rule, through webinars and through a Web portal for submission of questions (Refs. 2 and 3). Some PMO facilities, in addition to manufacturing, processing, packing, or holding grade ''A'' milk or milk products, manufacture, process, pack, or hold other food subject to the final human preventive controls rule. Some of these facilities have asked us to clarify whether the extended compliance date for ''PMO facilities'' applies only to grade ''A'' milk and milk products covered by NCIMS under the PMO, or whether the extended compliance date applies broadly to all activities conducted by the facility (*e.g.,* activities related to other food produced at the facility).

In this document, we are clarifying that the extended compliance date of September 17, 2018, for ''PMO facilities'' applies only to grade ''A'' milk and milk products covered by NCIMS under the PMO, and not to the manufacturing, processing, packing, or holding of other food. As we discussed in Response 214 (80 FR 55908 at 55987 to 55988), we agreed that we should make use of the existing system of State regulatory oversight for Grade ''A'' milk and milk products provided through the NCIMS and the food safety requirements of the PMO. We described our reasons for deciding to extend the compliance date for ''PMO-regulated facilities'' to comply with the requirements of subparts C and G to September 17, 2018. Those reasons related to the current provisions of the PMO, the work already begun by NCIMS to modify the PMO to include all of the requirements established in the final human preventive controls rule, and complex implementation issues concerning the interstate movement of milk and milk products and imported milk. We explained that in establishing a compliance date of September 17, 2018, for PMO facilities, we considered: (1) The extent of revisions that must be made to incorporate the requirements of this rule for hazard analysis and risk-based preventive controls into the PMO; (2) the process to revise the PMO; and (3) the date at which the necessary revisions to the PMO could begin to be made. All of these discussions in the human preventive controls final rule related to the activities regulated by NCIMS under the PMO.

III. Economic Analysis of Impacts

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all 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, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of this final rule (Ref. 4). We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule is making no change to the compliance date announced for facilities regulated under the NCIMS system in the human preventive controls rule published on September 17, 2105, we have determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the 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 one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

IV. Environmental Impact, No Significant Impact

We have determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

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

VI. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Office of the Federal Register, ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food,'' September 10, 2015. Available at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-21920.pdf.*

2. FDA, ''FSMA Webinar Series: Preventive Controls for Human and Animal Food Final Rules,'' 2015. Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm461512.htm.*

3. FDA, ''Contact FDA About FSMA,'' 2015. Available at *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.*

4. FDA, ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Clarification of Compliance Date for Certain Food Establishments,'' 2015. Available at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

Dated: November 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29340 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 570

[Docket Nos. FR 5797–I–01 and FR 5797–C–02]

RIN 2506–AC39

Changes to Accounting Requirements for the Community Development Block Grants (CDBG) Program; Correction

AGENCY: Office of the General Counsel, HUD.

ACTION: Interim final rule; correction.

SUMMARY: This document corrects a technical error in HUD's interim final rule on CDBG accounting requirements, published November 12, 2015.

DATES: *Effective date:* December 14, 2015.

FOR FURTHER INFORMATION CONTACT: Stanley Gimont, Director, Office of Block Grant Assistance, Department of Housing and Urban Development, Office of Community Planning and Development, 451 7th Street SW., Suite 7286, Washington, DC 20410 at 202–708–3587, (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service, toll-free, at 800–877–8339.

SUPPLEMENTARY INFORMATION: HUD published a document in the **Federal Register** on November 12, 2015, at 80 FR 69864, amending the accounting requirements for the CDBG program, including 24 CFR 570.489. The amendments included clarification of how HUD determines compliance with planning and administration cost limits. In the preamble to the rule, at page 69867, first column, HUD stated that the regulations revised by rule modify the limits on administrative and planning expenses by adding to the existing compliance test a new test for grants with an origin year of 2015and subsequent years, which would continue to remain in place for all grants. However, language was inadvertently included in the regulatory text that limited the existing test to CDBG grants with an origin year prior to 2015. This document corrects that limiting language.

Correction

In interim final rule FR Doc. 2015–28700, published on November 12, 2015 (80 FR 69864), make the following correction:

On page 69872, in the first column, in § 570.489, correct paragraph (a)(3)(ii) to read as follows:

§ 570.489 Program administrative requirements.

(a) * * *

(3) * * *

(ii) The combined expenditures by the State and its funded units of general local government for planning, management, and administrative costs shall not exceed 20 percent of the aggregate amount of the origin year grant, any origin year grant funds reallocated by HUD to the State, and the amount of any program income received during the program year.

* * * * *

Dated: November 13, 2015.

Camille Acevedo,

Associate General Counsel for Legislation and Regulations.

[FR Doc. 2015–29478 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2509

RIN 1210–AB74

Interpretive Bulletin Relating to State Savings Programs That Sponsor or Facilitate Plans Covered by the Employee Retirement Income Security Act of 1974

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Interpretive bulletin.

SUMMARY: This document sets forth the views of the Department of Labor (Department) concerning the application of the Employee Retirement Income Security Act of 1974 (ERISA) to certain state laws designed to expand the retirement savings options available to private sector workers through ERISA-covered retirement plans. Concern over adverse social and economic consequences of inadequate retirement savings levels has prompted several states to adopt or consider legislation to address this problem. The Department separately released a proposed regulation describing safe-harbor conditions for states and employers to avoid creation of ERISA-covered plans as a result of state laws that require private sector employers to implement in their workplaces state-administered payroll deduction IRA programs (auto-IRA laws). This Interpretive Bulletin does not address such state auto-IRA laws.

DATES: This interpretive bulletin is effective on November 18, 2015.

FOR FURTHER INFORMATION CONTACT: Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: In order to provide a concise and ready reference to its interpretations of ERISA, the Department publishes its interpretive bulletins in the Rules and Regulations section of the **Federal Register**. The Department is publishing in this issue of the **Federal Register**, ERISA Interpretive Bulletin 2015–02, which interprets ERISA section 3(2)(A), 29 U.S.C. 1002(2)(A), section 3(5), 29 U.S.C. 1002(5), and section 514, 29 U.S.C. 1144, as they apply to state laws designed to expand workers' access to retirement savings programs. Some states have adopted laws or are exploring approaches designed to expand the retirement savings options available to their private sector workers through ERISA-covered retirement plans. One of the challenges the states face in expanding retirement savings opportunities for private sector employees is uncertainty about ERISA preemption of such efforts. ERISA generally would preempt a state law that required employers to establish and maintain ERISA-covered employee benefit pension plans. The Department also has a strong interest in promoting retirement savings by employees. The Department recognizes that some employers currently do not provide pension plans for their employees. The

Department believes that it is important that employees of such employers be encouraged to save for retirement, and it is in the interest of the public that employers be encouraged to provide opportunities for their employee retirement savings. The Department therefore believes that states, employers, other plan sponsors, workers, and other stakeholders would benefit from guidance on the application of ERISA to these state initiatives.

List of Subjects in 29 CFR Part 2509

Employee benefit plans, Pensions.

For the reasons set forth in the preamble, the Department is amending Subchapter A, Part 2509 of Title 29 of the Code of Federal Regulations as follows:

Subchapter A—General

PART 2509—INTERPRETIVE BULLETINS RELATING TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974

■ 1. The authority citation for part 2509 continues to read as follows:

Authority: 29 U.S.C. 1135. Secretary of Labor's Order No. 1–2011, 77 FR 1088 (Jan. 9, 2012). Sections 2509.75–10 and 2509.75–2 issued under 29 U.S.C. 1052, 1053, 1054. Sec. 2509.75–5 also issued under 29 U.S.C. 1002. Sec. 2509.95–1 also issued under sec. 625, Public Law 109–280, 120 Stat. 780.

■ 2. Add § 2509.2015–02 to read as follows:

§ 2509.2015–02 Interpretive bulletin relating to state savings programs that sponsor or facilitate plans covered by the Employee Retirement Income Security Act of 1974.

(a) *Scope.* This document sets forth the views of the Department of Labor (Department) concerning the application of the Employee Retirement Income Security Act of 1974 (ERISA) to certain state laws designed to expand the retirement savings options available to private sector workers through ERISA-covered retirement plans. Concern over adverse social and economic consequences of inadequate retirement savings levels has prompted several states to adopt or consider legislation to address this problem.[1] An impediment to state adoption of such measures is uncertainty about the effect of ERISA's broad preemption of state laws that ''relate to'' private sector employee benefit plans. In the Department's view, ERISA preemption principles leave room for states to sponsor or facilitate ERISA-based retirement savings options for private sector employees, provided employers participate voluntarily and ERISA's requirements, liability provisions, and remedies fully apply to the state programs.

(b) *In General.* There are advantages to utilizing an ERISA plan approach. Employers as well as employees can make contributions to ERISA plans, contribution limits are higher than for other state approaches that involve individual retirement plans (IRAs) that are not intended to be ERISA-covered plans,[2] and ERISA plan accounts have stronger protection from creditors. Tax credits may also allow small employers to offset part of the costs of starting certain types of retirement plans.[3] Utilizing ERISA plans also provides a well-established uniform regulatory structure with important consumer protections, including fiduciary obligations, automatic enrollment rules, recordkeeping and disclosure requirements, legal accountability provisions, and spousal protections.

The Department is not aware of judicial decisions or other ERISA guidance directly addressing the application of ERISA to state programs that facilitate or sponsor ERISA plans, and, therefore, believes that the states, employers, other plan sponsors, workers, and other stakeholders would benefit from guidance setting forth the general views of the Department on the application of ERISA to these state initiatives. The application of ERISA in an individual case would present novel preemption questions and, if decided by a court, would turn on the particular features of the state-sponsored program at issue, but, as discussed below, the Department believes that neither ERISA section 514 specifically, nor federal preemption generally, are insurmountable obstacles to all state programs that promote retirement saving among private sector workers through the use of ERISA-covered plans.

Marketplace Approach

One state approach is reflected in the 2015 Washington State Small Business Retirement Savings Marketplace Act.[4] This law requires the state to contract with a private sector entity to establish a program that connects eligible employers with qualifying savings plans available in the private sector market. Only products that the state determines are suited to small employers, provide good quality, and charge low fees would be included in the state's ''marketplace.'' Washington State employers would be free to use the marketplace or not and would not be required to establish any savings plans for their employees. Washington would merely set standards for arrangements marketed through the marketplace. The marketplace arrangement would not itself be an ERISA-covered plan, and the arrangements available to employers through the marketplace could include ERISA-covered plans and other non-ERISA savings arrangements. The state would not itself establish or sponsor any savings arrangement. Rather, the employer using the state marketplace would establish the savings arrangement, whether it is an ERISA-covered employee pension benefit plan or a non-ERISA savings program. ERISA's reporting and disclosure requirements, protective standards and remedies would apply to the ERISA plans established by employers using the marketplace. On the other hand, if the plan or arrangement is of a type that would otherwise be exempt from ERISA (such as a payroll deduction IRA arrangement that satisfies the conditions of the existing safe harbor at 29 CFR 2510.3–2(d)), the state's involvement as organizer or facilitator of the marketplace would not by itself cause that arrangement to be covered by ERISA. Similarly, if, as in Washington State, a marketplace includes a type of

[1] For information on the problem of inadequate retirement savings, *see* the May 2015 Report of the United States Government Accountability Office (GAO), RETIREMENT SECURITY—Most Households Approaching Retirement Have Low Savings (GAO Report–15–419) (available at *www.gao.gov/assets/680/670153.pdf*). *Also see* GAO's September 2015 Report–15–566, RETIREMENT SECURITY—Federal Action Could Help State Efforts to Expand Private Sector Coverage (available at *www.gao.gov/assets/680/672419.pdf*).

[2] Some states are developing programs to encourage employees to establish tax-favored IRAs funded by payroll deductions rather than encouraging employers to adopt ERISA plans. Oregon, Illinois, and California, for example, have adopted laws along these lines. Oregon 2015 Session Laws, Ch. 557 (H.B. 2960) (June 2015); Illinois Secure Choice Savings Program Act, 2014 Ill. Legis. Serv. P.A. 98–1150 (S.B. 2758) (West); California Secure Choice Retirement Savings Act, 2012 Cal. Legis. Serv. Ch. 734 (S.B. 1234) (West). These IRA-based initiatives generally require specified employers to deduct amounts from their employees' paychecks, unless the employee affirmatively elects not to participate, in order that those amounts may be remitted to state-administered IRAs for the employees. The Department is addressing these state ''payroll deduction IRA'' initiatives separately through a proposed regulation that describes safe-harbor conditions for employers to avoid creation of ERISA-covered plans when they comply with state laws that require payroll deduction IRA programs. This Interpretive Bulletin does not address those laws.

[3] For more information, *see Choosing a Retirement Solution for Your Small Business,* a joint project of the U.S. Department of Labor's Employee Benefits Security Administration (EBSA) and the Internal Revenue Service. Available at *www.irs.gov/pub/irs-pdf/p3998.pdf.*

[4] 2015 Wash. Sess. Laws chap. 296 (SB 5826) (available at *http://app.leg.wa.gov/billinfo/summary.aspx?bill=5826&year=2015*).

plan that is subject to special rules under ERISA, such as the SIMPLE–IRA under section 101(h) of ERISA, the state's involvement as organizer or facilitator of the marketplace would not by itself affect the application of the special rules.

Prototype Plan Approach

Another potential approach is a state sponsored ''prototype plan.'' At least one state, Massachusetts, has enacted a law to allow nonprofit organizations with fewer than 20 employees to adopt a contributory retirement plan developed and administered by the state.[5] Banks, insurance companies and other regulated financial institutions commonly market prototype plans to employers as simple means for them to establish and administer employee pension benefit plans.[6] The financial institutions develop standard form 401(k) or other tax-favored retirement plans (such as SIMPLE–IRA plans) and secure IRS approval. Typically, employers may choose features such as contribution rates to meet their specific needs. Each employer that adopts the prototype sponsors an ERISA plan for its employees. The individual employers would assume the same fiduciary obligations associated with sponsorship of any ERISA-covered plans. For example, the prototype plan documents often specify that the employer is the plan's ''named fiduciary'' and ''plan administrator'' responsible for complying with ERISA, but they may allow the employer to delegate these responsibilities to others. The plan documents for a state-administered prototype plan could designate the state or a state designee to perform these functions. Thus, the state or a designated third-party could assume responsibility for most administrative and asset management functions of an employer's prototype plan. The state could also designate low-cost investment options and a third-party administrative service provider for its prototype plans.

Multiple Employer Plan (MEP) Approach

A third approach, (referenced, for example, in the ''Report of the Governor's Task Force to Ensure Retirement Security for All Marylanders''),[7] involves a state establishing and obtaining IRS tax qualification for a ''multiple employer'' 401(k)-type plan, defined benefit plan, or other tax-favored retirement savings program. The Department anticipates that such an approach would generally involve permitting employers that meet specified eligibility criteria to join the state multiple employer plan. The plan documents would provide that the plan is subject to Title I of ERISA and is intended to comply with Internal Revenue Code tax qualification requirements. The plan would have a separate trust holding contributions made by the participating employers, the employer's employees, or both. The state, or a designated governmental agency or instrumentality, would be the plan sponsor under ERISA section 3(16)(B) and the named fiduciary and plan administrator responsible (either directly or through one or more contract agents, which could be private-sector providers) for administering the plan, selecting service providers, communicating with employees, paying benefits, and providing other plan services. A state could take advantage of economies of scale to lower administrative and other costs.

As a state-sponsored multiple employer plan (''state MEP''), this type of arrangement could also reduce overall administrative costs for participating employers in large part because the Department would consider this arrangement as a single ERISA plan. Consequently, only a single Form 5500 Annual Return/Report would be filed for the whole arrangement. In order to participate in the plan, employers simply would be required to execute a participation agreement. Under a state MEP, each employer that chose to participate would not be considered to have established its own ERISA plan, and the state could design its defined contribution MEP so that the participating employers could have limited fiduciary responsibilities (the duty to prudently select the arrangement and to monitor its operation would continue to apply). The continuing involvement by participating employers in the ongoing operation and administration of a 401(k)-type individual account MEP, however, generally could be limited to enrolling employees in the state plan and forwarding voluntary employee and employer contributions to the plan. When an employer joins a carefully structured MEP, the employer is not the ''sponsor'' of the plan under ERISA, and also would not act as a plan administrator or named fiduciary. Those fiduciary roles, and attendant fiduciary responsibilities, would be assigned to other parties responsible for administration and management of the state MEP.[8] Adoption of a defined benefit plan structure would involve additional funding and other employer obligations.[9]

For a person (other than an employee organization) to sponsor an employee benefit plan under Title I of ERISA, such person must either act directly as the employer of the covered employees or ''indirectly in the interest of an employer'' in relation to a plan.[10] ERISA sections 3(2), 3(5). A person will be considered to act ''indirectly in the interest of an employer, in relation to a plan,'' if such person is tied to the contributing employers or their employees by genuine economic or representational interests unrelated to the provision of benefits.[11] In the

[5] The retirement plan will be overseen by the Massachusetts State Treasurer's Office. Mass. Gen. Laws ch.29, § 64E (2012). In June 2014, the Massachusetts Treasurer's Office announced that the IRS had issued a favorable ruling on the proposal, but noted that additional approval from the IRS is still needed (*see www.massnonprofitnet.org/blog/nonprofitretirement/*). *See also* GAO's Report 2015 Report–15–566, RETIREMENT SECURITY—Federal Action Could Help State Efforts to Expand Private Sector Coverage, which included the following statement at footnote 93 regarding the Massachusetts program: ''The Massachusetts official told us that each participating employer would be considered to have created its own plan, characterizing the state's effort as development of a volume submitter 401(k) plan, which is a type of employee benefit plan that is typically pre-approved by the Internal Revenue Service.'' (GAO report is available at *www.gao.gov/assets/680/672419.pdf*).

[6] *See* IRS Online Publication, *Types of Pre-Approved Retirement Plans* at *www.irs.gov/Retirement-Plans/Types-of-Pre-Approved-Retirement-Plans.*

[7] Governor's Task Force to Ensure Retirement Security for All Marylanders, *1,000,000 of Our Neighbors at Risk: Improving Retirement Security for Marylanders* (February 2015) (available at *www.dllr.state.md.us/retsecurity/*).

[8] A state developing a state sponsored MEP could submit an advisory opinion request to the Department under ERISA Procedure 76–1 to confirm that the MEP at least in form has assigned those fiduciary functions to persons other than the participating employers. ERISA Procedure 76–1 is available at *www.dol.gov/ebsa/regs/aos/ao_requests.html.*

[9] State laws authorizing defined benefit plans for private sector employers (as prototypes or as multiple employer plans) might create plans covered by Title IV of ERISA and subject to the jurisdiction of the Pension Benefit Guaranty Corporation (PBGC). Subject to some exceptions, the PBGC protects the retirement incomes of workers in private-sector defined benefit pension plans. A defined benefit plan provides a specified monthly benefit at retirement, often based on a combination of salary and years of service. PBGC was created by ERISA to encourage the continuation and maintenance of private-sector defined benefit pension plans, provide timely and uninterrupted payment of pension benefits, and keep pension insurance premiums at a minimum. More information is available on the PBGC's Web site at *www.pbgc.gov.*

[10] Different rules may apply under the Internal Revenue Code for purposes of determining the plan sponsor of a tax-qualified retirement plan.

[11] *See, e.g.,* Advisory Opinion 2012–04A. *See also MDPhysicians & Associates, Inc.* v. *State Bd. Ins.,* 957 F.2d 178,185 (5th Cir.), *cert. denied,* 506 U.S. 861 (1992) (''the entity that maintains the plan and the individuals that benefit from the plan [must be]

Department's view, a state has a unique representational interest in the health and welfare of its citizens that connects it to the in-state employers that choose to participate in the state MEP and their employees, such that the state should be considered to act indirectly in the interest of the participating employers.[12] Having this unique nexus distinguishes the state MEP from other business enterprises that underwrite benefits or provide administrative services to several unrelated employers.[13]

(c) *ERISA Preemption.* The Department is aware that a concern for states adopting an ERISA plan approach is whether or not those state laws will be held preempted. ERISA preemption analysis begins with the ''presumption that Congress does not intend to supplant state law.'' *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.,* 514 U.S. 645, 654 (1995). The question turns on Congress's intent ''to avoid a multiplicity of regulation in order to permit nationally uniform administration of employee benefit plans.'' *Id.* at 654, 657. *See also Fort Halifax Packing Co.* v. *Coyne,* 482 U.S. 1, 11 (1987) (goal of ERISA preemption is to ''ensure . . . that the administrative practices of a benefit plan will be governed by only a single set of regulations.'').

Section 514 of ERISA provides that Title I ''shall supersede any and all State laws insofar as they . . . relate to any employee benefit plan'' covered by the statute. The U.S. Supreme Court has held that ''[a] law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan.'' *Shaw* v. *Delta Air Lines, Inc.,* 463 U.S. 85, 96–97 (1983) (footnote omitted); *see, e.g., Travelers,* 514 U.S. at 656. A law has a ''reference to'' ERISA plans if the law ''acts immediately and exclusively upon ERISA plans'' or ''the existence of ERISA plans is essential to the law's operation.'' *California Div. of Labor Standards Enforcement* v. *Dillingham Constr., N.A.,* 519 U.S. 316, 325–326 (1997). In determining whether a state law has a ''connection with ERISA plans,'' the U.S. Supreme Court ''look[s] both to 'the objectives of the ERISA statute as a guide to the scope of the state laws that Congress understood would survive,' as well as to the nature of the effect of the state law on ERISA plans,'' to ''determine whether [the] state law has the forbidden connection'' with ERISA plans. *Egelhoff* v. *Egelhoff,* 532 U.S. 141, 147 (2001) (quoting *Dillingham,* 519 U.S. at 325). In various decisions, the Court has concluded that ERISA preempts state laws that: (1) Mandate employee benefit structures or their administration; (2) provide alternative enforcement mechanisms; or (3) bind employers or plan fiduciaries to particular choices or preclude uniform administrative practice, thereby functioning as a regulation of an ERISA plan itself.[14]

In the Department's view, state laws of the sort outlined above interact with ERISA in such a way that section 514 preemption principles and purposes would not appear to come into play in the way they have in past preemption cases. Although the approaches described above involve ERISA plans, they do not appear to undermine ERISA's exclusive regulation of ERISA-covered plans. The approaches do not mandate employee benefit structures or their administration, provide alternative regulatory or enforcement mechanisms, bind employers or plan fiduciaries to particular choices, or preclude uniform administrative practice in any way that would regulate ERISA plans.

Moreover, the approaches appear to contemplate a state acting as a participant in a market rather than as a regulator. The U.S. Supreme Court has found that, when a state or municipality acts as a participant in the market and does so in a narrow and focused manner consistent with the behavior of other market participants, such action does not constitute state regulation. *Compare Building and Construction Trades Council* v. *Associated Builders and Contractors of Massachusetts/Rhode Island, Inc.,* 507 U.S. 218 (1993); *Wisconsin Department of Industry, Labor and Human Relations* v. *Gould,* 475 U.S. 282 (1986); *see also American Trucking Associations, Inc.* v. *City of Los Angeles,* 133 S. Ct. 2096, 2102 (2013) (Section 14501(c)(1) of the Federal Aviation Administration Authorization Act, which preempts a state ''law, regulation, or other provision having the force and effect of law related to a price, route, or service of any motor carrier,'' 49 U.S.C. 14501(c)(1), ''draws a rough line between a government's exercise of regulatory authority and its own contract-based participation in a market''); *Associated General Contractors of America* v. *Metropolitan Water District of Southern California,* 159 F.3d 1178, 1182–84 (9th Cir. 1998) (recognizing a similar distinction between state regulation and state market participation). By merely offering employers particular ERISA-covered plan options[15] (or non-ERISA plan options), these approaches (whether used separately or together as part of a multi-faceted state initiative) do not dictate how an employer's plan is designed or operated or make offering a plan more costly for employers or employees. Nor do they make it impossible for employers operating across state lines to offer uniform benefits to their employees.[16] Rather than impair federal regulation of employee benefit plans, the state laws would leave the plans wholly subject to ERISA's regulatory requirements and protections.

Of course, a state must implement these approaches without establishing standards inconsistent with ERISA or providing its own regulatory or judicial remedies for conduct governed exclusively by ERISA. ERISA's system of rules and remedies would apply to these arrangements. A contractor retained by a state using the marketplace approach would be subject

tied by a common economic or representation interest, unrelated to the provision of benefits.'' (quoting *Wisconsin Educ. Assoc. Ins. Trust* v. *Iowa State Bd.,* 804 F.2d 1059, 1063 (8th Cir. 1986)).

[12] The Department has also recognized other circumstances when a person sponsoring a plan is acting as an ''employer'' indirectly rather than as an entity that underwrites benefits or provides administrative services. *See* Advisory Opinion 89–06A (Department would consider a member of a controlled group which establishes a benefit plan for its employees and/or the employees of other members of the controlled group to be an employer within the meaning of section 3(5) of ERISA); Advisory Opinion 95–29A (employee leasing company may act either directly or indirectly in the interest of an employer in establishing and maintaining employee benefit plan).

[13] *See* Advisory Opinion 2012–04A (holding that a group of employers can collectively act as the ''employer'' in sponsoring a multiple employer plan only if the employers group was formed for purposes other than the provision of benefits, the employers have a basic level of commonality (such as the participating employers all being in the same industry), and the employers participating in the plan in fact act as the ''employer'' by controlling the plan).

[14] *Travelers,* 514 U.S. at 658 (1995); *Ingersoll-Rand Co.* v. *McClendon,* 498 U.S. 133, 142 (1990); *Egelhoff* v. *Egelhoff,* 532 U.S. 141, 148 (2001); *Fort Halifax Packing Co.* v. *Coyne,* 482 U.S. 1, 14 (1987).

[15] In the Department's view, a state law that required employers to participate in a state prototype plan or state sponsored multiple employer plan unless they affirmatively opted out would effectively compel the employer to decide whether to sponsor an ERISA plan in a way that would be preempted by ERISA.

[16] The Court in *Travelers* approved a New York statute that gave employers a strong incentive to provide health care benefits through Blue Cross and Blue Shield as opposed to other providers. The Court noted that the law did not ''mandate'' employee benefit plans or their administration, or produce such acute economic effects, either directly or indirectly, by intent or otherwise ''as to force an ERISA plan to adopt a certain scheme of substantive coverage or effectively restrict its choice of insurers.'' *Travelers,* 514 U.S. at 668. *See also De Buono* v. *NYSA–ILA Medical and Clinical Services Fund,* 520 U.S. 806, 816 (1997).

to the same ERISA standards and remedies that apply to any company offering the same services to employers. Similarly, a prototype plan or multiple employer plan program that a state offers to employers would have to comply with the same ERISA requirements and would have to be subject to the same remedies as any private party offering such products and services.[17]

Even if the state laws enacted to establish programs of the sort described above ''reference'' employee benefit plans in a literal sense, they should not be seen as laws that ''relate to'' ERISA plans in the sense ERISA section 514(a) uses that statutory term because they are completely voluntary from the employer's perspective, the state program would be entirely subject to ERISA, and state law would not impose any outside regulatory requirements beyond ERISA. They do not require employers to establish ERISA-covered plans, forbid any type of plan or restrict employers' choices with respect to benefit structures or their administration. These laws would merely offer a program that employers could accept or reject. *See Dillingham,* 519 U.S. at 325–28.

In addition, none of the state approaches described above resemble the state laws that the Court held preempted in its pre-*Travelers* ''reference to'' cases. Those laws targeted ERISA plans as a class with affirmative requirements or special exemptions. *See, e.g., District of Columbia* v. *Greater Wash. Bd. of Trade,* 506 U.S. 125, 128, 129–133 (1992) (workers' compensation law that required employee benefits ''set by reference to [ERISA] plans'') (citation omitted); *Ingersoll-Rand Co.* v. *McClendon,* 498 U.S. 133, 135–136, 140 (1990) (common law claim for wrongful discharge to prevent attainment of ERISA benefits); *Mackey* v. *Lanier Collection Agency & Serv., Inc.,* 486 U.S. 825, 828 & n.2, 829–830 (1988) (exemption from garnishment statute for ERISA plans). In the case of the state actions outlined above, any restriction on private economic activity arises, not from state regulatory actions, but from the application of ERISA requirements to the plans, service providers, and investment products, that the state, as any other private sector participant in the market, selects in deciding what it is willing to offer.

Finally, it is worth noting that even if the state laws implementing these approaches ''relate to'' ERISA plans in some sense of that term, it is only because they create or authorize arrangements that are fully governed by ERISA's requirements. By embracing ERISA in this way, the state would not on that basis be running afoul of section 514(a) because ERISA fully applies to the arrangement and there is nothing in the state law for ERISA to ''supersede.'' In this regard, section 514(a) of ERISA, in relevant part, provides that Title I of ERISA ''shall supersede any and all state laws insofar as they may now or hereafter relate to any employee benefit plan . . . .'' To the extent that the state makes plan design decisions in fashioning its prototype plan or state sponsored plan, or otherwise adopts rules necessary to run the plan, those actions would be the same as any other prototype plan provider or employer sponsor of any ERISA-covered plan, and the arrangement would be fully and equally subject to ERISA.

This conclusion is supported by the Department's position regarding state governmental participation in ERISA plans in another context. Pursuant to section 4(b)(1) of ERISA, the provisions of Title I of ERISA do not apply to a plan that a state government establishes for its own employees, which ERISA section 3(32) defines as a ''governmental plan.'' The Department has long held the view, however, that if a plan covering governmental employees fails to qualify as a governmental plan, it would still be subject to Title I of ERISA.[18] In these circumstances, the failure to qualify as a governmental plan does not prohibit a governmental employer from providing benefits through, and making contributions to, an ERISA-covered employee benefit plan.[19] Thus, the effect of ERISA is not to prohibit the state from offering benefits, but rather to make those benefits subject to ERISA. Here too, ERISA does not supersede state law to the extent it merely creates an arrangement that is fully governed by ERISA.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2015–29427 Filed 11–16–15; 4:15 pm]

BILLING CODE 4510–29–P

[17] State laws relating to sovereign immunity for state governments and their employees would have to be evaluated carefully to ensure they do not conflict with ERISA's remedial provisions.

[18] *See, e.g.,* Advisory Opinion 2004–04A.

[19] *See* Information Letter to Michael T. Scaraggi and James M. Steinberg from John J. Canary (April 12, 2004).

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket No. USCG–2015–0318]

RIN 1625–AA00

Safety Zone; Turritella FPSO, Walker Ridge 551, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a safety zone around the Turritella FPSO system, Walker Ridge 551 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Placing a safety zone around the facility will significantly reduce the threat of allisions, collisions, security breaches, oil spills, releases of natural gas, and thereby protect the safety of life, property, and the environment.

DATES: This rule is effective December 18, 2015.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2015–0318 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Rusty Wright, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504–671–2138, *rusty.h.wright@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

DHS Department of Homeland Security
FR **Federal Register**
FPSO Floating Production Storage Offloading Vessel
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf
USCG United States Coast Guard

II. Background Information and Regulatory History

Shell Exploration & Production Company requested that the Coast Guard establish a safety zone around the Turritella FPSO, which is a ship-shaped offshore production facility that stores crude oil in tanks located in its hull. It will attach to a moored turret buoy and

move in a 360 degree arc around the position 26°25′38.74″ N., 90°48′45.34″ W. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Therefore, on July 28, 2015 we published a NPRM with a request for comments entitled, ''Safety Zones: Turritella FPSO system, Walker Ridge 551, Outer Continental Shelf on the Gulf of Mexico'' in the **Federal Register** (80 FR 44910). We received no comments on the NPRM.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in 14 U.S.C. 85, 43 U.S.C. 1333, Department of Homeland Security Delegation No. 0170.1, and 33 CFR part 147, which collectively permit the establishment of safety zones for facilities located on the OCS for the purpose of protecting life, property and the marine environment.

The Coast Guard has determined that a safety zone is necessary to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. The purpose of the rule is to significantly reduce the threat of allisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the environment.

For the purpose of safety zones established under 33 CFR part 147, the deepwater area is considered to be waters of 304.8 meters (1,000 feet) or greater depth extending to the limits of the Exclusive Economic Zone (EEZ) contiguous to the territorial sea of the United States and extending to a distance up to 200 nautical miles from the baseline from which the breadth of the sea is measured. Navigation in the vicinity of the safety zone consists of large commercial shipping vessels, fishing vessels, cruise ships, tugs with tows and the occasional recreational vessel. The deepwater area also includes an extensive system of fairways.

IV. Discussion of Comments, Changes and the Final Rule

As noted above, we received no comments on our NPRM published July 28, 2015. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone extending 500 meters (1640.4 feet) around the stern of the FPSO when it is moored to the turret buoy. If the FPSO detaches from the turret buoy, the safety zone of 500 meters (1640.4) will be measured from the center point of the turret buoy. No vessel, except those attending the facility, or those less than 100 feet in length and not engaged in towing will be permitted to enter the safety zone without obtaining permission from Commander, Eighth Coast Guard District or a 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, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 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. 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.

This rule is not a significant regulatory action due to the location of the Turritella FPSO—on the Outer Continental Shelf—and its distance from both land and safety fairways. Vessel traffic can pass safely around the safety zone using alternate routes. Exceptions to this rule include vessels measuring less than 100 feet in length overall and not engaged in towing. Deviation to transit through the safety zone may be requested. Such requests will be considered on a case-by-case basis and may be authorized by the Commander, Eighth Coast Guard District or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 0 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section 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 Government

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 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 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 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone around an OCS Facility to protect life, property and the marine environment. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. The environmental analysis checklist supporting this determination and 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 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 85; 43 U.S.C. 1333; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.863 to read as follows:

§ 147.863 Turritella FPSO System Safety Zone.

(a) *Description.* The Turritella, a Floating Production, Storage and Offloading (FPSO) system is to be installed in the deepwater area of the Gulf of Mexico at Walker Ridge 551. The FPSO can swing in a 360 degree arc around the center point of the turret buoy's swing circle at 26°25′38.74″ N., 90°48′45.34″ W., and the area within 500 meters (1640.4 feet) around the stern of the FPSO when it is moored to the turret buoy is a safety zone. If the FPSO detaches from the turret buoy, the area within 500 meters (1640.4 feet) around the center point at 26°25′38.74″ N., 90°48′45.34″ W. is a safety zone.

(b) *Regulation.* No vessel may enter or remain in this safety zone except the following:

(1) An attending vessel;

(2) A vessel under 100 feet in length overall not engaged in towing; or

(3) A vessel authorized by the Commander, Eighth Coast Guard District.

Dated: October 27, 2015.

David R. Callahan,

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

[FR Doc. 2015–29449 Filed 11–17–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 147

[Docket No. USCG–2015–0320]

RIN 1625–AA00

Safety Zone; Titan SPAR, Mississippi Canyon 941, Outer Continental Shelf on the Gulf of Mexico

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is establishing a safety zone around the Titan SPAR system, located in Mississippi Canyon Block 941 on the Outer Continental Shelf (OCS) in the Gulf of Mexico. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Placing a safety zone around the facility will significantly reduce the threat of allisions, collisions, security breaches, oil spills, releases of natural gas, and thereby protect the safety of life, property, and the environment.

DATES: This rule is effective December 18, 2015.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2015–0320 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Rusty Wright, U.S. Coast Guard, District Eight Waterways Management Branch; telephone 504–671–2138, *rusty.h.wright@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking
OCS Outer Continental Shelf
SPAR A large diameter, vertical cylinder supporting a deck
USCG United States Coast Guard

II. Background Information and Regulatory History

Bennu Oil and Gas requested that the Coast Guard establish a safety zone extending 500 meters (1640.4 feet) from each point on the Titan SPAR facility structure's outermost edge located in the deepwater area of the Gulf of Mexico on the OCS. The purpose of the safety zone is to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. Therefore, on July 24, 2015 we published a NPRM with a request for comments entitled, ''Safety Zones: Titan SPAR, Mississippi Canyon 941, Outer Continental Shelf on the Gulf of Mexico'' in the **Federal Register** (80 FR 43998). We received no comments on the NPRM.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 14 U.S.C. 85, 43 U.S.C. 1333, Department of Homeland Security Delegation No. 0170.1, and Title 33, CFR part 147, which collectively permit the establishment of safety zones for facilities located on the OCS for the purpose of protecting life, property and the marine environment. The Coast Guard has determined that a

safety zone is necessary to protect the facility from all vessels operating outside the normal shipping channels and fairways that are not providing services to or working with the facility. The purpose of the rule is to significantly reduce the threat of allisions, oil spills, and releases of natural gas, and thereby protect the safety of life, property, and the environment.

For the purpose of safety zones established under 33 CFR part 147, the deepwater area is considered to be waters of 304.8 meters (1,000 feet) or greater depth extending to the limits of the Exclusive Economic Zone (EEZ) contiguous to the territorial sea of the United States and extending to a distance up to 200 nautical miles from the baseline from which the breadth of the sea is measured. Navigation in the vicinity of the safety zone consists of large commercial shipping vessels, fishing vessels, cruise ships, tugs with tows and the occasional recreational vessel. The deepwater area also includes an extensive system of fairways.

IV. Discussion of Comments, Changes and the Final Rule

As noted above, we received no comments on our NPRM published July 24, 2015. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a safety zone extending 500 meters (1640.4 feet) from each point on the Titan SPAR facility structure's outermost edge. No vessel, except those attending the facility, or those less than 100 feet in length and not engaged in towing will be permitted to enter the safety zone without obtaining permission from Commander, Eighth Coast Guard District or a 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, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

E.O.s 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. 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.

This rule is not a significant regulatory action due to the location of the Titan SPAR—on the Outer Continental Shelf—and its distance from both land and safety fairways. Vessel traffic can pass safely around the safety zone using alternate routes. Exceptions to this rule include vessels measuring less than 100 feet in length overall and not engaged in towing. Deviation to transit through the safety zone may be requested. Such requests will be considered on a case-by-case basis and may be authorized by the Commander, Eighth Coast Guard District or a designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard received 0 comments from the Small Business Administration on this rulemaking. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section 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 Government

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 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 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

(NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone around an OCS Facility to protect life, property and the marine environment. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. The environmental analysis checklist supporting this determination and 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 147

Continental shelf, Marine safety, Navigation (water).

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 147 as follows:

PART 147—SAFETY ZONES

■ 1. The authority citation for part 147 continues to read as follows:

Authority: 14 U.S.C. 85; 43 U.S.C. 1333; and Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 147.865 to read as follows:

§ 147.865 Titan SPAR Facility Safety Zone.

(a) *Description.* The Titan SPAR system is in the deepwater area of the Gulf of Mexico at Mississippi Canyon 941. The facility is located at 28°02′02″ N. 89°06′04″ W. and the area within 500 meters (1640.4 feet) from each point on the facility structure's outer edge is a safety zone.

(b) *Regulation.* No vessel may enter or remain in this safety zone except the following:

(1) An attending vessel;

(2) A vessel under 100 feet in length overall not engaged in towing; or

(3) A vessel authorized by the Commander, Eighth Coast Guard District.

Dated: October 27, 2015.

David R. Callahan,

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

[FR Doc. 2015–29448 Filed 11–17–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0376; FRL–9936–48]

2-Propenoic Acid, Polymer With Ethenylbenzene and (1-Methylethenyl)benzene; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene with a minimum average molecular weight (in amu) of 2,000 (CAS Reg. No. 52831–04–6) when used as an inert ingredient in a pesticide chemical formulation. BASF Corporation, submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene on food or feed commodities.

DATES: This regulation is effective November 18, 2015. Objections and requests for hearings must be received on or before January 19, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0376, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0376 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 19, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please

submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0376, by one of the following methods.

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

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

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP) IN–10814 filed by BASF Corporation, 100 Park Avenue, Florham Park, NJ 07932. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene (CAS Reg. No. 52831–04–6). That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. There were no comments received in response to the notice of filing.

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

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d).

2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length as specified in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

8. The polymer's minimum number average MW is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 500 and less than 25% oligomeric material below MW 1,000, and the polymer does not contain any reactive functional groups.

Thus, 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The minimum number average MW of 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene is 2,000 daltons. Generally, a polymer of this

size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

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

EPA has not found 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene to share a common mechanism of toxicity with any other substances, and 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that -2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative*.

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene.

VIII. Other Considerations

A. Existing Exemptions From a Tolerance

There are no existing tolerance exemptions for 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

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

The Codex has not established a MRL for 2-propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene.

IX. Conclusion

Accordingly, EPA finds that exempting residues of polymers of tamarind seed gum, 2-hydroxypropyl ether from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section

12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 9, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.960, add alphabetically the following polymer to the table to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
* * * * *	
2-Propenoic acid, polymer with ethenylbenzene and (1-methylethenyl)benzene, minimum number average molecular weight (in amu), 2,000	52831–04–6.
* * * * *	

[FR Doc. 2015–29466 Filed 11–17–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0179; FRL–9933–61]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerances for residues of flutriafol in or on hop, dried cones. Cheminova A/S, c/o Cheminova, Inc. requested this tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). Additionally, tolerances are being removed that were inadvertently returned from an earlier Final rule.

DATES: This regulation is effective November 18, 2015. Objections and requests for hearings must be received on or before January 19, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0179, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0179 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 19, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0179, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-for Tolerance and This Action

In the **Federal Register** of April 22, 2015 (80 FR 22466) (FRL–9925–79), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8294) by Cheminova Inc., c/o Cheminova A/S, 1600 Wilson Blvd., Suite 700, Arlington, VA 22209–2510. The petition requested that 40 CFR 180.629 be amended by establishing tolerances for residues of the fungicide flutriafol, ((±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1H–1,2,4-triazole-1-ethanol), in or on hops, dried cones at 20 parts per million (ppm). That document referenced a summary of the petition prepared by Cheminova Inc., c/o Cheminova A/S, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing. For purposes of accuracy, the Agency notes that a harmless error was made in the notice of filing publication and is correcting that misstatement here: The petition was actually filed by Cheminova A/S, c/o Cheminova, Inc.

Additionally, in the **Federal Register** of February 4, 2015 (80 FR 5946) (FRL–9922–06) EPA established tolerances for residues of flutriafol, in or on several commodities, including cotton, gin byproducts at 6.0 ppm and cotton, undelinted seed at 0.50 ppm. When establishing the general tolerances in paragraph (a) for cotton, gin byproducts at 6.0 ppm and cotton, undelinted seed at 0.50 ppm, EPA inadvertently forgot to remove the existing tolerances for cotton, gin byproducts at 0.02 ppm and cotton, undelinted seed at 0.01 ppm from the table in paragraph (d) for *Indirect or inadvertent residues.* These indirect tolerances were made redundant by the establishment of the tolerances in the *General* section at a higher level for the same commodities. Therefore, EPA is removing the cotton, gin byproducts and cotton, undelinted seed tolerances established in § 180.629(d).

III. Aggregate Risk Assessment and Determination of Safety

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

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Consistent with the mammalian toxicity profiles of the other triazole fungicides, the prevalent adverse effects following oral exposure to flutriafol were in the liver. Effects consisted of increases in liver enzyme release (alkaline phosphatase), liver weights, and histopathology findings (hepatocyte vacuolization to centrilobular hypertrophy and slight increases in hemosiderin-laden Kupffer cells, minimal to severe fatty changes, and bile duct proliferation/cholangiolar fibrosis). Progression of toxicity occurred with time as some effects were only observed at chronic durations.

Slight indications of effects in the hematopoietic system were sporadically seen in all species consisting of slight anemia, increased platelets, white blood cells, neutrophils, and lymphocytes. The effects in the neurotoxicity screening batteries were observed only at higher doses and were considered secondary effects (decreased motor activity and hindlimb grip strength, ptosis, lost righting reflex, hunched posture, and ataxia). Flutriafol showed no evidence of dermal toxicity, or immunotoxicity. Flutriafol showed no evidence of carcinogenicity in rodents or *in vitro.*

There is evidence of increased quantitative and qualitative pre- and postnatal susceptibility for flutriafol in rats and rabbits. In the first of two rat developmental toxicity studies, developmental effects (delayed ossification or non-ossification of the skeleton in the fetuses) were observed at a lower dose than that where maternal effects were observed. In the second rat developmental study, developmental effects (external, visceral, and skeletal malformations; embryo lethality; skeletal variations; a generalized delay in fetal development; and fewer live fetuses) were more severe than the decreased food consumption and body-weight gains observed in the dams at the same dose. For rabbits, intrauterine deaths occurred at a dose level that also caused adverse effects in maternal animals. In the 2-generation reproduction studies, effects in the offspring decreased litter size and percentage of live births (increased pup mortality) and liver toxicity can be attributed to the systemic toxicity of the parental animals (decreased body weight and food consumption and liver toxicity) observed at the same dose.

Flutriafol is categorized as having high oral acute toxicity in the mouse. It is categorized as having low acute toxicity via the oral, dermal and inhalation routes in rats. Flutriafol is minimally irritating to the eyes and is not a dermal irritant. Flutriafol was not shown to be a skin sensitizer when tested in guinea pigs.

Flutriafol is considered to be ''Not likely to be Carcinogenic to Humans'' based on the results of the carcinogenicity studies in rats and mice. The results of the rat chronic toxicity/carcinogenicity study and the mouse carcinogenicity study are negative for carcinogenicity. All genotoxicity studies on flutriafol showed no evidence of clastogenicity or mutagenicity.

Specific information on the studies received and the nature of the adverse effects caused by flutriafol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in the **Federal Register** of June 6, 2014 (79 FR 32666) (FRL–9910–38).

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human

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

A summary of the toxicological endpoints for flutriafol used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of June 6, 2014.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flutriafol, EPA considered exposure under the petitioned-for tolerances as well as all existing flutriafol tolerances in 40 CFR 180.629. EPA assessed dietary exposures from flutriafol in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for flutriafol. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) Nationwide Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA) conducted from 2003–2008. As to residue levels in food, EPA made the following assumptions for the acute exposure assessment: Tolerance-level residues or tolerance-level residues adjusted to account for the residues of concern for risk assessment and 100 percent crop treated (PCT). Since adequate processing studies have been submitted which indicate that tolerances for residues in/on apple juice, grape juice, dried prunes, and tomato puree are unnecessary and since tolerances for residues in/on raisin and tomato paste tolerances are established, the DEEM (ver. 7.81) default processing factors for these commodities were reduced to 1. The DEEM (ver. 7.81) default processing factors were retained for the remaining relevant commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA conducted from 2003–2008. As to residue levels in food, EPA made the following assumptions for the chronic exposure assessment: Tolerance-level residues or tolerance-level residues adjusted to account for the residues of concern for risk assessment and 100 PCT. Since adequate processing studies have been submitted which indicate that tolerances for residues in/on apple juice, grape juice, dried prunes, and tomato puree are unnecessary and since tolerances for residues in/on raisin and tomato paste tolerances are established, the DEEM (ver. 7.81) default processing factors for these commodities were reduced to 1. The DEEM (ver. 7.81) default processing factors were retained for the remaining relevant commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flutriafol does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for flutriafol. Tolerance-level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for flutriafol in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of flutriafol. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Based on the First Index Reservoir Screening Tool (FIRST), and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of flutriafol for acute exposures are estimated to be 15.9 parts per billion (ppb) for surface water and 193 ppb for ground water.

For chronic exposures assessments the EDWC's are estimated to be 5.39 ppb for surface water and 165 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 193 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 165 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Flutriafol is not registered for any specific use patterns that would result in residential exposure.

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

Flutriafol is a member of the triazole-containing class of pesticides. Although conazoles act similarly in plants (fungi) by inhibiting ergosterol biosynthesis, there is not necessarily a relationship between their pesticidal activity and their mechanism of toxicity in mammals. Structural similarities do not constitute a common mechanism of toxicity. Evidence is needed to establish that the chemicals operate by the same, or essentially the same, sequence of major biochemical events. In conazoles, however, a variable pattern of toxicological responses is found; some are hepatotoxic and hepatocarcinogenic in mice. Some induce thyroid tumors in rats. Some induce developmental, reproductive, and neurological effects in rodents. Furthermore, the conazoles produce a diverse range of biochemical events including altered cholesterol levels, stress responses, and altered DNA methylation. It is not clearly understood whether these biochemical events are directly connected to their toxicological outcomes. Thus, there is currently no evidence to indicate that conazoles share common mechanisms of toxicity and EPA is not following a cumulative risk approach based on a common mechanism of toxicity for the conazoles. For information regarding EPA's procedures for cumulating effects

from substances found to have a common mechanism of toxicity, see EPA's Web site at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

Triazole-derived pesticides can form the metabolite 1,2,4-triazole (T) and two triazole conjugates triazolylalanine (TA) and triazolylacetic acid (TAA). To support existing tolerances and to establish new tolerances for triazole-derivative pesticides, EPA conducted an initial human-health risk assessment for exposure to T, TA, and TAA resulting from the use of all current and pending uses of any triazole-derived fungicide as of September 1, 2005. The risk assessment was a highly conservative, screening-level evaluation in terms of hazards associated with common metabolites (*e.g.,* use of a maximum combination of uncertainty factors) and potential dietary and non-dietary exposures (*i.e.,* high-end estimates of both dietary and non-dietary exposures). In addition, the Agency retained the additional 10X Food Quality Protection Act (FQPA) safety factor (SF) for the protection of infants and children. The assessment included evaluations of risk for various subgroups, including those comprised of infants and children. The Agency's complete risk assessment can be found in the propiconazole reregistration docket at *http://www.regulations.gov*. Docket ID Number EPA–HQ–OPP–2005–0497.

The most recent update to that aggregate human health risk assessment for free traizoles and its conjugates was conducted on April 9, 2015. This assessment considered all proposed/registered triazole derived pesticides uses with the resulting risk less than the Agency's level of concern. An update to the aggregate human health risk assessment for free triazoles and its conjugates may be found in this current docket, docket ID number EPA–HQ–OPP–2015–0179–0014 entitled, ''Common Triazole Metabolites: Updated Aggregate Human Health Risk Assessment to Address The New Section 3 Registrations for Use of Propiconazole on Tea, Dill, Mustard Greens, Radish, and Watercress; Use of Difenoconazole on Globe Artichoke, Ginseng and Greenhouse Grown Cucumbers and Conversation of the Established Foliar Uses/Tolerances for Stone Fruit and Tree Nut Crop Groups to Fruit, Stone, Group 12–12 and the Nut, Tree, Group 14–12.; and Use of Flutriafol on Hops.''

D. Safety Factor for Infants and Children

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

2. *Prenatal and postnatal sensitivity.* The potential impact of *in utero* and perinatal flutriafol exposure was investigated in three developmental toxicity studies (two in rats, one in rabbits) and 2 multi-generation reproduction toxicity studies in rats. In the first of two rat developmental toxicity studies, increased quantitative susceptibility was observed with developmental effects (delayed ossification or non-ossification of the skeleton in the fetuses) seen at a lower dose than maternal effects. In the second rat developmental study, a qualitative susceptibility was noted. Although developmental toxicity occurred at the same dose level that elicited maternal toxicity, the developmental effects (external, visceral, and skeletal malformations; embryo lethality; skeletal variations; a generalized delay in fetal development; and fewer live fetuses) were more severe than the decreased food consumption and body-weight gains observed in the dams. For rabbits, there was in increased qualitative fetal susceptibly. Intrauterine deaths occurred at a dose level that also caused adverse effects in maternal animals. In the 2-generation reproduction studies, a qualitative susceptibility was also seen. Effects in the offspring decreased litter size and percentage of live births (increased pup mortality) and liver toxicity can be attributed to the systemic toxicity of the parental animals (decreased body weight and food consumption and liver toxicity).

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

i. The toxicity database for flutriafol is complete.

ii. There is no indication that flutriafol is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. Signs of neurotoxicity were reported in the acute and subchronic neurotoxicity studies at the highest dose only; however, these effects were primarily seen in animals that were agonal (at the point of death) and, thus, are not indicative of neurotoxicity. In addition, there was no evidence of neurotoxicity in any additional short-term or long-term toxicity studies in rats, mice, and dogs.

iii. There are no concerns or residual uncertainties for prenatal and/or postnatal toxicity. Although there is evidence for increased quantitative and qualitative susceptibility in the prenatal study in rats and rabbits and the 2-generation reproduction study rats, there are no concerns for the offspring toxicity observed in the developmental and reproductive toxicity studies for the following reasons: (1) clear NOAELs and LOAELs were established in the fetuses/offspring for each of these studies; (2) the dose-response for these effects are well-defined and characterized; (3) developmental endpoints are used for assessing acute dietary risks to the most sensitive population (females 13–49 years old) as well as all other short and intermediate-term exposure scenarios; (4) the acute reference dose for females 13–49 is 1,000 fold lower than the dose at which quantitative susceptibility in the first developmental rat study was observed; and (5) the chronic reference dose is greater than 300-fold lower than the dose at which the offspring effects were observed in the 2-generation reproduction studies.

iv. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to flutriafol in drinking water. These assessments will not underestimate the exposure and risks posed by flutriafol.

E. Aggregate Risks and Determination of Safety

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

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to flutriafol will occupy 39% of the aPAD for females 13–49 years, the population group receiving the greatest % aPAD.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flutriafol from food and water will utilize 96% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. There are no residential uses for flutriafol.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there is no short-term residential exposure, and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for flutriafol.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because there is no intermediate-term residential exposure, and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for flutriafol.

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

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology gas chromotography/nitrogen-phosphorus detector (GC/NPD) for the proposed tolerances is available to enforce the tolerances recommended herein is available to enforce the tolerance expression.

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

B. International Residue Limits

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

The Codex has not established a MRL for flutriafol.

V. Conclusion

Therefore, tolerances are established for residues of flutriafol, ((±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1H-1,2,4-triazole-1-ethanol), in or on hop, dried cones at 20 ppm. Additionally, the tolerances for cotton, gin byproducts, and cotton, undelinted seed established in 180.629(d) are being removed.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

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

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

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

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

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 10, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

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

■ 2. In § 180.629:

■ a. Add alphabetically the commodity ''Hop, dried cones'' to the table in paragraph (a).

■ b. Remove the commodities ''Cotton, gin byproducts,'' and ''Cotton, undelinted seed'' from the table in paragraph (d).

The addition reads as follows:

§ 180.629 Flutriafol; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Hop, dried cones	20
* * * * *	

* * * * *

[FR Doc. 2015–29462 Filed 11–17–15; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 174, and 179

[Docket No. PHMSA–2012–0082 (HM–251)]

RIN 2137–AE91

Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Response to appeals.

SUMMARY: On May 8, 2015, the Pipeline and Hazardous Materials Safety Administration, in coordination with the Federal Railroad Administration (FRA), published a final rule entitled ''Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains,'' which adopted requirements designed to reduce the consequences and, in some instances, reduce the probability of accidents involving trains transporting large quantities of Class 3 flammable liquids. The Hazardous Materials Regulations provide a person the opportunity to appeal a PHMSA action, including a final rule. PHMSA received six appeals regarding the final rule, one of which was withdrawn. This document responds to the five remaining appeals submitted by the Dangerous Goods Advisory Council (DGAC), American Chemistry Council (ACC), Association of American Railroads (AAR), American Fuel & Petrochemical Manufacturers (AFPM), and jointly the Umatilla, Yakama, Warm Springs, and Nez Perce tribes (Columbia River Treaty Tribes) and the Quinault Indian Nation (Northwest Treaty Tribes).

DATES: November 18, 2015.

ADDRESSES: You may find information on this rulemaking and the associated appeals (Docket No. PHMSA–2012–0082) at the Federal eRulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ben Supko, (202) 366–8553, Standards and Rulemaking Division, Pipeline and Hazardous Materials Safety Administration or Karl Alexy, (202) 493–6245, Office of Safety Assurance and Compliance, Federal Railroad Administration, 1200 New Jersey Ave. SE., Washington, DC 20590.

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III. Summary

I. Background

Under 49 CFR 106.110–106.130,[1] a person may appeal a PHMSA action, including a final rule. Appeals must reach PHMSA no later than 30 days after the date PHMSA published the regulation. On May 8, 2015, PHMSA, in coordination with FRA, published a final rule entitled ''Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains'' (HM–251, 80 FR 26644) (the final rule). The final rule adopted requirements designed to reduce the consequences and, in some instances, reduce the probability of, accidents involving trains transporting large quantities of flammable liquids. The final rule defines certain trains transporting large volumes of flammable liquids as ''high-hazard flammable trains'' (HHFT)[2] and regulates their operation in terms of enhanced tank car designs, speed restrictions, braking systems, and routing. In response to the final rule, PHMSA received six appeals, one of which was withdrawn. The five active appeals were submitted by the DGAC, ACC, AAR, AFPM, and jointly the Columbia River Treaty Tribes and the Northwest Treaty Tribes.

Section 106.130 requires PHMSA to notify those who appeal, in writing, of the action on the appeal, within 90 days after the date that PHMSA published the action being appealed. Based on the final rule's publication date of May 8, 2015, PHMSA was required to provide a response or notice of delay by August 6, 2015. On August 6, 2015, PHMSA posted a notice of delay on its Web site and subsequently published that notice in the **Federal Register** on August 10, 2015 (Notice 15–14; 80 FR 47987).[3]

This document summarizes and responds to the appeals of the DGAC,

[1] All references to sections of the regulations in this document refer to title 49 CFR.

[2] HHFT ''means a single train transporting 20 or more loaded tank cars of a Class 3 flammable liquid in a continuous block or a single train carrying 35 or more loaded tank cars of a Class 3 flammable liquid throughout the train consist.'' § 171.8.

[3] *http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_79961459E55D0ADB8FF510CF4A93EC93E3A00000/filename/Notice_No_15_14_Delay_in_Appeals.pdf*

ACC, AAR, AFPM, and jointly the Columbia River Treaty Tribes and the Northwest Treaty Tribes. PHMSA has consolidated the appeals and structured this document to address the content of the appeals by topic area. The topic areas include (1) Scope of Rulemaking; (2) Tribal Impacts and Consultation; (3) Information Sharing/Notification; (4) Testing and Sampling Programs; (5) Retrofit Timeline and Tank Car Reporting Requirements; (6) Thermal Protection for Tank Cars; and (7) Advanced Brake Signal Propagation Systems. In each section, PHMSA summarizes the pertinent appeals on the topic area, by appellant, and then provides PHMSA and FRA's response to the appeals on that topic area. The document concludes with a summary of further actions in response to the appeals.

II. Response to Appeals

A. Scope of Rulemaking

Dangerous Goods Advisory Council

DGAC expresses concern that the definition of ''HHFT'' as adopted in the final rule would subject manifest trains [4] to the applicable additional requirements for HHFTs. DGAC contends that shippers cannot know if tank cars they offer to a carrier will be assembled into a manifest train that meets the definition of HHFT, triggering requirements for those tank cars to meet the enhanced standards the final rule establishes. Additionally, DGAC states that at the time of pick-up, railroads cannot make this determination either. DGAC expects that the inability of both shippers and carriers to determine if a future manifest train will be an HHFT will necessitate approximately 40,000 additional DOT Specification 111 (DOT–111) tank cars to be retrofitted to the DOT Specification 117R (DOT–117R) requirements or replaced with the new DOT Specification 117 (DOT–117) tank cars under the final rule. DGAC believes that the definition of HHFT in the final rule is harmfully broad and should be revised to limit its applicability to railroad operations only and not to determine a tank car specification.

DGAC also states that both the term and definition for a ''high-hazard flammable unit train'' (HHFUT) [5] were not proposed in the NPRM. DGAC believes the addition of a new definition for HHFUT is unnecessary and requests that the definition be eliminated.

DGAC also believes that speed restrictions in the final rule should apply only to crude oil and ethanol trains. It states speed restrictions on all flammable liquids may cause delays in rail service for other rail operations, which could cause significant safety impacts. DGAC opines that more time in transit, more or longer trains, and more overall congestion could cause more incidents.

DGAC also states that the scope of the final rule is not harmonized with applicable Canadian regulations. While it believes Canada has taken a ''commodity-based approach'' to the phase-out of legacy DOT–111 tank cars and corresponding retrofit timeline, it states that the U.S. approach is based on classification and packing group. DGAC believes that a commodity-based approach, addressing crude oil and ethanol, makes the most sense because it would address the material being transported in unit trains from a reasonable risk approach. DGAC also continues to encourage PHMSA, FRA, and Transport Canada (TC) to better identify the root causes of crashes and derailments involving these flammable liquids.

In summary, DGAC contends that the applicability of the final rule should be limited to the transportation of crude oil and ethanol trains, which, it says, was the stated intention of the rule. DGAC argues that, if the Department wishes to pursue enhanced tank car standards and operational requirements for other Class 3 (flammable liquid) materials, it should do so in a separate rulemaking.

American Chemistry Council

ACC requests that PHMSA revise the final rule to ensure that the requirement to retrofit existing tank cars applies only to cars carrying crude oil and ethanol. Other than tank cars transporting crude oil or ethanol, ACC states that the preamble and the Regulatory Impact Analysis (RIA) show that PHMSA's final rule did not intend to require retrofits of most tank cars transporting other flammable liquids.

ACC requests ''that the HHFT definition be reserved for regulations that apply to railroad train operations, not to tank car design.'' They assert that the HHFT definition should not trigger design standards that would apply to most tank cars intended to contain Class 3 flammable liquids. ACC does not contest the application of the HHFT concept to operational controls, such as establishing speed limits or braking requirements.

Furthermore, like DGAC, ACC contends that the final rule will necessitate that approximately 40,000 [6] additional DOT–111 tank cars either be retrofitted to meet the DOT–117R requirements or be replaced with the new DOT–117 tank cars. ACC suggests that this is in contrast to the stated focus on crude oil and ethanol. ACC echoes DGAC, stating that the shipper has no control over how railroads pick up cars and assemble manifest trains. While chemical shippers can, and often do, tender fewer than 20 tank cars loaded with flammable liquids at a time, there is no certainty that those chemicals will always be on a manifest train with fewer than 35 tank cars loaded with a flammable liquid. ACC asserts that the final rule does not align with the increased risk of derailment associated with unit trains and notes that flammable liquid chemicals are not shipped in unit trains. For that reason, ACC considers the HHFT definition to be overly broad and not aligned with the increased risk of derailment associated with unit trains. ACC urges that the scope be clarified so that the final rule will apply to crude oil unit trains, citing the relevant discussion in the Notice of Proposed Rulemaking. See 79 FR 45040. ACC indicates that because even a single tank car loaded with a Class 3 (flammable liquid) material tendered by one of its members may be placed in an HHFT, all tank cars intended to contain Class 3 (flammable liquid) materials will have to meet the design criteria set forth in the final rule. Furthermore, ACC explains that after publication of the final rule, railroads explicitly told ACC members that they will not manage manifest train operations to avoid triggering the regulatory requirements of the HHFT definition.

ACC contends that removing the retrofitting requirements for Class 3 flammable liquids that are not crude oil or ethanol would alleviate shop capacity problems and provide greater harmonization with TC's analogous retrofit schedule. ACC contends that PHMSA's adherence to using packing group, rather than to using risk, severely

[4] A ''manifest train'' means a freight train with a mixture of car types and cargoes.

[5] HHFUT ''means a single train transporting 70 or more loaded tank cars containing Class 3 flammable liquid.'' § 171.8.

[6] The members of ''the [Railway Supply Institute] RSI Committee on Tank Cars . . . collectively build more than ninety-five percent (95%) of all new railroad tank cars and own and provide for lease over seventy percent (70%) of railroad tank cars operating in North America.'' On page 56 of those comments, in Table C–3, RSI estimated that at the end of 2015 tank car fleets will contain the following:

- 87,507 tank cars (of all types) used for the movement of crude oil;
- 27,899 tank cars (of all types) in ethanol service; and
- 39,122 tank cars that carry flammable liquids other than crude oil or ethanol.

complicates the implementation of the rules in the two countries. ACC states that some of the Class 3 flammable liquid materials that will be affected by the final rule are classified in Packing Group (PG) I, so those tank cars will reach PHMSA's deadlines for retrofit or replacement before the tank cars that carry either ethanol or PG II crude oil. ACC states that the different prioritizations chosen by TC and by PHMSA will exacerbate conflicts over tank car shop space.

In sum, ACC believes that the scope of the final rule will inadvertently affect nearly 40,000 legacy DOT–111 tank cars that transport Class 3 flammable liquids that were not accounted for in the accompanying RIA. ACC states that because a shipper cannot know how a carrier will assemble a train, the possibility that a shipper's tank car will be placed into an HHFT will force all shippers of Class 3 materials to retrofit or purchase tank cars to meet the DOT–117R or DOT–117 specification. ACC believes that, coupled with a retrofit timeline that does not match the Canadian timeline, the final rule will fail to properly address the risks associated with hazardous materials offered and transported in unit trains.

Association of American Railroads

AAR contests the scope of the final rule because it permits shippers to continue to package Class 3 flammable liquid materials in tank cars that do not meet the new DOT–117 tank car standard. AAR states that PHMSA has created two pools of tank cars, those that meet the heightened standard for HHFTs and those that do not. As a result, AAR asserts, shippers may continue to offer Class 3 flammable liquid materials in DOT–111 tank cars as long as the DOT–111 is not placed in an HHFT. According to AAR, this places an unjustified burden on the railroads to continuously analyze the composition of each train transporting Class 3 flammable liquid materials in DOT–111 tank cars. AAR claims that PHMSA's argument, that through fleet management the railroads can avoid this issue, is baseless. AAR believes that PHMSA should harmonize with Canada by banning the use of DOT–111 tank cars for transporting any Class 3 flammable liquid materials. By failing to harmonize with Canada in this respect, AAR contends that the U.S. market will become flooded with legacy DOT–111 tank cars, which will further exacerbate the fleet management challenges U.S. railroads will face to construct trains to avoid meeting the definition of an HHFT.

To support its appeal, AAR submitted waybill data from its subsidiary Railinc showing numbers of flammable liquid shipments tendered in smaller groups of cars that do not by themselves meet the definition of an HHFT. Data from the first quarter of 2015 illustrate that 37,000 cars of flammable liquids (other than crude oil and ethanol) were tendered in blocks of 20 cars or fewer. During the same period, 37,576 tank cars of other flammable liquids (other than the 25,009 tank cars of crude oil or 39,956 tank cars of ethanol) were tendered in groups of fewer than 35 cars. According to AAR, had the final rule been in effect, a total of 102,541 cars of flammable liquids could have moved in existing DOT–111s.[7] AAR contends that PHMSA should specify a sunset date for discontinuing the use of DOT–111 tank cars for hazardous materials not in an HHFT.

PHMSA and FRA Response

In regards to DGAC's, ACC's, and AAR's appeals on the scope of the final rule, we disagree with those appellants' assertions and maintain that the method we determined to apply the new regulatory requirements and the regulatory analysis to support those decisions were conducted through careful consideration of the risks flammable liquids pose and the comments received during the rulemaking process. The position these appellants are taking in the appeals is based on anecdotal evidence and an interpretation of tank car fleet numbers that exaggerates the scope of the rulemaking. While we respect the argument that both shippers and carriers of Class 3 flammable liquids by rail will face new challenges in the wake of these regulations, we maintain that they are capable of working together to comply with the requirements established by the final rule.

DGAC, AAR, and ACC contend that both shippers and carriers cannot predict whether tank cars offered for transportation will be placed in a train set meeting the definition of an HHFT. By relying on this rationale, DGAC and ACC contend that the final rule will require nearly 40,000 tank cars to be replaced with the new DOT–117 tank car or be retrofitted to the DOT–117R requirements because a tank car possibly placed in an HHFT. These numbers are based on the 2015 Railway Supply Institute (RSI) fleet forecast predicting the number of DOT–111 tank cars transporting Class 3 flammable liquids (other than crude oil and ethanol). The solution they urge is limiting the scope of the rule to crude oil and ethanol.

We disagree. We believe that limiting the scope of the rulemaking to crude oil and ethanol would not align with the intent and applicability of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). The HMR are risk based and focus on the hazards presented during transportation. Focusing only on a subset of flammable liquids is a short-sighted regulatory approach and has the potential to lead to inconsistencies and safety concerns in the future. PHMSA's goal is to provide regulatory certainty that addresses the risks posed by all HHFTs.

In the NPRM, PHMSA proposed a definition of an HHFT with a threshold of 20 cars in a train. This aligned with AAR's ''Key Train'' definition in its circular OT–55–N, indicating the railroads currently recognize that trains of this make-up represent a high risk.[8] Additionally, the NPRM tied the applicability of the new tank car specification to the HHFT definition. In response to the NPRM, PHMSA received numerous comments suggesting that both shippers and carriers would be placed in an untenable position because it is impossible to determine when tank cars would be in an HHFT. To address commenters' concerns, we revised the definition of HHFT to 20 cars in a block or 35 throughout the train. The risk-based equivalency of 20 cars in a block and 35 cars throughout the train is calculated in the RIA on page 323.[9] PHMSA based this change on calculations finding that 20 cars in a block is roughly equivalent to 35 cars placed throughout a train, as well as AAR's comments noting that such a change would alleviate concerns about manifest trains operating in High Threat Urban Areas (HTUAs).

Similarly, PHMSA denies DGAC's request to remove the definition of HHFUT. Again, PHMSA developed the definition based on an analysis of comments received on the NPRM and careful cost analysis. While the definition of HHFUT was not expressly proposed in the NPRM, the NPRM did propose requirements for enhanced brake signal propagation systems for all trains meeting the definition of HHFT. PHMSA believes that the HHFUT definition captures the subset of HHFTs that represent the highest risk and where the most benefits from ECP

[7] The detailed figures AAR provided can be found in its appeal under Docket No. PHMSA–2012–0082.

[8] *http://www.boe.aar.com/CPC-1258%20OT-55-N%208-5-13.pdf.* Note that the current circular is OT–55–O: *http://www.boe.aar.com/CPC-1312%20OT-55-O%201.27.2015.pdf.*

[9] PHMSA–2012–0082–3442

braking will be gained and that the definition is within the scope of the NPRM proposals.

Regarding the appellants' concerns that the tank car specification is linked to the number of cars in the train, PHMSA understands that railroads have significant fleet management programs in place. On page 221 of the RIA, PHMSA details the agency's understanding of railroads' capability to conduct fleet management. We are aware that both shippers and carriers have fleet managers to predict or control whether a given tank car will be used in manifest train service or unit train service. Despite these fleet management capabilities and programs, the appellants indicate they have little control over the number of cars loaded with Class 3 (flammable liquid) materials in a train. To argue that neither party can predict a train's composition—particularly when transporting hazardous materials—implies an alarming lack of awareness in appellants' own operations. Indeed, train crews are actually required to maintain a document that reflects the current position in the train of each rail car containing a hazardous material. *See* § 174.26.

AAR contends that all cars transporting flammable liquids should be retrofitted to the DOT–117R requirements. On the other hand, the shippers contend no cars, other than those transporting crude oil and ethanol, should be retrofitted. PHMSA believes the final rule strikes the correct balance by requiring retrofits of all tank cars in crude oil and ethanol service plus the 354 tank cars in PG III service by estimating roughly 10 percent of trains transporting PG III commodities might meet the HHFT definition, and thus, that 10 percent of the cars would require retrofitting.[10] Further, PHMSA expects that the railroads will manage the assembly of loaded tank cars and manage the classification of trains to exclude tank cars from HHFTs that do not meet the new DOT–117 and DOT–117R tank car specifications.

Therefore, as previously stated, the estimated number of tank cars in PG III flammable liquid service that would be used to make up HHFTs, and hence have to meet the new requirements, is 354 tank cars, not the nearly 40,000 DGAC and ACC allege. The costs presented in the RIA were based on an analysis of public waybill data and include the costs of retrofitting the 354 tank cars mentioned above. The analysis showed that no other flammable liquid commodities of any packing group—other than crude oil or ethanol—were shipped in quantities that would trigger the HHFT requirements.

Further, our analysis of the waybill data indicated that far fewer than 10 percent of PG III cars would be affected by the HHFT definition. Nevertheless, to be conservative, we assumed roughly 10 percent of trains transporting PG III commodities might meet the HHFT definition, therefore 10 percent of the cars would require retrofitting. After adjusting for retirement of some cars and accounting for Canada's fleet share, we calculated that 10 percent of the remaining cars equaled the 354 cars that we incorporated into the cost analysis.

ACC's assertion that nearly 40,000 tank cars would have to be retrofitted or replaced to meet the enhanced tank car standards due to their possible placement in an HHFT is grossly exacerbated by the railroads advising ACC that they will not manage fleets to avoid their shipments becoming subject to the new regulations. PHMSA does not agree that this is a valid basis for revising the scope of the final rule's requirements. We explicitly limited the reach of the final rule to trains transporting large quantities of flammable liquids, and defined HHFT to exclude typical manifest trains that do not transport the large quantities of flammable liquids. For railroads to state that they will not manage train sets undermines the risk-based goal of the final rule to exclude commodities not typically shipped in large quantities.

DGAC, ACC, and AAR also contend that the U.S. packing group approach is not harmonized with Canada's commodity-based approach to the phase out of DOT–111 tank cars and corresponding retrofit timeline. Again, we disagree. By designating DOT–111 tank cars for phase out by packing group, we are aligned with Canada. While the Canadian approach expressly states crude oil and ethanol, we chose to use PG I, which encapsulates crude oil, and PG II, which encapsulates ethanol. DOT and TC were in constant communication while developing the respective rulemaking actions.

AAR also appealed the rule for not specifying a sunset date for the continued use of DOT–111 tank cars for all Class 3 flammable liquids. AAR contends that this will cause the non-retrofitted Canadian fleet to flood the U.S. market, making it increasingly difficult to manage the operational complexities of two pools of tank cars. Even if AAR's contention is true, we chose to authorize the continued use of DOT–111 tank cars for the transportation of hazardous materials not in an HHFT because it would have been cost prohibitive to prohibit all Class 3 flammable liquids in DOT–111 tank cars. As stated in the RIA and final rule preamble, we believe that we appropriately addressed the risk of continued use of such cars by prohibiting the use of legacy DOT–111 tank cars for HHFT service. For these reasons, the DGAC, ACC, and AAR appeals on the scope of the final rule are denied.

B. Tribal Impacts and Consultation

Columbia River Treaty Tribes and Northwest Treaty Tribes

The Columbia River Treaty Tribes and the Northwest Treaty Tribes (''Treaty Tribes'') submitted an appeal to the Secretary on June 5, 2015. The Treaty Tribes' arguments suggest that by omitting formal tribal consultation, DOT did not follow Executive Order (E.O.) 13175 and DOT guidance. By way of remedy, the Treaty Tribes urge PHMSA to ''reopen a notice and comment period for the Tank Car Rule [and] carry out tribal consultations on all aspects of the Tank Car Rule.''

The Treaty Tribes' appeal lays out various arguments for tribal consultation under E.O. 13175 and DOT guidance. First, the appeal argues that PHMSA erred in concluding that the rulemaking ''does not significantly or uniquely affect tribes.'' Second, the Treaty Tribes' appeal argues that the final rule ''impose[s] substantial direct effects or compliance costs'' on Indian tribal governments. Third, the Treaty Tribes' appeal finds fault with PHMSA's discussion of its ''superseding preemption'' authority for hazardous materials regulations in the final rule's discussion of tribal consultation.

PHMSA and FRA Response

We appreciate the comments the Treaty Tribes and other Tribes provided to the NPRM, which are addressed in the final rule. However, PHMSA respectfully disagrees with the Treaty Tribes appellants and maintains that the appellants' concerns were addressed during the rulemaking process. Overall, the comments from Indian tribal governments to the NPRM expressed concerns about the potential environmental, economic, and safety impacts of crude oil train derailments on tribal lands. PHMSA responded to those concerns by adopting a final rule designed to reduce the severity of and/or prevent derailments in an effort to improve public safety and protection of the environment. PHMSA and FRA conducted an extensive and thorough review of all comments received, and considered the concerns of all

[10] PHMSA–2012–0082–3442 at p. 15.

stakeholders, including Indian tribal governments. In the final rule, PHMSA summarized and discussed the comments of our stakeholders, including in-depth discussions of the comments of Indian tribal governments, and provided justifications for our adopted proposals and for those proposals we did not adopt.

Executive Order 13175

E.O. 13175 establishes processes for when a Federal agency is ''formulating and implementing policies that have tribal implications.'' [11] This E.O., re-affirmed by President Obama in a November 5, 2009, ''Tribal Consultation'' memorandum, [12] states that ''[p]olicies that have tribal implications'' refers to ''regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects 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.'' In addition, under DOT Order 5301.1 and other DOT tribal policies, components of DOT must consult with Indian tribal governments before taking any actions that ''significantly or uniquely'' affect them.[13] In the final rule, PHMSA discussed E.O. 13175, and reasonably concluded that the rulemaking did not: (1) Have tribal implications; (2) significantly or uniquely affect tribes; or (3) impose substantial direct effects or compliance costs on tribal governments.[14]

Significant or Unique Tribal Effects

The Treaty Tribes argue that consultation was required because of alleged unique and substantial effects of the final rule on the Treaty Tribes and their interests. Specifically, the Treaty Tribes' appeal discusses the unique history of their fishing rights and states, ''[h]ad PHMSA consulted with the Northwest treaty tribes, it would have learned of the tribal and federal interests in their collective usual and accustomed fishing areas and potential impacts resulting from the proposed Tank Car Rule.'' The Treaty Tribes discussed their concerns with the rail routing analysis discussion of environmentally sensitive areas. Though the Treaty Tribes' fishing rights may be unique, the trigger for the consultation requirement is a federal action that has a significant or unique effect upon tribes. Here, no such federal action exists. The enhanced safety provisions in the final rule, are designed to decrease the likelihood and severity of derailments and resulting spills, in an effort to improve public safety and protect the environment. The requirements adopted in the final rule do not apply directly to tribes. They apply to railroads and hazardous materials shippers. Any potential effect on tribes would take place several stages removed from the federal action of the final rule.

PHMSA believes that these regulations work to the benefit of all communities and areas affected by the rail transportation of flammable liquids. For this reason, PHMSA affirms that the impact of the final rule is not ''significant'' or ''unique'' to communities or resources under the jurisdiction of tribal governments.

Relationship Between Tribes and United States

The Treaty Tribes argue that the rule affects the relationship between tribes and the U.S., triggering the consultation provisions of E.O. 13175. The NPRM requested comments on whether the railroad's notification requirements should proceed through tribal emergency response commissions. This proposal was not adopted in the final rule. The tribes argue that this impacted the relationship between the tribes and the federal government. However, the information-sharing provisions would have directed the railroads to share information with the tribes. Although this may or may not affect the tribes' relationships with the railroads, it would not affect the relationship between tribes and the federal government.

As further discussed in the Notification Section of this document, the Treaty Tribes asked that PHMSA reinstitute the notice provisions of the Secretary's May 7, 2014 Emergency Order. DOT has kept in place the May 2014 Emergency Order that requires railroads to provide Bakken crude oil information directly to State Emergency Response Commissions (SERCs). PHMSA plans to revisit these provisions in an upcoming rulemaking and has pledged to maintain the Emergency Order until such a rulemaking codifying these provisions is published. Accordingly, for the reasons previously stated, this rulemaking has not affected the relationship between tribes and the federal government.

Preemption/Distribution of Power and Responsibilities

Finally, the Treaty Tribes argue that ''PHMSA asserts the preemption provisions of 49 U.S.C. 5126 and 20106 supersede'' the need for tribal consultation. This is an inaccurate characterization of PHMSA's position. In the final rule, we state that ''PHMSA has determined that this rulemaking does not significantly or uniquely affect tribes, and does not impose substantial direct effects or compliance costs on such governments.'' Although the rule referenced the preemption authorities of PHMSA and FRA, the basis for the decision to forgo tribal consultation was the lack of direct tribal impacts. In this case, PHMSA reasonably determined that a consultation with tribal officials was not necessary under the guidelines of E.O. 13175 and DOT policies.

Remedy

Moreover, the Treaty Tribes' appeal asked that PHMSA ''reopen a notice and comment period for the Tank Car Rule [and] carry out tribal consultations on all aspects of the Tank Car Rule.'' Independent of the arguments discussed above, PHMSA and FRA suggest that granting this aspect of the Treaty Tribes' appeal would result in further rulemaking proceedings that would frustrate implementation of the final rule's safety advancements and potentially delay safety improvements due to regulatory uncertainty.

Outreach

While PHMSA does not believe E.O. 13175 required a consultation for the HHFT rulemaking, PHMSA recognizes the importance of government-to-government relationships with tribes. To this end, PHMSA has expanded its tribal outreach efforts. For example, in March 2015, DOT representatives met with representatives from the Prairie Island Tribe to discuss tribal concerns with the movement of Bakken crude oil through their community. In August 2015, PHMSA representatives attended the Northwest Tribal Emergency Management Council's annual meeting in Spokane, Washington. This provided an opportunity to speak directly with tribal emergency management leaders and emphasize the importance of effective tribal and federal cooperation. In addition, PHMSA provides hazardous materials emergency preparedness grant funding to tribes to carry out planning and training activities to ensure that

[11] ''Consultation and Coordination with Indian Tribal Governments,'' 65 FR 67249 (Nov. 9, 2000).

[12] ''Memorandum on Tribal Consultation,'' 74 FR 57881.

[13] ''U.S. Dept. of Transportation, Office of the Secretary of Transportation, Department of Transportation Programs, Policies, and Procedures Affecting American Indians, Alaska Natives, and Tribes,'' Order No. DOT 5303.1 (Nov. 16, 1999).

[14] Although PHMSA did not explicitly invoke DOT Order 5303.1, PHMSA analyzed the applicability of tribal consultation using the Order's applicability to actions that ''significantly or uniquely'' affect Indian tribal governments.

State, local, and tribal emergency responders are properly prepared and trained to respond to hazardous materials transportation incidents. For these reasons, the Treaty Tribes appeal to reopen a notice and comment period for the final rule and carry out tribal consultations on all aspects of the rule is denied.

C. Information Sharing/Notification

Columbia River Treaty Tribes and Northwest Treaty Tribes

The Treaty Tribes also appealed the notification provisions of the final rule. They have stated, ''On its face, the Tank Car Rule could be read to abandon the Emergency Order and cut back on both emergency responder and tribal access to train route and emergency response information.'' According to the Treaty Tribes, the notification provisions adopted in the final Rule ''weaken the notification scheme in a number of ways'' since the information provided is ''far less informative'' and its dissemination is limited to ''those with a need-to-know in an anti-terrorism context.'' For these reasons, the Treaty Tribes asked that PHMSA reinstitute the notice provisions of the Secretary's May 7, 2014 Emergency Order.

PHMSA and FRA Response

We agree with the Treaty Tribes. As discussed in the Treaty Tribes' petition, on May 7, 2014, the Secretary issued an Emergency Order in Docket No. DOT–OST–2014–0067 (''May 2014 Emergency Order'' or ''Order''). That Order requires each railroad transporting in commerce within the U.S. 1,000,000 gallons or more of Bakken crude oil in a single train to provide certain information in writing to the SERCs for each State in which it operates such a train. The Order requires railroads to provide: (1) The expected volume and frequency of affected trains transporting Bakken crude oil through each county in a State; (2) the routes over which the identified trains are expected to operate; (3) a description of the petroleum crude oil and applicable emergency response information; and (4) contact information for at least one responsible party at the railroad. In addition, the Order requires that railroads provide copies of notifications made to each SERC to FRA upon request and to provide SERCs updated notifications when there is a ''material change'' in the volume of affected trains. Subsequent to issuing the Order, in August 2014, PHMSA published the HHFT NPRM, which, in part, proposed to codify and clarify the requirements of the Order, and requested public comment on the proposal.

Based on the comments received to the NPRM, along with PHMSA and FRA's analysis of the issues involved in the HHFT final rule, PHMSA did not adopt the notification requirements of the proposed rule. PHMSA determined expansion of the existing route analysis and consultation requirements of § 172.820 to include HHFTs was the best approach to ensure emergency responders and others involved with emergency response planning and preparedness would have access to sufficient information regarding crude oil shipments moving through their jurisdictions to adequately plan and prepare from an emergency response perspective. Thus, the final rule expanded the applicability of § 172.820 to HHFTs. As part of these additional safety and security planning requirements, the final rule requires rail carriers operating HHFTs to comply with § 172.820(g), which requires that railroads ''identify a point of contact on routing issues and provide that contact's information (including his or her name, title, phone number and email address):

> (1) State and/or regional Fusion Centers that have been established to coordinate with state, local and tribal officials on security issues which are located within the area encompassed by the rail carrier's rail system; and (2) State, local, and tribal officials in jurisdictions that may be affected by a rail carrier's routing decisions and who directly contact the railroad to discuss routing decisions.

Thus, these notification provisions *require* railroads to proactively provide this contact information to ''State and/or regional Fusion Centers'' and ensure that ''state, local, and tribal officials . . . who directly contact the railroad to discuss routing decisions'' are provided the same information. Tribal officials can also coordinate with Fusion Centers to obtain this information. At the time of the final rule's publication, the notification provisions discussed above were set to supersede the May 2014 Emergency Order, once codified notification provisions are fully implemented (*i.e.,* March 31, 2016).

Subsequent to publication of the final rule, PHMSA received feedback from stakeholders (including tribal authorities) expressing intense concern about the Department's decision to forgo the proactive notification requirements of the Order and in the NPRM. Generally, these stakeholders expressed the view that given the unique risks posed by the frequent rail transportation of large volumes of flammable liquids, including Bakken crude oil, PHMSA should not eliminate the proactive information sharing provisions of the Order and rely solely on the consultation and communication requirements in existing § 172.820. These stakeholders expressed concern that the final rule may limit the availability of emergency response information by superseding the May 2014 Emergency Order.

In response to these concerns and after further evaluating the issue within the Department, in a May 28, 2015 notice (Notice), PHMSA announced that it would extend the Order indefinitely, while it considered options for codifying the disclosure requirement permanently.[15] Furthermore, on July 22, 2015, FRA issued a public letter instructing railroads transporting crude oil that they must continue to notify SERCs of the expected movement of Bakken crude oil trains through individual states.[16]

The Treaty Tribes' appeal reiterates these concerns about the codified notification provisions, stating that they ''cut back on both emergency responder and tribal access to train route and emergency response information.'' In light of the May 28, 2015 PHMSA Notice and other DOT communications, PHMSA believes that we have adequately addressed the Treaty Tribes' concerns about the information sharing provisions of the final rule and the Treaty Tribes' explicit support for the notification procedures in the May 2014 Emergency Order. Since DOT has already re-examined the decision to allow the final rule to supersede the May 2014 Emergency Order and determined that the Order will remain in full force and effect until the agency considers options for codifying it on a permanent basis, PHMSA believes we have been responsive to this aspect of the Treaty Tribes' appeal. In accordance with the Notice, PHMSA continues to consider options for codifying the central aspects of the Order permanently in a future rulemaking action. The treaty tribes will have the opportunity to comment on these future regulatory proposals in the course of that rulemaking proceeding. In addition, PHMSA is seeking opportunities similar to attending the Northwest Tribal Emergency Management Council's meeting held in Spokane, Washington, to engage further with the tribal communities affected by our regulations. Continued opportunities to reach out directly to tribal emergency

[15] *http://www.phmsa.dot.gov/hazmat/phmsa-notice-regarding-emergency-response-notifications-for-shipments-of-petroleum-crude-oil-by-rail.*

[16] *http://hazmatship.com/images/stories/pdf2/2015_07_22_Notification+FINAL.pdf?mc_cid=f88dda2d67&mc_eid=1fbd28d3ea.*

management leaders will improve the cooperation between PHMSA and the tribes.

D. Testing and Sampling Program

Dangerous Goods Advisory Council

DGAC does not believe the sampling and testing program adopted in § 173.41 is justified or warranted and requests that we eliminate this provision. DGAC asserts that the classification sampling and testing program would not change the tank car selection or emergency response guidebook responses. DGAC also expresses concern that sampling during transportation could create a safety risk as closed packages are re-opened.

If PHMSA does not repeal the program, DGAC requests additional clarification. Specifically, DGAC requests that we revise the final rule to include a definition for ''unrefined petroleum-based products,'' consistent with the discussion in the preamble. *See* 80 FR 26704. DGAC further requests additional guidance on the provision in § 173.41(a)(2), which states ''and when changes that may affect the properties of the material may occur . . . ,'' and additional guidance on the recordkeeping requirements.

Finally, DGAC requests that we provide a delayed compliance date of March 31, 2016 for implementation of the requirements in § 173.41 if the requirement is maintained. This date aligns with the delayed compliance date of March 31, 2016, provided for a rail carrier to complete the initial planning process required in § 172.820. DGAC believes that a delayed compliance date is necessary because ''affected parties have certain testing procedures in place, the development, distribution and training of affected hazardous materials employees in a more 'formal' program by July 7, 2015 is not reasonable.''

PHMSA and FRA Response

In regards to DGAC's appeal on the sampling and testing program, PHMSA maintains that that sampling and testing program is justified and necessary. In its safety recommendation, R–14–6, the National Transportation Safety Board (NTSB) recognized the importance of requiring ''shippers to sufficiently test and document the physical and chemical characteristics of hazardous materials to ensure the proper classification, packaging, and record-keeping of products offered in transportation.'' The entire premise of the HMR is built around the shipper's responsibility to properly classify a hazardous material. Under § 171.2(e), ''No person may offer or accept a hazardous material for transportation in commerce unless the hazardous material is properly classed, described, packaged, marked, labeled, and in condition for shipment as required or authorized by applicable requirements of this subchapter.'' Proper classification ensures the correct regulatory provisions are being followed both when the material is initially offered and during downstream shipments. The HMR requires correct classification and communication, even when the shipper has the option to use a more stringent packaging. Classification also includes ensuring that all correct hazard classes are identified. Many provisions in the HMR also require the shipper to have knowledge about the material that exceeds the information provided by the shipping papers or Emergency Response Guidebook (ERG). For example, it is forbidden to offer ''a material in the same packaging, freight container, or overpack with another material, the mixing of which is likely to cause a dangerous evolution of heat, or flammable or poisonous gases or vapors, or to produce corrosive materials'' under § 173.21(e). For petroleum crude oil, the shipper may additionally need to identify properties such as corrosivity, vapor pressure, specific gravity at loading and reference temperatures, and the presence and concentration of specific compounds (*e.g.,* sulfur), depending on the different packaging options selected and the conditions under which the material is being offered. Considering the challenges posed by materials with variable composition and potentially variable properties, such as crude oil, providing criteria for sampling and testing of unrefined petroleum-based products is a critical first step in safe transportation of these materials. Proper classification and the assignment of a packing group for a hazardous material determines what packaging is appropriate for that material.

Industry also recognizes the importance and unique challenges of properly classifying petroleum crude oil. The American Petroleum Institute spearheaded efforts to develop an industry standard for the classification of petroleum crude oil, resulting in the development of American National Standards Institute (ANSI)/American Petroleum Institute (API) Recommend Practices (RP) 3000, ''Classifying and Loading of Crude Oil into Rail Tank Cars.'' This API standard went through a public comment period during its development in order to be designated as an American National Standard.

We also disagree that providing more specificity or guidance to the program is necessary. The term ''unrefined petroleum-based products'' is clear as written. ''Petroleum'' is used throughout the HMR. The term ''unrefined'' is sufficiently clear in the context of the petroleum industry. Therefore, the term ''unrefined petroleum-based products'' would be any material that is petroleum based, and has not undergone refinement. For example, heat treating to reduce vapor pressure or to remove the dissolved gases in crude oil so that it may be transported for refinement would not meet the American Fuel & Petrochemical Manufacturers (AFPM) or other industry definitions of ''refining.'' [17]

We disagree that additional guidance is necessary, as the requirement in § 173.41(e) to document and maintain records of the sampling and testing program is clear. In both the NPRM and final rule, we stated respectively that we are not proposing or adopting a requirement for the retention of test results. Therefore, the documentation in paragraph (e) must describe the program itself.

We also disagree that the requirements of when to sample are unclear or present a safety risk. The sampling and testing program is only required prior to the offering of the material for transportation. This is further clarified in § 173.41(a) (2), which states, ''Sampling prior to the initial offering of the material for transportation and when changes that may affect the properties of the material occur (*i.e.,* mixing of the material from multiple sources, or further processing and then subsequent transportation).'' Therefore, sampling would be required before the initial offering for transportation, and in some situations when the material is re-offered for transportation. The examples in the description provide flexibility to accommodate changing industry practices, and should not be replaced with a prescriptive list. Overall, API RP 3000 provides a more specific example of how the sampling requirements of § 173.41 may be met. As we stated in the final rule,

> Shippers must continue to use the testing methods for classification of flammable liquids outlined in § 173.120 and flammable gases in § 173.115. However, API RP 3000 is otherwise consistent with the sampling program requirements in § 173.41(a)(1)-(6) and may be used to satisfy these adopted sampling provisions. Furthermore, voluntary use of API RP 3000 provides guidance for compliance with these provisions, but still

[17] *http://www.afpm.org/The-Refinery-Process/*

allows flexibility for meeting requirements through other methods.

See 80 FR 26706.

Finally, we disagree that a delayed compliance date of March 31, 2016 should be provided for implementation of the requirements in § 173.41 to provide shippers adequate time to implement changes for training and documentation. The date established for rail routing requirements allows for the collection of six months of data and completion of a risk assessment. The sampling and testing requirements are simply a mechanism to document existing regulatory requirements for proper classification of energy products. In addition, the Department issued Emergency Order DOT–OST–2014–0025 on February 25, 2014 (EO 25), which was subsequently revised and amended on March 6, 2014.[18] EO 25 required those who offer crude oil for transportation by rail to ensure that the product is properly tested and classified in accordance with federal safety regulations. Further, EO 25 required that all rail shipments of crude oil that are properly classed as a flammable liquid in PG III material be treated as a PG I or II material. The Amended EO 25 also authorized PG III materials to be described as PG III for the purposes of hazard communication. The Amended EO 25 differs from the original in that it prohibits persons who ordinarily offer petroleum crude oil for shipment as UN 1267, petroleum crude oil, Class 3, PG I, II, or III from reclassifying such crude oil with the intent to circumvent the requirements of this Amended Order. As discussed in the final rule, the sampling and testing program requirements superseded EO 25 and made it no longer necessary. By extending the compliance date, PHMSA would create a safety gap which was previously covered under EO 25 as amended. For these reasons, the appeal submitted by DGAC on the sampling and testing program is denied.

E. Retrofit Timeline and Tank Car Reporting Requirements

American Fuel and Petrochemical Manufacturers

AFPM supports PHMSA and FRA's plan to establish a reporting obligation on retrofit progress and shop capacity. However, it asserts that the final rule's reporting requirement is insufficient to accomplish its intended purpose. In its appeal, AFPM recommends a substantial expansion of reporting timelines and requested data to ensure all types of tank car retrofits are evaluated and not just non-jacketed DOT–111 legacy tank cars in Packing Group I service.

PHMSA and FRA Response

In regards to AFPM's appeal, PHMSA believes that the final rule's established industry reporting obligation on retrofit progress and shop capacity will achieve the stated goals. The first phase of the retrofit timeline includes a January 1, 2017, deadline for retrofitting non-jacketed DOT–111 tank cars in PG I service. Owners of non-jacketed DOT–111 tank cars in PG I service for use in an HHFT who are unable to meet the January 1, 2017, retrofit deadline specified in § 173.243 (a)(1), are required to submit a report by March 1, 2017, to the Department. Groups representing tank car owners may submit a consolidated report to the Department in lieu of individual reports from each tank car owner. The report must include the following information regarding retrofitting progress:

- The total number of tank cars retrofitted to meet the DOT–117R standard;
- The total number of tank cars built or retrofitted to meet the DOT–117P standard;
- The total number of DOT–111 tank cars (including those built to CPC–1232 industry standard) that have not been modified;
- The total number of tank cars built to meet the DOT–117 standard; and
- The total number of tank cars built or retrofitted to a DOT–117, 117R or 117P that are electronically controlled pneumatic (ECP) brake ready or ECP brake equipped.

In developing the retrofit schedule, PHMSA and FRA examined the available shop capacity, the comments received, historical performance of the rail industry dealing with retrofit requirements, and the potential impacts associated with the retrofit schedule. The final rule also stated the Department could request additional reports with reasonable notice if necessary to facilitate the timely retrofits of those tank cars posing the highest risk. PHMSA and FRA are confident that the adopted reporting requirements are sufficient in that they will achieve the Department's stated goals. In addition, the Department may request additional reports as needed to verify industry progress toward retrofitting requirements. For the reasons stated, the appeal submitted by AFPM on the retrofit and tank car reporting of the final rule is denied.

F. Thermal Protection for Tank Cars

Association of American Railroads

In its appeal, AAR requests that we require enhanced thermal protection when new or retrofitted tank cars are built with jackets. That thermal protection would be beyond what is required in the final rule and allow further tank car survivability in a pool fire scenario. AAR asserts that PHMSA should require an enhanced thermal blanket with thermal conductivity no greater than 2.65 BTU per inch, per hour, per square foot, and per degree Fahrenheit at a temperature of 2000 F, ± 100F.

PHMSA and FRA Response

In regards to AAR's appeal, PHMSA believes AAR has not presented a compelling basis for amending this aspect of the final rule. The final rule requires tank cars in HHFTs to have thermal protection that meets the requirements of § 179.18, while also having a pressure relief device that complies with § 173.31. Section 179.18 establishes a performance standard that requires a tank to be able to withstand a pool fire for at least 100 minutes and a torch fire for at least 30 minutes. The 100-minute standard is intended to provide time for emergency response and accident assessment. Section 173.31 requires a reclosing pressure relief device for any tank car transporting a Class 3 (flammable liquid). Further, the pressure relief device ''must be made of materials compatible with the lading, having sufficient flow capacity to prevent pressure build-up in the tank to no more than the flow rating pressure of the pressure relief device in fire conditions as defined in Appendix A of the AAR Specifications for Tank Cars.'' *See* § 179.15. AAR contends that PHMSA should adopt a different standard. Specifically, AAR argues that PHMSA should require that all tank cars transporting flammable liquids be equipped with a thermal blanket that allows for thermal conductivity not to exceed 2.65 BTU per inch, per hour, per square foot, and per degree Fahrenheit at a temperature of 2,000 °F, ± 100 °F. Using the standard AAR proposes would potentially provide 800 minutes of protection in a pool fire. Further, it contends that PHMSA should require that all tank cars transporting flammable liquids be equipped with a pressure relief device that will allow the release of only enough quantity to prevent a thermal tear.

[18] The March 6, 2014 ''Amended and Restated Emergency Restriction and Prohibition Order (Amended Order)'' sought to clarify the original February 25, 2014 Order and superseded and replaced it in its entirety. *See http://www.phmsa.dot.gov/pv_obj_cache/pv_obj_id_D03C7A1E859361738D791378144472BF368F0200/filename/Amended_Emergency_Order_030614.pdf.*

AAR's suggestion that its thermal blanket proposal would provide greater protection than that currently HMR requirements, raises a number of concerns. First, the units for thermal conductivity are incorrect. Although it may seem counter-intuitive, increasing the thickness of the thermal blanket using the method provided by AAR, would actually increase the thermal conductivity and decrease the performance of the thermal protection system. Additionally, there is no experiential or experimental basis for AAR's use of a 2,000 °F fire temperature. The current requirement of a 1,600 °F pool fire temperature is based on experimental data from a pool fire test involving liquefied petroleum gas (LPG). The experimental data, including the heat flux, were normalized over the entire surface of the car to represent total engulfment in a pool fire.

Furthermore, it is unclear whether existing thermal blankets would meet AAR's proposed standard or even whether AAR's proposed standard requiring thermal blankets would provide an added benefit compared to that prescribed by PHMSA. AAR provided no evidence that requiring a thermal blanket and specifying the properties of the material will enhance safety. AAR asserts that, based on AFFTAC modeling, a tank car equipped with a thermal blanket can withstand a pool fire for hours, or in some circumstances, a tank car could indefinitely withstand a pool fire without failure and loss of lading. PHMSA and FRA have two concerns with this assertion. As an initial matter, while thermal conductivity is an input to the AFFTAC model, the model does not account for degradation of the material in a pool fire, and therefore it assumes the thermal conductivity is constant for the duration of a pool fire. However, if the thermal protection begins to degrade soon after 100 minutes (assuming constant properties) the results AFFTAC would be overly optimistic. Additionally, AFFTAC is not capable of analyzing a lading comprised of more than two components, such as crude oil. It has been suggested that two component materials can be used as a surrogate for crude oil. Before the design of the AAR proposed thermal protection system meeting the DOT–117 standard can be approved, the accuracy of using a two-component system as a surrogate for crude oil must be demonstrated.

Assuming that AAR's proposal would add time—an assumption that, at this point, is unsupported by any objective data—AAR has not provided any evidence that there is a practical benefit to extending the time period before the lading is released from a location other than from the pressure relief device. The primary intent of the 100-minute requirement in the HMR is to provide first responders time to assess the accident and initiate remedial actions such as evacuating an area. There has not been any evidence presented that the current requirement is insufficient for achieving these goals.

Finally, AAR's proposal sets up a technical standard, but it does not necessarily establish a minimum time requirement for survivability of the tank car. The potential for variability under the AAR proposal would present added uncertainty. In developing a first response strategy, a minimum level of certainty is needed, and controlling the anticipated variables is vital. This information is vital for first responders, who need to have a reasonable understanding of the expected time frame after an event to establish an effective plan that can be executed within the baseline time that is available.

PHMSA addressed its rationale for choosing a minimum standard that requires a DOT–117/DOT–117R tank car to withstand a pool fire for at least 100 minutes and torch fire for at least 30 minutes in the preamble to the final rule. *See* 80 FR at 26670–26671. It noted that AAR's T87.6 Task Force agreed that a survivability time of 100 minutes in a pool fire should be used as a benchmark for adequate performance. Additionally, the 100-minute pool fire baseline is consistent with the current federal regulations for pressure cars transporting Class 2 materials, and serves as the existing performance standard for pressure tank cars equipped with a thermal protection system. PHMSA also noted that the 100-minute pool fire baseline had been ''established to provide emergency responders with adequate time to assess a derailment, establish perimeters, and evacuate the public as needed, while also giving time to vent the hazardous material from the tank and prevent an energetic failure of the tank car.'' *See* 80 FR 26671.

With respect to pressure relief devices, which are designed to work in conjunction with the thermal protection system, PHMSA noted that there was widespread concurrence among commenters for a redesigned pressure relief device for DOT–117 cars. *See* 80 FR at 26670–26671. The simulations performed by PHMSA indicated that a reclosing pressure relief valve was of primary importance, because when a tank car is exposed to a pool fire the PRD will maintain a low pressure in the tank and potentially extend the time before a tank car will thermally rupture. PHMSA also determined that high-flow capacity, reclosing pressure relief devices can be acquired reasonably in the market and they can be installed on new or retrofitted tank cars. These factors support the performance standard chosen by PHMSA for pressure relief devices. For the reasons stated, the appeal submitted by AAR on thermal protection in the final rule is denied.

G. Advanced Brake Signal Propagation Systems

Dangerous Goods Advisory Council

DGAC appeals to PHMSA requesting the elimination of the electronically controlled pneumatic (ECP) brake requirement from the final rule. The DGAC appeal rests on three main arguments. First, DGAC agrees with the comments AAR and API submitted in response to the NPRM. Second, DGAC argues that the timeline for implementing the ECP brake requirement is inconsistent with the retrofit schedule adopted in the final rule and will require ECP brakes to be installed before retrofitting. Third, DGAC alleges there will be difficulties moving HHFUTs from Canada to the U.S. because Canada has not adopted similar ECP brake requirements.

PHMSA and FRA Response

In regards to DGAC's appeal to eliminate the ECP brake requirement, PHMSA maintains that the retrofit schedule is consistent, and that the final rule will not lead to the unspecified difficulties that concern DGAC. Further, we respectfully disagree with DGAC's first argument agreeing with AAR and API regarding this issue. PHMSA considered the comments submitted by AAR and API in drafting the final rule, and as part of its appeal, DGAC provides no new information to support the AAR and API comments. Rather than restating its previous analysis here, PHMSA directs DGAC to the discussion of the ECP brake requirement in the final rule and the RIA. *See* 80 FR 26692–26703; and RIA, p. 33–36, 207–278.

The timeline for implementing ECP brakes on HHFUTs will allow the rail industry to orderly schedule retrofits to comply with both requirements. PHMSA expects that in most instances ECP brakes will be installed when a tank car is sent to the service shop for retrofitting. This will avoid taking the car out of service more than is absolutely necessary. There should be no need to install ECP brakes on a tank car prior to retrofitting the car. The RIA to the final rule estimates that about

60,000 tank cars will need to have ECP brakes installed. Approximately one-third of these cars will be new construction, and the remaining cars, retrofits. *See* RIA, pp. 218–219.

Currently, crude oil and ethanol are the only Class 3 (flammable liquids) transported in trains that fall within the HHFUT definition. These hazardous materials are assigned to a packing group based on their flash point and initial boiling point. Crude oil may be classified as PG I (high danger), PG II (medium danger), or PG III (low danger).

The final rule requires all DOT–111 and non-jacketed CPC–1232 tank cars used in PG I service to be retrofitted no later than April 1, 2020.[19] PHMSA anticipates that the industry will apply a vast majority of those retrofitted cars to unit train service because it makes financial sense to put the first retrofitted cars to use in the highest priority service. The ECP brake requirement for an HHFUT transporting at least one tank car loaded with PG I material does not go into effect until January 1, 2021. Therefore, PHMSA and FRA believe that the combination of new cars and retrofits completed prior to January 1, 2021, should be sufficient to supply the tank cars needed to operate in ECP brake mode. *See* RIA, p. 146.

The same is true with respect to those HHFUTs transporting loaded tank cars of ethanol or crude oil not in PG I service. These trains must operate in ECP brake mode as of May 1, 2023, when traveling in excess of 30 mph. The final rule requires retrofitting all DOT–111 tank cars used in PG II service no later than May 1, 2023. Non-jacketed CPC–1232 tank cars used in PG II follow closely behind with a retrofit deadline of July 1, 2023. For the reasons stated above, PHMSA reaffirms its position and disagrees that the timeline for implementing the ECP brake requirement is inconsistent with the retrofit schedule adopted in the final rule. *See* RIA, p. 146.

Lastly, PHMSA discussed U.S./Canada harmonization efforts in the final rule. *See* 80 FR 26662. PHMSA recognizes that the transportation of flammable liquids by rail is a cross-border issue. In developing the final rule, U.S. DOT and TC worked closely to ensure that the new tank car standards for HHFTs do not create barriers to movement, but harmonization is not required in every instance. PHMSA and FRA strongly believe that the ECP brake requirement for HHFUTs is an important measure to help protect public safety and the environment in the U.S. That said, PHMSA and FRA carefully considered cross-border issues with respect to ECP braking, particularly when a train is crossing from Canada into the U.S., and provided authorization in the final rule for continued transportation. If an HHFUT without ECP brakes arrives in the U.S. from Canada, that train may continue in transportation at a speed that does not exceed 30 mph. This solution eliminates cross-border barriers to transportation and should alleviate any of the unspecified difficulties that concern DGAC. For these reasons, DGAC's appeal to eliminate the ECP brake requirement of the final rule is denied.

Association of American Railroads

AAR also asks us to eliminate the new ECP brake standard for HHFUTs traveling in excess of 30 mph. AAR contends that PHMSA should remove the ECP brake requirement from the final rule, and provides 10 arguments that purportedly support its position.

PHMSA and FRA Response

In regards to AAR's appeal with respect to ECP braking, AAR's arguments do not present a compelling basis for repealing the ECP brake requirement in the final rule. PHMSA stands by the Final Rule's established two-tiered approach to braking systems that focuses on increasing safety for trains transporting large quantities of flammable liquids. All HHFTs traveling in excess of 30 mph must operate using a two-way end-of-train (EOT) device or a distributed power system. All HHFUTs traveling in excess of 30 mph must operate using ECP brakes. The ECP brake requirement begins on January 1, 2021, for any HHFUT transporting at least one loaded tank car of PG I material. For all other HHFUTs, the ECP brake requirement is mandatory beginning May 1, 2023.

The basis for the ECP brake requirement was thoroughly researched prior to publication of the final rule. ECP brakes allow for shorter stopping distances and reduced in-train forces. In the ECP brake mode of operation, all cars brake simultaneously by way of an electronic signal. ECP brake systems simultaneously apply and release freight car air brakes through a hardwired electronic pathway down the length of the train, and allow the engineer to ''back off'' or reduce the braking effort to match the track grade and curvature, without having to completely release the brakes and having to recharge the main reservoirs before another brake application can be made. These differences in the operation of the two braking systems give ECP brakes several business benefits. Operationally, ECP brakes have the potential to save fuel and reduce emissions, reduce wear and stress on wheels and brake shoes, and provide train engineers greater control on the braking characteristics of trains. From a safety perspective, ECP brakes greatly reduce the risk of runaway trains due to a diminished reservoir air supply, and reduce the probability of an incident by providing 40 to 60 percent shorter stopping distances. ECP brake wiring also provides the train a platform for the gradual addition of other train-performance monitoring devices using sensor-based technology to maintain a continuous feedback loop on the train's condition for the train crew. PHMSA is highly confident that this requirement will minimize the effects of derailments involving HHFUTs by limiting the number of cars involved in the derailment and decreasing the probability of tank car punctures. Indeed, an NTSB study published after PHMSA published the final rule supports the safety basis for ECP brakes, finding that ECP brakes provide better stopping performance than conventional air brakes and distributed power (DP) units in full service and emergency braking applications.[20]

1. North American Experience With ECP Brakes

AAR's initial assertion is that PHMSA ignores the actual experience of North American railroads in operating trains equipped with ECP brakes. It contends that the experience of these railroads demonstrates that ECP brakes are unreliable. Additionally, AAR states that ECP brakes do not function materially better than trains with conventional air brakes that make use of DP and dynamic braking. Finally, AAR claims that neither PHMSA nor FRA made any effort to collect information from railroads about their experiences with ECP brakes and that PHMSA failed to incorporate the data that was gathered into its analysis.

We disagree. In coordination with FRA, PHMSA did consider the experience of North American railroads

[19] Non-jacketed DOT–111 tank cars used in PG I service must be retrofitted by January 1, 2017 (or, under a schedule, not later than January 1, 2018). Jacketed DOT–111 tank cars used in PG I service must be retrofitted by March 1, 2018. Non-jacketed CPC–1232 tank cars used in PG I service must be retrofitted by April 1, 2020.

[20] NTSB recently published the results of its simulation study of train braking as part of its investigation into the December 30, 2013, incident in Casselton, ND, where a crude oil unit train collided with a derailed car resulting in the derailment of 21 tank cars. *See* Train Braking Simulation Study, Renze, K.J., July 20, 2015, at *http://dms.ntsb.gov/public/55500–55999/55926/577439.pdf.*

when we developed the requirement for ECP brakes on HHFUTs that operate in excess of 30 mph. Both the final rule and the RIA discuss at length the North American experience with ECP brakes. *See* RIA, pp. 216–236; 80 FR 26997–26998. The information relied upon by PHMSA and FRA included comments from the railroads and suppliers, reports and papers presented by railroad officials discussing ECP brake effectiveness, and testimony at previous public hearings held by FRA. Examples of comments that PHMSA and FRA relied upon include AAR's comments on dynamic braking and RSI's comments on the costs of installing ECP brakes on newly constructed and retrofitted tank cars. *See* RIA, pp. 216–217, 218, 239, and 262–263.

Examples of reports and presentations from railroad personnel include the following:

- ''Electronically-Controlled Pneumatic (ECP) Brake Experience at Canadian Pacific,'' Wachs, K., et al., which was presented at the 2011 International Heavy Haul Association (IHHA) Conference, in Calgary, AB, Canada. *See* RIA, pp. 216–217, 263, and 267.
- ''Norfolk Southern ECP Brake Pilot Project Update,'' Forrester, J., presented at the 2010 National Coal Transportation Association O & M Committee Meeting in Coeur d'Alene ID. *See* RIA, pp. 236–237.
- ''ECP Perspectives,'' Maryott, D. presented at the 2008 Air Brake Association Proceedings of the 100th Annual Convention and Technical Conference in Chicago, IL. *See* RIA, pp. 236.

Much of the value of these reports, which were initiated and completed outside this rulemaking, was that PHMSA and FRA received hard numbers and data resulting from the direct testing of North American railroad operations using ECP brakes. The data from these reports included information on fleet reductions, rail wear, wheel wear, stop time, restart time, and stopping distances. Additionally, PHMSA and FRA relied on statements at two FRA public hearings held on October 4, 2007, and October 19, 2007, that were held during FRA's rulemaking process establishing ECP brake system standards. The public hearing included comments from Mr. Michael Iden, an official of Union Pacific Railroad Company (UP), who described an example of how regulatory relief from brake inspections on trains with ECP brakes would help to save fuel while also reducing congestion (by allowing an ECP-equipped train to overtake slower trains that require more frequent brake inspections).[21] Based on the totality of the evidence available, PHMSA and FRA unanimously concluded that applying an ECP braking requirement to a limited subset of trains, HHFUTs, is warranted when transporting extremely large quantities of Class 3 (flammable liquids).[22]

AAR relies on a report titled ''Assessment of the Enhanced Braking Requirements in the Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains Final Rule of May 1, 2015'' (hereinafter referred to as the ''Oliver Wyman Report''), which lists a number of purported quotes from interviews with unnamed railroad officials in support of the contention that PHMSA and FRA did not incorporate the railroads' negative comments about ECP brakes into its analysis. These anecdotes (from UP, Canadian Pacific Railway (CP), and CSX Transportation, Inc.) essentially suggest that ECP brakes were tried and abandoned a number of years ago. These statements are not persuasive, as PHMSA and FRA acknowledged in the RIA at pages 223–225 that there may be problems at the outset with using ECP brakes, just as there are with any newer technology. There is evidence that ECP brake technology has advanced since these railroads stopped operating trains using ECP brakes, *see* RIA, pp. 225–226, but there is no discussion in the Oliver Wyman Report about whether these railroads have considered re-adopting ECP brakes in limited circumstances, such as with captive unit train fleets.

The purported quotes in the Oliver Wyman Report from officials of BNSF Railway Company (BNSF) and Norfolk Southern Railway Company (NS), while current, provide conclusions rather than analysis. In the rare instances where the Oliver Wyman Report does provide tangible numbers, there are no references that would allow PHMSA and FRA to research and verify the information and assess its applicability. *See e.g.,* pp. 8, concerning the rate of failures on BNSF. If these railroads have actual data reflecting the real-world effectiveness of ECP brakes in North America, they have not provided it in the course of this appeal or the rulemaking process.[23] Similarly, FRA has not received a written status report from BNSF on the progress of the testing for the 5,000 Mile ECP test train that has been due to the agency since April 2015.[24] Therefore, AAR's unsupported contentions concerning the North American experience with ECP brakes do not present a compelling reason to revisit PHMSA and FRA's ECP brake requirement for HHFUTs on trains traveling in excess of 30 mph.

2. Foreign Experience With ECP Brakes

AAR raises two issues about PHMSA's reliance on international experiences with ECP brakes. First, AAR contends that it was inappropriate for PHMSA to rely on the experiences of Australian and other foreign railroads with ECP brakes. AAR believes the ECP

[21] PHMSA recognizes that Mr. Iden also provided a statement as part of UP's comment to the docket for this rulemaking. *See* PHMSA–2012–0082–2558. In that statement, he restated his caution that ''ECP braking should begin with high-mileage high-utilization cars.'' PHMSA agrees, which is why it has limited ECP braking to the highest use type trains. However, Mr. Iden now maintains that distributed power delivers comparable benefits to ECP brakes. In making this determination, Mr. Iden states that UP came to this conclusion through in-depth examination of event recorders of test trains. UP has not published the data or the analysis upon which this report was based. It did not provide this information to Booz Allen, which was actively collecting ECP brake information at the time of UP's tests, and it did not produce the information to PHMSA or FRA during this rulemaking.

[22] PHMSA's view also is supported by a 2014 presentation prepared by AAR's transportation research and testing organization, the Transportation Technology Center Inc. (TTCI). This presentation has been added to the docket. The TTCI ECP Brakes presentation is informative on the issue of the North American ECP braking experience and provides a distinct counterpoint to AAR's own arguments in this forum against the ECP braking provisions in the final rule. The presentation is broadly consistent with PHMSA's analysis in the RIA, confirming the many of the benefits of ECP brakes while also noting some of the difficulties acknowledged by PHMSA.

[23] The Oliver Wyman Report contends that FRA committed to collect data from ECP brake testing during the past eight years. This statement mischaracterizes FRA's statements. FRA's ECP brake rulemaking contains no such statements. *See* 73 FR 61512. FRA did contract with Booz Allen to collect and analyze ECP brake data, but that contract closed in 2010, and was not renewed largely because the railroads failed to provide data for analysis. Of course, the railroads have been free to provide data to FRA or publish papers expanding and reflecting upon their understanding of the effectiveness of ECP braking since 2010, but—except for the 2011 CP paper referenced earlier—the record is devoid of such documents.

[24] On August 18, 2015, BNSF and NS did make an oral presentation to FRA concerning the 5,000-mile pilot train. However, no written or electronic reports have been provided to the agency for review (the railroads cited the need for legal review) . This oral presentation identified concerns related to unanticipated penalty brake applications and repair times. FRA has not received written documentation to support the oral presentation or assess the integrity of the results and determine the underlying cause of these alleged events (for example, it may be helpful to compare the results to normal ECP-equipped trains that operate 3,500 miles between brake tests or how the pilot train compared to lines where there is more experience handling ECP-equipped trains). But, at least some of the problems BNSF presented orally appear to be ''teething'' issues that should be resolved as railroad personnel servicing the 5,000-mile pilot train along its route become more familiar with ECP brake technology and as equipment to service the train becomes more available.

brake operations in these other countries are dissimilar to operations in the U.S. AAR states this is because the international systems discussed tend to be closed-loop mining railroads that do not interchange with other railroads and rarely break apart the trainsets. Second, AAR claims that PHMSA and FRA mischaracterize the conclusions of the Sismey and Day Report, published in 2014, that conducted a survey of Australian railroads using ECP brakes to gauge their experiences with ECP brakes. *See* ''The ECP Brake—Now it's Arrived, What's the Consensus?,'' Sismey, B. and Day, L., presented to the Conference on Railway Excellence, 2014, Adelaide, Australia. Neither of these issues supports eliminating the ECP brake requirement from the final rule.

PHMSA and FRA believe that AAR's argument overstates the differences between the international ECP brake model and unit trains in the U.S., particularly HHFUTs. As noted on page 220 of the RIA, PHMSA and FRA expect that the limited number of HHFUTs will stay together for an extended period of time to meet the demand for service. The tank cars in an HHFUT are not regularly being switched to different destinations. These types of trains are not acting like a typical manifest train that commonly enters a yard to be broken up and have its cars reclassified and redirected into other trains. Instead, they are making continuous loops to and from the loading and unloading facilities. This is how these trains are currently marketed. *See* RIA, pp. 220, 232–233. The final rule builds off of that model. Of course, there may be facilities that cannot take an entire unit train at once. This may necessitate breaking the train apart for the limited purpose of serving the facility. PHMSA and FRA account for this circumstance by recognizing that U.S. railroads will likely use overlay ECP brake systems. This would allow operations at a facility without using ECP brakes, ensuring a measure of flexibility. Once that service is completed, PHMSA reasonably expects that the cut of tank cars will retake its place in the HHFUT to make its return trip. These similarities make the Australian (and other international experiences) relevant.

The claim that PHMSA mischaracterizes the Sismey and Day Report is surprising in light of PHMSA and FRA's reading of the Oliver Wyman Report. The Oliver Wyman Report cites to selective information from the Sismey and Day Report, which mischaracterizes its findings. To be clear, PHMSA and FRA accurately cite to the Sismey and Day Report in the RIA. *See* pp. 34–36. On page 34 of the RIA, PHMSA and FRA note that the report details how ECP brakes have performed in practice since Australian railroads began using the technology. PHMSA and FRA fully recognize in the RIA that the report highlights the benefits of ECP brakes and the associated challenges experienced by Australian railroads. In summarizing the conclusion of the Sismey and Day report, PHMSA and FRA note that ''[t]he report concludes that the challenges experienced in practice are largely resolved and that there is a business case to expand the use of ECP brakes into intermodal service.'' PHMSA and FRA do not see the basis for AAR's claims given the ''Conclusion'' of the Sismey and Day Report, which is as follows:

> ECP is here to stay and is becoming more widely accepted and understood. There have been issues in the introduction and implementation of ECP brakes which can be categorized as manufacturing/teething issues and unexpected surprises.
>
> These have not been experienced by all operators of ECP brakes. Solutions have now largely been identified to allow them to be managed to the point where their impact on operations is reduced or eliminated.
>
> There is as yet untapped potential for ECP brakes to improve train operations on Australia's rail networks.

Watershed events for the future of ECP brakes and the rail industry:

- Introduction of ECP brakes on unit mineral trains which happened from 2005 onwards.
- Retrofit of ECP brakes on unit mineral trains which are underway in the Pilbara from 2012 onwards.
- The emergence of viable business cases for Introduction of ECP brakes onto intermodal unit trains and onto the wider wagon fleet used in general service.

See p. 30, ''The ECP Brake—Now it's Arrived, What's the Consensus?''.

There is one additional issue raised by AAR through the Oliver Wyman Report that merits discussion. This is the highlighting of purported difficulties experienced by international users who commingled trains using ECP brakes with trains using conventional air brakes. The Oliver Wyman Report claims, based on an anecdotal report of a single unnamed employee, that the former Quebec Cartier Mining Railroad or QCM (now AccelorMittal) has experienced difficulties with operations where three of the company's eight trains are equipped with ECP brakes while the other five trains have conventional brakes. The report claims that severe problems have occurred when trying to pick up bad order cars when some cars are equipped with ECP brakes while others are equipped with conventional air brakes. The Oliver Wyman Report then attributes to the unnamed employee a statement that the railroad is considering standardizing braking using just ECP brakes or just conventional air brakes.

To be clear, the Oliver Wyman Report provides no hard evidence that QCM has instituted a plan to eliminate its fleet of trains equipped with ECP brakes or its trains equipped with conventional air brakes.[25] However, the situation described above with bad ordered cars would not present the same problem for an HHFUT equipped with ECP brakes in the U.S. The QCM uses a stand-alone ECP brake system on its trains. The stand-alone ECP brake system eliminates the ability to revert to conventional air brake mode. PHMSA expects that U.S. railroads will use an overlay ECP brake system, which allows a car to be transported in ECP brake or conventional air brake mode. This was discussed extensively in the RIA. *See* pp. 219–220, 225, and 230.

PHMSA also notes that QCM made a business decision to introduce trains equipped with ECP brakes onto its line in 1998. This means that QCM has voluntarily operated with a mixed allotment of ECP brake trains and conventional air brake trains for about 17 years. If the purported difficulties of maintaining ECP trains along with conventional air brake trains were as severe as the Oliver Wyman Report suggests, then PHMSA and FRA expect that QCM would have abandoned either ECP brakes or conventional air brakes long before June 12, 2015, which is the date of the Oliver Wyman Report.

3. Business Benefits of ECP Brakes

AAR argues that ''PHMSA relied on the purported business benefits of ECP braking as predicted in a 2006 report by Booz Allen Hamilton,'' and did not make an effort to verify whether real-world experience with ECP brakes validated the Booz Allen predictions. It is AAR's view ''that the benefits predicted by Booz Allen nine years ago did not materialize in subsequent field tests in North America and operations in foreign countries.'' Therefore, it states that PHMSA and FRA erred by calculating business benefits based on the Booz Allen analysis. AAR relies on the Oliver Wyman Report to support its contentions, *see* pp. 24–48, but its contentions simply are not supported by the facts. PHMSA and FRA considered a number of sources in addition to the

[25] The Oliver Wyman Report does not state whether QCM would convert to all ECP brakes or all conventional air brakes.

Booz Allen Report to develop the final rule, including comments to the NPRM, reports and presentations analyzing ECP brake operations in North America and abroad, and testimony during two FRA public hearings on ECP brakes.

Fuel Savings: The Oliver Wyman Report states that there are likely some fuel savings, but they are not ''validated.'' The Oliver Wyman Report states that the 5.4 percent fuel savings on CP occurred, but that the actual savings over an entire system would be less, because the terrain over which it realized the 5.4 percent savings was advantageous. The Oliver Wyman Report then states that PHMSA's 2.5 percent estimate of fuel savings, less than half that realized by CP, and half of that predicted by the Booz Allen Report, was arbitrary, with no basis.

As explained in the RIA on pages 216–217, 262–263, and 267, PHMSA and FRA assumed a reduction of more than 50 percent from the real-world CP experience because PHMSA recognized that the terrain where the testing occurred maximized fuel benefits. This was very conservative, and a larger estimate of fuel savings could have been justified. At no point does the Oliver Wyman Report present hard evidence that railroads would experience less fuel savings than the 2.5 percent PHMSA and FRA estimate. Instead, the Oliver Wyman Report offers something from the Sismey and Day Report that stated ''the general feeling was that there may be some fuel savings with ECP braked trains but no one would hazard a guess on the magnitude.'' The Oliver Wyman Report also quotes an unnamed employee from the QCM to support its position. This employee purportedly commented to Oliver Wyman that there had been no fuel consumption benefits from ECP brakes compared to conventional systems. This anecdotal evidence from an unnamed source is directly contradicted by independent published reports that we cited in the final rule about QCM, noting that its ECP-equipped trains had led to a decrease in fuel use of 5.7 percent. *See* 80 FR 26697. This evidence supports the reasonableness of PHMSA and FRA's fuel savings estimate, with the likelihood that any errors were to the conservative side. Even if we accepted the Oliver Wyman Report's unsubstantiated statement that ECP brakes would result in ''some fuel savings,'' the 2.5 percent we used for fuel savings in the final rule is a reasonable estimate of ''some savings.'' Therefore, we decline to reduce that estimate to zero as AAR urges.

Wheel Savings:

The Oliver Wyman Report states at p. 96:

> [w]heel impact load detectors (WILD) have found wheels on ECP brake-equipped trains with defects such as tread build up, flat spots, and wheel shelling. In the current ECP brake operation, these trains are handled as unit trains and are less subject to switching operations, therefore it appears, from BNSF's ECP experience, that higher brake usage is leading to increased wear and stress on wheels than might otherwise be seen on conventional air brake equivalent trains.

The Oliver Wyman Report merely makes the statement above but does not present evidence to support that ECP-equipped trains have experienced more of these types of defects than equivalent unit trains with conventional air brakes operating under the same conditions on the same track. Notwithstanding, some initial increase in wheel wear, such as thermal mechanical shelling, is explainable—and, possibly, expected—during the familiarization phase when new train crews gather knowledge about the braking capabilities of ECP braking. PHMSA and FRA addressed this issue in the RIA on page 217. However, the Oliver Wyman Report does not provide the necessary context for the information to allow PHMSA and FRA to draw any judgments about its statements. To adequately evaluate such reports, it is important to untangle the potential causes so that we can determine whether the reported wheel wear was caused by issues related to ECP braking. The Oliver Wyman Report does not do that. As a result, it is impossible to conclude that the reported wheel wear is caused by ECP braking as opposed to factors related to track conditions or usage.

PHMSA and FRA do note that the phrase ''higher brake usage'' possibly could explain the greater wheel wear found by some ECP brake operations. The wheel wear per unit time per car is higher because the cars tend to operate more miles. The savings in wheel wear, detailed on pages 263–266 of the RIA, are based on car-miles, as explained in the flow assumptions on pages 252–254 of the RIA. There is no evidence to suggest the cars with ECP brakes have more wheel wear per car-mile. As an example, if the cars have more wheel wear per unit of time and are experiencing a 50 percent reduction in wheel wear, that implies the cars are used for more than twice as many miles per car-year as cars not equipped with ECP brakes. PHMSA and FRA believe this is a reasonable inference to draw from the data and notes that it further contradicts other AAR assertions that more ECP-equipped tank cars will be needed. Evidence that ECP-equipped wheel temperatures are more even, as offered in the Oliver Wyman Report, makes it likely that savings per car mile are being realized in ECP-equipped trains. Neither AAR, nor the Oliver Wyman Report, offers any evidence of less wheel savings per car-mile than estimated in the RIA.

The Oliver Wyman Report also states that rail renewal will not be coordinated with wheel maintenance because the tank car maintenance will be the responsibility of the tank car owners, not the railroad. FRA staff, including inspectors with recent employment experience on railroads, are not aware of any efforts to coordinate wheel maintenance with rail renewal on any operating railroads. This seems doubly irrelevant, as the RIA does not estimate rail savings as a quantifiable business benefit, while the Oliver Wyman Report describes a failure to coordinate maintenance in a way that is not current railroad practice.

Brake Inspections: The Oliver Wyman Report contends that North American operations have produced no data to support PHMSA's claim that the overall tank car fleet size can be reduced because cycle times will improve due to longer intervals between brake inspection stops with ECP brake equipment.

The Oliver Wyman Report contention does not comport with reality. Railroads do see advantages from increasing the current 1,000-mile brake inspection distance to 3,500 miles.[26] FRA allowed the longer distance between inspections in its 2008 ECP Brake rule at the request of railroads as an incentive to the railroads to test ECP brake equipment and because of the safety features inherent in ECP brake systems. *See* 73 FR 61512 (Oct. 16, 2008). FRA has recently granted a request from BNSF and NS allowing these railroads to move forward with a pilot program that increases the distance between brake inspections to 5,000 miles on certain ECP-equipped trains. This pilot program allows BNSF and NS to conduct test operations using an ECP-equipped train from the Powder River Basin to Macon, Georgia with only one brake inspection per trip compared to four inspections (one Class I and three Class IA inspections) for the same train operated using conventional brakes. It follows

[26] The recent TTCI ECP Brakes presentation notes that permitting 3,500 miles between brake inspections results in about 50 fewer inspections per year for high-mileage cars. TTCI concluded that the current regulatory relief on brake inspections for trains with ECP brakes is a ''‘reliable’ benefit for high mileage cars ($220/car/year),'' with a potential peak of $300/car/year. These estimates are comparable—although slightly less—to the $330/car/year benefits PHMSA estimated.

that if the railroads did not envision a benefit to the decreased frequency of brake inspections, they would not be pursuing the 5,000-mile waiver.

Cycle Times: The Oliver Wyman Report argues that PHMSA's assumptions regarding reduced cycle times and reductions in car fleet size are overstated because trains must still regularly stop for servicing events and crew changes. Additionally, the Oliver Wyman Report contends that the speed of a single train will be influenced by other trains on the system, and skipping inspections does not exempt a train from network congestion. These arguments, which are addressed in part above, do not present a compelling rationale for eliminating the ECP brake requirement for HHFUTs.

Class IA brake tests can take several hours, and are usually performed in yards. If the ECP-equipped train is ready for departure eight hours earlier than usual, the train may be dispatched ahead of other trains that would have been dispatched before it in that eight-hour window, and, it will, on average, arrive at the next yard eight hours earlier, as congestion effects are likely to be random. Also, there is no reason to revise the estimated reduction in tank car fleet size assumed by PHMSA and FRA. Train crew changes do not require Class IA brake tests, and are not relevant to this issue. Further, the Oliver Wyman Report's suggestion that wheel wear is increased because of increased usage would indicate that unit trains are experiencing shorter cycle times.

Brake Shoe Savings: The Oliver Wyman Report contends based on a singular statement from an unnamed BNSF employee that it is unlikely that any brake shoe savings would be possible for ECP brakes compared to conventionally braked trains.

While PHMSA and FRA did not calculate any savings for brake shoes in its analysis of business benefits, it appears that there might be a benefit, based on the comment in the Sismey and Day Report, cited in the Oliver Wyman Report, that shoe wear was very even on ECP-equipped trains when compared to trains with conventional air brakes. Thus, the concerns raised by the Oliver Wyman Report in this area are not relevant to PHMSA and FRA's determinations about ECP brakes.

Network Capacity Benefits: The Oliver Wyman Report questions the RIA to the extent that it includes a statement that ''FRA found that ECP brakes offered major benefits in train handling, car maintenance, fuel savings, and increased capacity under the operating conditions present.'' The Oliver Wyman Report is unclear about the basis for this claim because it contends that ''FRA has not publically reported on any data collection and analysis from North American railroad test operations using ECP brakes.''

The increased capacity discussed in the RIA comes from a statement in the Booz Allen Report. However, those benefits were based on ECP brakes being installed on a large proportion of the trains on a line. PHMSA and FRA do not expect the same situation with respect to HHFUTs. As a result, PHMSA and FRA did not include capacity benefits in the quantified business benefits.

4. Reliance on Business Benefits Compared to Safety Benefits of ECP Brakes

AAR contends that PHMSA must rely on theoretical business benefits, even if not supported by actual experience, because AAR believes the costs far exceed the potential safety benefits of the final rule. We disagree. The safety benefits of ECP brakes are integral to the final rule. As such, PHMSA and FRA relied on both the business benefits and safety benefits to support the ECP brake requirement adopted in the final rule.

PHMSA and FRA consider the safety benefits to be a fundamental element of the overall benefits and believe that the safety benefits estimated in the RIA are reasonable based on the evidence. The safety benefits of ECP brakes are thoroughly described in detail in the RIA on pages 78–120 discussing both low consequence events and high consequence events. This discussion examines the probability of these events occurring and includes a range of benefits. Furthermore, the RIA thoroughly examines the effectiveness rate for ECP brakes on pages 246–251 in the context of accident mitigation and avoidance, finding that ECP brakes reduce the probability of tank car punctures in the event of derailment by about 20 percent.

With respect to AAR's argument that PHMSA overly relied on theoretical business benefits, PHMSA and FRA requested comments from the industry in the NPRM. Industry did not submit any data to contradict our findings.[27] Moreover, between the NPRM and final rule, PHMSA and FRA continued to conduct research to determine benefits that would be most accurate looking at real world experiences. The business benefits relied upon by PHMSA came from documented sources, including testimony and reports from Class I railroads. These sources include reports addressing operations on CP, BNSF, Quebec Cartier Mining, UP, and NS, as well as operations on international railroads. PHMSA and FRA's views were also informed by review of the Booz Allen report prepared for FRA in 2006. All these reports are cited in the RIA on pages 34, 217, 235, 236, and 263.

These sources discuss the actual effects of ECP brake usage on multiple railroads. Indeed, long before PHMSA began the rulemaking process for the final rule, BNSF reported fleet reductions on trains equipped with ECP brakes. Similarly, NS reported that ECP-equipped trains experienced a reduction in dwell time, operated at track speed for longer periods of time, were able to better control their speed, and had faster loading processes and better car loading performances than trains with conventional braking. This information is consistent with the recent TTCI ECP Brakes presentation noted above, which found among other things that ECP brakes could increase equipment utilization, allow for longer trains, and permit higher train speeds. While this presentation was not used in the development of the final rule, it is helpful in informing the current discussion on ECP brakes. However, even without the TTCI ECP Brakes presentation, PHMSA is confident the information cited in the RIA supports its analysis.

5. Cost Related to Implementation of ECP Brakes

AAR argues that PHMSA underestimated the cost of implementing ECP braking in the final rule, and that the actual cost to implement ECP brakes on HHFUTs is more than six times PHMSA's estimate. This argument is based on AAR's contention that ECP brake-equipped tank cars and locomotives will not run in dedicated sets, segregated from the rest of the fleet. AAR contends that segregated fleets are not operationally possible. As a result, it suggests that 10 times as many locomotives will need to be equipped with ECP brakes as we estimated and that PHMSA underestimated the number of tank cars needed for ECP brake service on HHFUTs by more than 25 percent. *See* Oliver Wyman Report, pp. 49–70.

These arguments are not new. PHMSA and FRA considered AAR's comments to the NPRM on this subject. We expect that railroads will be able to manage HHFUT fleets, which can be kept as captive fleet unit trains. Similar to unit coal trains that currently operate with ECP brakes, HHFUTs are expected

[27] Even in the appeal process, the Oliver Wyman Report provides little verifiable data to support its findings. Instead, the report relies almost exclusively on interviews conducted with various unnamed railroad employees.

to stay together, including the locomotive. *See* RIA, p. 220. While railroads may regularly shift locomotives under current operations, PHMSA and FRA are confident that, like coal unit trains, railroads can manage a specialized fleet of ECP-equipped locomotives to handle HHFUTs. *See* RIA, p. 221. In this sense, managing locomotives for HHFUTs likely is similar to managing distributed power locomotives, which is already a common practice. Not all trains have distributed power, but the railroads have a history of being able to manage these assets efficiently.

PHMSA and FRA do recognize there are costs associated with keeping a fleet of HHFUT locomotives. As a result, PHMSA and FRA estimated that it would cost around $80 million (undiscounted) to equip all the necessary locomotives with ECP brakes. This included equipping four locomotives for every train, even though we expect that railroads will only need an average of three locomotives for operations. We also included the cost of wrap-around cables to provide a backup preventing the lack of locomotives from becoming a bottleneck. Wrap-around cables allow a train to operate in ECP brake mode even when one or more locomotives or cars are not equipped with ECP brakes. Additionally, PHMSA and FRA accounted for fleet management costs.

The Oliver Wyman Report assumes that all locomotives will be equipped with ECP brakes, with a total cost of about $1.8 billion. This appears to overestimate the costs, as it assumes that railroads cannot manage their locomotive fleets. Given the railroads' history of effectively managing their equipment, it is unlikely that railroads will equip all locomotives. However, if a railroad chooses to equip all locomotives, it will be an operating practices decision and not due to the regulation.

The costs that PHMSA and FRA used are well documented in the RIA. They incorporate the comments PHMSA received to the NPRM. Many of these comments came from the rail industry, including AAR, RSI, and car manufacturers. For example, we estimated that it would cost $7,800 to retrofit a tank car with ECP brakes and $7,300 to equip a new car with ECP brakes. This was based on comments from RSI. The average cost—based on the estimated number of new construction tank cars needed compared to the number of retrofit tank cars needed—was $7,633. AAR in its ''Supplemental Comments,'' which were posted to the docket on January 30, 2015, stated that the cost of ECP brakes per tank car is $7,665. The Oliver Wyman Report states that the cost per tank car for ECP brakes is $9,665. *See* p. 58. Based on the evidence available, PHMSA made a reasonable estimate of the cost of equipping each required tank car with ECP brakes.

With respect to the cost of locomotives, the Oliver Wyman Report estimates the cost of equipping a current locomotive to be $88,300 and provides no estimate for equipping new locomotives. PHMSA and FRA anticipate that 2,532 locomotives would be needed to operate all HHFUTs in ECP brake mode. As discussed, this number is based on an average of three locomotives per HHFUT plus an additional locomotive for each HHFUT to act as a buffer when another locomotive is shopped. Therefore, based on current production, PHMSA and FRA expect that the railroads will be able to operate HHFUTs using new locomotives. We estimate the incremental cost of equipping a new locomotive with ECP brakes over current technology electronic brakes (*i.e.* Wabtec Fastbrake or New York Air Brake CCB–2) to be about $40,000. This information was provided by FRA's Motive Power and Equipment Division, and was based on the Division's background knowledge resulting from information from the manufacturers. As a result, PHMSA and FRA are confident that the estimate is reasonable.

The Oliver Wyman Report also assumes that every employee must be trained on ECP brake systems. PHMSA and FRA believe the ECP brake requirements in the final rule can reasonably be accomplished without training every employee. Indeed, we significantly increased the number of employees we estimated would need to be trained from the NPRM to the final rule. This was because PHMSA and FRA reassessed their initial position from the NPRM based on the public comments. Using the waybill sample, we determined that approximately 68 percent of the total ton-miles were on routes that had crude oil or ethanol unit trains. As a result, PHMSA and FRA adjusted the number of employees to include 68 percent of the total crews. According to these estimates, around 51,500 employees would need to be trained, as described on page 242 of the RIA.

The Oliver Wyman Report also states that it takes significantly more time to make repairs on trains equipped with ECP brakes. We acknowledged that the lack of training and unfamiliarity with the ECP brake components likely contribute to such delays.[28] *See* RIA, pp. 223–224. However, once all employees who work at locations with ECP-equipped HHFUTs are adequately trained, PHMSA and FRA expect the repair time will be reduced to match that of conventional brakes.

6. Potential for Network Disruption

AAR contends that mandating ECP brakes will cause significant collateral damage because ECP brakes are unreliable. AAR similarly believes that deployment of ECP brakes will disrupt major arteries in the national railroad network, thereby degrading the performance and capacity of the network. Further, AAR argues that the ECP brake requirement could delay Positive Train Control (PTC) implementation, which has been deemed safety-critical.

PHMSA and FRA addressed these arguments in the RIA in our discussion on the reliability of ECP brakes. *See* RIA, pp. 222–226. PHMSA and FRA conducted substantial research into the implementation of ECP brakes and found no examples of damage to the network where ECP brakes were properly integrated. As a result, we expect that with the correct infrastructure in place—such as sufficient training of railroad personnel and proper deployment of equipment and ECP brake components to ensure that they are readily available when needed—railroads can manage the ECP brake implementation without a disruption to the network. As noted in the RIA, at least one manufacturer has stated that the issue with ECP brake systems ''is not reliability, but rather, availability of power and shops.'' ''The Science of Train Handling'', William C. Vantuono, Railway Age, June 2012, at 25–26. Because of these issues, PHMSA recognized that there may be delays associated with ECP brake implementation at the initial stages, as there would be during the roll-out of any newer technology. However, given that the ECP brake operations are not required on HHFUTs until January 1, 2021, for trains transporting a loaded tank car of Class 3, PG I, flammable liquid, and May 1, 2023, for all other HHFUTs transporting Class 3 flammable liquids, PHMSA believes there is sufficient time built into the implementation to ensure the network is not significantly disrupted by delays attributable to ECP braking technology.

AAR's reliance on the Oliver Wyman Report does not alter PHMSA and FRA's

[28] The current lack of availability of the necessary ECP brake system components can also contribute to delays.

position. The Oliver Wyman Report claims that ''[a]dding a second braking technology to a large portion of the North American rolling stock fleet will materially increase the operational complexity of the railroad industry, and will reverse gains in productivity achieved over the past 35 years.'' *See* Oliver Wyman Report, p. 79. We analyzed the size of the fleet that would be required to be equipped with ECP brakes in the RIA. The number of cars and locomotives required to operate an HHFUT fleet equipped with ECP brakes likely would be relatively small and captive (a maximum of 633 unit trains on the network at any given time, *see* RIA, p. 219) when compared to the total universe of train movements.

The Oliver Wyman Report also raises a number of issues, including concerns about ECP cables, ECP brake-equipped locomotives, ECP brake car components, crosstalk, and unexpected stopping. None of these purported issues support eliminating the ECP brake requirement in the final rule. Much of what is presented is anecdotal evidence based on reports from unnamed railroad personnel that are lacking in data or analysis. Further, some of the railroads cited as providing information on their ECP braking experience have no experience with the current version of ECP brakes that is compliant with July 2014 update to the AAR Standard S–4200 series. For example, CP has not used ECP braking since removing it from limited operations in 2012, while UP has not operated ECP-equipped trains in approximately six years.

AAR raised the ECP brake cable issue in its comments to the NPRM and PHMSA and FRA addressed those comments in the final rule. *See* 80 FR 26702. AAR commented that the cables and batteries for ECP brakes would need to be replaced every five years. PHMSA and FRA accounted for this cost in the RIA on page 228.

We also addressed the crosstalk issue in the RIA at page 225. Crosstalk occurs when there is an interruption in the signal, usually caused when two ECP brake trains pass in close proximity, which results in an ECP-equipped train going into emergency brake mode. PHMSA and FRA acknowledged that this was an issue in earlier iterations of ECP brake systems, but software updates to the ECP brake programming had resolved the problem. *See* ''The ECP Brake—Now it's Arrived, What's the Consensus?'' Indeed, AAR acknowledged this by incorporating the software update into the AAR Standard S–4200 series in July 2014.

The Oliver Wyman Report further contends that PHMSA and FRA incorrectly assessed the effect of ECP brakes on wheel wear. The basis for this contention appears to be some recent ''test operations'' on BNSF where wheel defects such as tread build up, flat spots, and wheel shelling have been found. *See* Oliver Wyman Report, p. 94. PHMSA and FRA note that the quoted ''BNSF 14 Run Overview 2014'' has not been provided for reference, and, as discussed above, the report does not present any evidence that ECP-equipped trains actually experience more of these types of defects than equivalent trains with conventional air brakes operating under the same conditions over the same track. Although some initial increase in wheel wear, such as thermal mechanical shelling, would be explainable during the familiarization phase when new train crews gather knowledge about the braking capabilities of ECP brakes, *see* RIA, p. 217, the Oliver Wyman Report does not put its information in a context that allows PHMSA and FRA to draw any judgments about that information. The same is true with respect to the reporting of a recent situation where a single train had 14 separate wheel exceptions taken. The Oliver Wyman Report merely concludes the wheel exceptions were due to ECP braking without examining the potential causes to determine whether the reported wheel wear was actually caused by issues related to ECP braking or something else. Therefore, as presented, there is no evidence that the reported wheel wear is caused by ECP braking as opposed to factors related to usage or other track conditions. This is important because wheel wear is a function of use. Further, as noted above, the phrase ''higher brake usage'' possibly explains the greater wheel wear found in some operations. The wheel wear per unit time per car is higher because the cars operate more miles. PHMSA and FRA calculated the savings in wheel wear, detailed on pages 263–266 of the RIA, based on car-miles, as explained in the flow assumptions on pages 252–254 of the RIA. There is no evidence to suggest these cars have more wheel wear per car-mile.

The Oliver Wyman Report also argues that PHMSA and FRA did not address potential problems with buffer cars for HHFUTs. In the RIA, p. 238, we address the costs associated with equipping the buffer cars with wrap around cables. This was considered the lowest cost option. PHMSA and FRA recognized that there are other options, as the Oliver Wyman Report details. The Oliver Wyman Report option of equipping a fleet of buffer cars with ECP brakes is significantly more expensive than the reasonable alternative we provided. If railroads chose to use a permanent fleet of ECP-equipped buffer cars, that would be a business decision, not a regulatory requirement.

Finally, AAR contends that the ECP brake requirements in the final rule may delay implementation of PTC. Railroads are currently required by statute to implement PTC by the end of the year 2015. The ECP brake requirement for HHFUTs does not become effective until January 1, 2021, or May 1, 2023, depending on the commodity being transported. This means that railroads should have PTC implemented well in advance of the ECP brake requirement. Thus, we do not foresee a situation where the ECP brake requirements will delay PTC implementation.

7. Reliance on the Sharma Report

AAR contends that PHMSA and FRA erred in using the new Sharma & Associates report (Sharma Report) to calculate the benefits due to the reduced probability of punctures on HHFUTs operating in ECP brake mode. It argues that the assumptions used in the Sharma Report are flawed in numerous ways. AAR provides the ''Summary Report Review of Analysis Supporting 'Hazardous Materials: Enhanced Tank Car Standards and Operational Controls for High-Hazard Flammable Trains' Final Rule'' (TTCI Summary Report), which TTCI personnel prepared, as a supporting document. We disagree with AAR's contentions. For the reasons discussed below, PHMSA and FRA find that AAR's arguments do not support eliminating the ECP brake requirement in the final rule.

Statistical approach: The statistical approach used in the Sharma Report to analyze the potential benefits of ECP brakes in the final RIA is not flawed. The confidence band suggested by the TTCI Summary Report is applicable to situations where a minimum value is being specified. The confidence band is needed to understand the range of values and the potential for values to fall below the specified value. For example, when specifying tensile strength of a material (based on average test values) it is important to know the potential variability, in the form of a confidence band, of the strength. In the case of the RIA, PHMSA and FRA's analysis determined the effectiveness of ECP brakes based on the average of the calculated number of punctures. Implicit in a comparison of averages is that in some cases the effectiveness will be less than the average and in others greater than the average.

Consider the notion of ''test'' versus ''simulation.'' As an example, if one were conducting a physical test to determine the effect of a change in thickness on the impact energy of a specimen, one might have to conduct several tests and then apply statistical techniques to the measured values to arrive at the results. On the other hand, if one were using a finite element simulation to measure the same condition, one set of simulations would be sufficient. In fact, every simulation with the same set of input parameters would produce the same output. The variability that is associated with ''testing'' is not there.

Another problem with using the conventional statistical methods, such as confidence intervals and margins of error, is that the cases PHMSA is ''sampling'' are not random. In fact, they were deliberately chosen to represent a range of input conditions. Additionally, the methods suggested in the TTCI Summary Report would not be appropriate because there is no variance in the ''measured'' results of our trials. Each trial (a simulation with a specific set of inputs) always produces the exact same set of outputs. Hence, our ''variation'' is not produced by the random variation of factors beyond our control; it is essentially the result of specific input conditions, though the outputs are not predictable from the outset.

The Sharma Report considers all different combinations of initial speed and number of cars behind the point of derailment (POD). The sample size for the conventional and ECP brake systems consists of 162 cases (separate derailment simulations) each. For the two-way EOT brake configuration, 90 cases were considered. As indicated above, these cases were used to simulate average derailment conditions using each brake configuration. The methodology is not trying to predict the outcome of a specific derailment within some margin of error, nor is it being used to assure that all outcomes meet some minimum requirement within some confidence interval (such as how a set of tensile tests would be used to establish a design stress for a material). For these reasons, the TTCI Summary Report analogy of an election is, again, flawed, as the system is not trying to predict the results of one particular event.

Inconsistent values in tables: The TTCI Summary Report also points to number of inconsistencies in the values reported for the most likely number of punctures and the analyses in which they are used throughout the RIA. PHMSA recognizes that there was a transcription error in Table BR4 of the RIA, see p. 210, and corrects those errors here. Table BR4 should read as follows:

TABLE BR4—RISK IMPROVEMENT DUE TO BRAKING, WITH POD DISTRIBUTED THROUGHOUT THE TRAIN

Tank type	Speed, mph	Most-Likely number of punctures			Percent improvement due to ECP brakes only compared to two-way EOT
		Conventional brakes	Two-way EOT (DP: lead + rear)	ECP Brakes	
7/16″ TC128, 11 gauge jacket, ½″ full-height head shield	30	3.75	3.25	2.91	10.5
	40	6.80	6.14	4.64	24.4
	50	9.31	7.86	7.23	8.0
9/16″ TC128, 11 gauge jacket, ½″ full-height head shield	30	3.03	2.66	2.12	20.3
	40	5.64	5.09	3.78	25.7
	50	7.82	6.57	6.01	8.5

The TTCI Summary Report suggested that the effectiveness rate calculated in Table BR7 would change as a result of the transcription error in Table BR4. However, this is incorrect because Table BR7 calculates the effectiveness of ECP brakes after the effectiveness of the tank car upgrades is calculated. In other words, the ECP brake effectiveness values reported in Table BR7 reflect the effectiveness of ECP brakes in derailments involving DOT–117 and DOT–117R specification tank cars. As a result, Table BR7 continues to read as follows:

TABLE BR7—EFFECTIVENESS RATE OF ECP BRAKES WEIGHTED BY VOLUME OF PRODUCT SPILLED IN A DERAILMENT

	Number of incidents	Total spill volume	Share of total volume	ECP effectiveness rate at 30, 40, 50 mph	Cumulative effectiveness rate (%)
Below 34 mph	33	798,433	22.8	20.10	4.6
35–44 mph	8	1,488,350	49.2	25.80	12.7
45 mph and above	5	980,180	28	8.60	2.4
Total	46	3,499,656	100	.....	19.7

Modeling used in the final rule: The TTCI Summary Report contends the modeling and analytical approach used in the final rule is sufficiently different from the modeling and analytical approach used in the NPRM, suggesting that reliance on the final Sharma report for the final rule warranted additional notice and comment. Yet AAR discussed this very work in detail in its comments to the NPRM review. AAR's comments to the NPRM appended a 13-page critique of the LS-Dyna methodology authored by Dr. Steven Kirkpatrick of Applied Research Associates. In addition, the main body of AAR's comments to the NPRM contained several references to both Dr. Kirkpatrick's critique as well as Sharma's reliance on the LS-Dyna work. In developing the final rule, we refined the modeling and analytical approach used in the NPRM to account for and take into consideration many elements

of AAR's comments and Dr. Kirkpatrick's critique. For example, the modeling conducted during preparation of the NPRM was limited to modeling the results of a derailment of a 100-car train, assuming the derailment occurred at the first car behind a train's locomotive. In response to AAR's comments and Dr. Kirkpatrick's critique, in developing the final rule, we conducted additional modeling again using a 100-car train model, but this time to more accurately represent real life derailment scenarios, we modeled and analyzed the effects of cars derailing throughout the train consist (*i.e.,* assuming the 20th, 50th, and 80th cars in a consist derail), not just the first car. Similarly, to address AAR and Dr. Kirkpatrick's concerns regarding the impactor size used in the modeling, we conducted a sensitivity analysis using both smaller and larger-sized impactors than used in the NPRM modeling. This sensitivity analysis demonstrated that impactor size affected the number of tank cars punctured and the velocity at which those cars punctured only negligibly.

One element of the analysis that was introduced for the final rule was the mechanism for calculating overall effectiveness based on the distribution of PODs along the train. This addition to the analysis was in response to the critique of the technique by AAR/TTCI in comments to the NPRM suggesting that this distribution be accounted for in the analysis. This element was added to the analysis in the final rule stage in response to AAR's comments critiquing the NPRM.

The Sharma Report model was validated in both the number of cars derailed and number of punctures in real life derailments such as Aliceville. Indeed, the rear car distance traveled in one set of Dyna simulations matched the Aliceville locomotive's event recorder data with a difference of less than four percent. This indicates that, in spite of all the potential variations, the derailment simulations closely matched what actually occurred in the Aliceville accident as evidenced by the event recorder download. *See* RIA, p. 214.

On the issue of impactor size distribution, the TTCI Summary Report notes that ''the distribution of impactor size was very similar.'' PHMSA and FRA disagree. The average impactor size variation between the three distributions was 58 percent. We would not characterize that as ''similar.'' Past work on tank car puncture resistance—including substantial work conducted by Dr. Kirkpatrick (and funded by the industry/AAR)—shows that the effect of a 58 percent variation in impactor size is quite significant.

Furthermore, the review of Sharma's modeling in AAR's comment to the NPRM suggested that the distribution presented above might be skewed towards smaller impactors. However, as noted by Dr. Kirkpatrick in his earlier work, when the combinations of complex impactor shapes (such as couplers and broken rail) and off-axis impactor orientations are considered, many objects will have the puncture potential of an impactor with a characteristic size that is less than 6 inches. *See* ''Detailed Puncture Analysis of Tank Cars: Analyses of Different Impactor Threats and Impact Conditions,'' Kirkpatrick, SW., DOT/FRA/ORD–13/17, March 2013.[29] The impactor distributions considered in PHMSA and FRA's analysis in the final rule are consistent with this notion.

Need for additional study: The TTCI Summary Report contends that the modeling and analysis utilize a number of assumptions and simplifications, the effects of which need further study. AAR made a similar comment in its comments on the NPRM, and the extended analysis in the final rule addressed these issues by studying/reviewing several additional elements of the methodology. PHMSA and FRA addressed several prior criticisms submitted in connection with the NPRM, including:

- The effect of varying the POD along the length of the train
- The effect of alternate train lengths
- The effect of varying internal pressures
- The effect of varying impactor sizing, etc.

In addition, the RIA for the final rule includes justification for many of the assumptions made in the analysis, including the friction coefficients used, the coupler model, and the lateral derailment load values. *See* RIA, pp. 63–72, 207–212, 213–216, and 246–247. In other words, this is similar to AAR's earlier critique on the topic and we addressed most elements of that critique in the RIA.

Derailment location: The TTCI Summary report states that ''the probability distribution for derailment location within the train does not appear to take train length into account,'' thus exaggerating the benefit of operating in ECP brake mode. The Sharma Report estimated the distribution of PODs using the best available data, which included all reasonable derailments. Any ''exaggeration'' of benefits towards ECP brakes due to the PODs being skewed towards the front of the train would tend to exaggerate the benefit of DP trains even more. Thus, even if the distribution was skewed towards the front, the Sharma Report does not exaggerate the relative benefits of ECP brakes compared to DP trains.

Use of derailment data from all train types: The TTCI Summary Report asserts that the analysis performed on the probability of derailments occurring throughout the train seems to use data from all train types to derive a distribution of derailment locations. This is true. The locations of train derailments are more uniformly spread under mixed traffic conditions compared to unit trains. This tends to push the average location of POD further towards the rear of the train. In fact, the POD, as a percent of the length of train for unit trains, is about half that of freight trains (21% compared to 41%). As a result, PHMSA and FRA expect that the use of derailment data of all train types (as opposed to unit trains only), results in a prediction of lower benefits for ECP braking. Using PODs from unit trains only would have led to ECP brake benefits being higher. We considered this during development of the final rule and determined our assumptions were conservative.

Analyzing the number of cars trailing POD: The TTCI Summary Report notes that ''[t]he critical parameter is not the first car in the train that was derailed, but rather the number of cars trailing the first car derailed.'' PHMSA and FRA agree. This is exactly how all the LS-Dyna modeling was done. We modeled 100 cars, 80 cars, 50 cars, and 20 cars behind the POD, and interpolated the results for the other cases.

Net braking ratios: The TTCI Summary report notes that PHMSA and FRA make multiple references in the RIA to the use of higher net braking ratios (NBR) with ECP brakes. While the RIA does make reference to a higher NBR, the LS-Dyna simulations were all performed with the same braking ratio. The results presented in the RIA are based on ECP brakes with 12 percent NBR, the same used for the other brake systems considered. *See* RIA, pp. 324. So, the benefits attributed to ECP brakes regarding the reduced number of cars punctured do not include any contribution from increased braking ratio.

However, it is important to note that even though the NBR allowed for the different brake systems are theoretically the same, the use of ECP brakes does, as a practical matter, allow a train to better approach the high end of the limit. This

[29] *https://www.fra.dot.gov/eLib/details/L04420.*

is because features inherent to ECP brake design allow a more uniform and consistent effective brake cylinder pressure to be maintained as compared to conventional pneumatic brakes.[30] Closed loop feedback control of the cylinder pressure is an inherently more reliable method of obtaining the commanded pressure than the open loop, volume displacement method used in conventional brake systems. Furthermore, trains equipped with ECP brakes can detect and report low brake cylinder pressure malfunctions on individual cars, which can then be addressed. In contrast, a malfunctioning pneumatic control valve generating lower than commanded pressure may go unnoticed indefinitely. Additionally, the overall braking ratio of a train equipped with ECP brakes can be much closer to the allowable upper limit than a conventionally-braked train because the cars in an ECP-equipped train are all braking at the same effective brake ratio (to the extent that the physical capacity of their individual construction allows). The brake ratios of cars in a conventionally-braked train can vary over the allowable range (8.5 percent to 14 percent loaded NBR), so the train average brake ratio is limited by this variation already built into the existing fleet. For these reasons, PHMSA and FRA expect that DOT–117/DOT–117R cars (with ECP brakes) can be built (or converted from existing cars) with an NBR close to 14 percent and operated (in ECP trains) with a train average brake ratio also very close to 14 percent. In contrast, the train average brake ratio of a train with conventional air brakes is likely to be significantly lower, even if some of the cars have close to a 14 percent NBR.

Control of unit trains: The TTCI report takes issue with a statement in the RIA to the final rule concerning unit train operations being more difficult to control than other types of trains. The excerpts, and TTCI's comments, are qualitative characterizations of unit train operations. However, the excerpt from the RIA did not influence the objective analysis we performed in support of this rule.

Peak ECP brake benefits: TTCI takes issue with the modeling that shows ECP brake effectiveness peaking at 40 mph. The TTCI Summary reports states, '' [i]ntuitively, it would seem that the benefit of ECP brakes would either increase or decrease as speed increases.'' Derailment performance is the result of several physical phenomena. Consider a derailment that happens at a very slow speed. Given the physical strength of the tanks and the energy levels involved, there would be no punctures for either a conventionally braked train or an ECP-equipped train. As a result, there would be no perceived derailment benefit to ECP brakes at very low speeds when the benefit is measured by puncture probability. As the speeds increase, and one starts seeing multiple punctures as a result of the derailment, the benefits of ECP braking become more apparent. However, at higher speeds, the percentage of braking time spent in the ''propagation mode'' (where ECP brakes offer the most benefit) is a smaller portion of the overall time spent braking. Consequently, the relative benefits of ECP braking start to diminish at speeds over 40 mph.

Derailment rates: The derailment rate we used was based on the most recent five complete years of data: 2009–2013. Using the most recent years to construct this rate largely incorporates the factor of 10 decrease in the observed derailment rate cited by TTCI into our estimate of future derailments. It is not realistic to expect tenfold decreases in the derailment rate to continue indefinitely. In our judgement, the rate decrease may have bottomed out, so we used a constant rate based on the most recent data, which reduces the rate to the fewest derailments per carload observed in the available data, to forecast future derailments.

Criticism of Train Operation and Energy Simulator (TOES) modeling: The TTCI Summary Report attempts to respond to perceived criticism of the TOES modeling TTCI used to evaluate emergency braking scenarios involving ECP brakes. As an example, the TTCI Summary Report takes issue with the statement in the RIA that TTCI's modeling ''only captures a part of the benefit of ECP.'' *See* RIA, p. 70. TTCI contends that

> [t]his statement implies that the ECP braking system has an effect on other aspects of the derailment dynamics that were included in the DOT analysis, such as impactor size distributions and tank car puncture resistance. In fact, the amount of energy is the only thing that ECP brakes (or any brake system, for that matter) can directly affect.

The TTCI Summary Report's contention, however, ignores the reduced coupler force benefits of ECP braking. The lower coupler forces inherent to an ECP brake application reduce the chaos/energy input into the simulation. The TTCI Summary Report did not consider or even acknowledge the benefits associated with this aspect of ECP braking.

The TTCI Summary Report also takes issue with statements in the RIA discussing PHMSA and FRA's conclusion that AAR's predictions of two-way EOT or DP performance are overestimated. *See* RIA, pp. 68 and 70. This is because AAR's comments, which rely on a TTCI Summary Report, expect that DP and two-way EOT devices offer a benefit if the derailment occurs in the rear half of the train. This is incorrect. There is no benefit to DP if the POD is in the second half of the train. Under derailment conditions (where trains break in two), DP offers no benefit over conventional brakes. By keeping the train together in their simulations, AAR attributed benefits to DP and two-way EOT devices where none exist. Indeed, this issue is addressed in NTSB's Train Brake Simulation Study, published on July 20, 2015. *See* p. 12. While this newly issued study was not used in the development of the final rule, it is informative on ECP brake performance in emergency braking compared to DP emergency braking. Indeed, the NTSB specifically looked at derailments with air hose separation and train separation occurring in the second half of the train and found ''there is no benefit to DP if the emergency is initiated in the second half of the train.''[31] Thus, the NTSB study determined that trains operating in ECP brake mode ''[are] not substantially affected by the location of the emergency initiation.''

Finally, The TTCI Summary Report argues that ''there is no analysis produced that shows that reducing the number of cars in the Aliceville derailment from 26 to 24.5 (or even 24) cars would have resulted in a significant—or any—benefit in terms of reduced severity of the accident.'' We disagree. The reduction of the number of cars punctured is fundamental to improving tank car safety. All the comments from AAR and the industry, whether it is adding head shields, jackets, or thickness, have aimed exactly for this result: reducing the number of cars punctured. One way to reduce the number of cars punctured is to stop them from entering the pile-up in the first place. By TTCI's own analysis, which is skewed towards overestimating the benefits of DP, ECP braking provides an eight percent reduction in the

[30] The NTSB's recent study notes that ECP brake systems can provide the same target NBR for each car in the consist and apply a consistent braking force to each car nearly simultaneously, which allows all cars to decelerate at a similar rate. This minimizes run-in forces, and therefore reduces the likelihood of a wheel derailment and the sliding of braked wheels. All of these factors potentially allow ECP brakes to operate nearer to AAR's upper limit for NBR. *See* ''Train Braking Simulation Study,'' pp. 10–11.

[31] NTSB also notes that this scenario is more consistent with recent tank car derailments than a derailment where there is no train separation.

number of cars entering the pile-up, and a further twelve percent reduction in kinetic energy, a combined benefit of about 20 percent due to ECP braking. If one then combines this benefit with the structural benefit such as jackets and head shields, one starts seeing cumulative significant reductions in damage severity, which is the intent of the final rule.

8. Integration of ECP Brakes With Positive Train Control (PTC)

Relying on the Oliver Wyman Report, AAR asserts that requiring ECP brakes on HHFUTs will present integration challenges with PTC for two reasons. First, implementation of the ECP brake requirement will require new braking algorithms. Second, there will be difficulties associated with installing two complex technologies on locomotives simultaneously. PHMSA and FRA addressed both of these arguments in the final rule and do not find either argument compelling.

The Oliver Wyman Report states that braking algorithms will need to be modified and that there will be great difficulty and expense creating algorithms for PTC for ECP trains. PHMSA and FRA previously addressed this argument in the preamble to the final rule. *See* 80 FR 26702–26703. We recognize that PTC coupled with ECP brakes may result in significant business benefits—such as increased fluidity and higher throughputs—but there is simply no regulatory requirement directing that ECP brake systems be integrated with PTC. Further, the Oliver Wyman Report assertion that integration is necessary for safety reasons is not supported by data or analysis. PTC operates on a block system with forced braking to ensure that a single block is not occupied by two trains at once. In other words, if one train is occupying the block, then a trailing train cannot enter the block. An algorithm based on a conventionally braked train will provide a conservative cushion for the stopping distance for a train operating in ECP brake mode, but it does not change the fact that under PTC only one train will occupy the block at a time. Operations during this time could be used to safely collect the data needed to develop the algorithm to apply to trains operating in ECP brake mode. Of course, once developed, the benefits of shorter stopping distances can then be safely integrated into the system, but such actions would be voluntary business decisions by a railroad based on a belief that integration between ECP brakes and PTC will provide efficiencies not otherwise available.

The Oliver Wyman Report further contends that there will be costs associated with placing locomotives in the shop to install ECP brake systems in addition to PTC programming. PHMSA and FRA accounted for the costs of installing ECP brakes on locomotives on page 219–220 of the RIA, assigning a cost of $40,000 per locomotive.[32] This is for new locomotives, because PHMSA and FRA expect that the allotment of locomotives needed to operate HHFUTs will come from new builds. As a result, shop time likely will be reserved for regular inspections (*e.g.,* 92-day and 368-day inspections), at which time the railroads may take the opportunity, to the extent necessary, to focus on PTC installation issues.

The Oliver Wyman Report attempts to buttress its argument on costs by stating that there will be hidden costs due to the complexity of integrating PTC and ECP brakes on the same locomotive. Such comments are purely anecdotal and not supported by any data or analysis. The purported costs are unquantified in the Oliver Wyman Report and appear to be based solely on the comments of an unnamed UP mechanical officer. PHMSA notes that UP has minimal experience with ECP brakes, using the technology for about eight months over six years ago.

Finally, PHMSA and FRA note that the Oliver Wyman Report states ECP braking is not a mature technology and, therefore, ''will increase operational disruption and failures that compromise safety.'' PHMSA and FRA addressed contentions about technological readiness in the RIA at page 222–225. It is unclear why the Oliver Wyman Report insists on characterizing ECP brake technology as ''immature.'' Such statements are unsupported and, indeed, contradicted by various other sources. In the RIA, we cited an independent report calling ECP a ''mature'' technology. To place the quote in context, PHMSA and FRA now cite to the entire paragraph:

> Application of ECP-brakes in freight trains is a technology that can reduce derailment frequency. The technology for ECP-brakes is mature and such brakes are applied in passenger trains and in block trains for freight in Spoornet, South Africa and by Burlington Northern Santa Fe (BNSF) and Norfolk Southern (NS) in the USA. ECP-brakes in freight trains would reduce the longitudinal forces in the train during braking and brake release, and in particular for low speed braking it would significantly reduce the risk of derailment.[33]

PHMSA and FRA recognize that ECP brakes are not in widespread use in the U.S., but that is not a proxy for maturity of the technology. AAR first began developing interchange standards for ECP brake systems in 1993. As noted in the RIA, North American railroads have used ECP brakes in some form since at least 1998. Australian railroads began widespread use of ECP brakes in 2005. The technology has grown and improved over that time as the industry has worked to resolve ''crosstalk'' and ''interoperability'' issues. Even TTCI, in its recent ECP Brakes presentation, notes that AAR ''agrees that ECP is a mature technology.'' Of course, this is not to suggest that no issues will arise with ECP brakes as railroads implement the braking system on HHFUTs. However, PHMSA and FRA account for such issues in the RIA, recognizing there will need to be significant investment in training and to ensure sufficient equipment is on hand to address normal operational issues. Therefore the accumulation of business benefits was assumed to be demonstrated one year after ECP trains are put into service, recognizing that this change in operating culture will take time. *See* RIA pg. 218.

9. Impact on Small Business

AAR contends that the final rule fails to address or mitigate the harmful impact on small business, including Class III railroads, commuter railroads, smaller contractors, and hazardous materials shippers. The basis for this contention is that federal law requires PHMSA and FRA to assess the impact of the final rule on small business and consider less burdensome alternatives. We did assess the impact of the final rule on small business and considered less burdensome alternatives to develop the final rule.

PHMSA and FRA conducted a Regulatory Flexibility Analysis (RFA), which looked at the costs associated with small businesses for the entire final rule. *See* 80 FR 26725–26735. The RFA included a focused analysis of braking requirements. *See* 80 FR 26732–26733. As stated in the RFA, about 22 percent of short lines (160 of 738 small railroads) transport flammable liquids in

[32] PHMSA notes that its $40,000 estimate is consistent with a recent TTCI ECP Brakes presentation. In that presentation, TTCI estimated the cost of equipping a locomotive with ECP brakes at $40,000 based on a 2011 study. That is less than half the cost estimated in the Oliver Wyman Report. PHMSA recognizes that costs can change over time, but the presentation is instructive on the issue of costs.

[33] *See* ''Assessment of freight train derailment risk reduction measures: A4—New Technologies and Approaches,'''', Report for European Railway Agency, Report No. BA 000777/05, April 19, 2011, at 9, *http://www.era.europa.eu/Document-Register/Documents/DNV%20Study%20-%20Final%20A4%20Report%20-%2020110419%20-%20Public.pdf.*

HHFTs and most small railroads the final rule affects do not operate at speeds higher than the restricted speeds. Indeed, before we issued the NPRM and the final rule, the American Short Line and Regional Railroad Association (ASLRRA) recommended to their members that they voluntarily operate unit trains of crude oil at a top speed of no more than 25 mph on all routes. ASLRRA issued this letter in response to the Secretary's Call to Action on February 12, 2014, and it has been added to the docket.

PHMSA and FRA did acknowledge that some small railroads may be affected by the ECP brake mandate because they accept unit trains of crude oil (and other trains that trigger the mandate) from Class I railroads. However, we accounted for this impact in two ways in the final rule. First, as discussed on page 220 of the RIA, PHMSA and FRA assumed an overlay ECP brake system. This will allow the tank cars to work both with ECP brakes and conventional air brakes. While the initial cost to the car owner is slightly higher than a stand-alone ECP brake system, we expect that the added flexibility of an overlay system makes it the most likely alternative to be chosen by car owners. Aa a result, any small railroad that accepts a unit train of crude oil would be able to use their own power (locomotives) because the trains would travel at a maximum speed of 30 mph and would be able to use conventional air brakes. Second, PHMSA and FRA also anticipate that Class I and smaller railroads will make use of alternatives, such as trackage rights or interchange agreements, which will allow smaller railroads to avoid equipping their locomotives with ECP brakes. Under this type of scenario, Class I railroad crews operating an HHFUT in ECP brake mode could continue operating over the smaller railroad's line, and the HHFUT would pass through the interchange with the train intact.

AAR also raised the concern that short line railroads would be assuming the responsibility for troubleshooting ECP brake-related problems by accepting HHFUTs from Class I railroads. AAR states that this type of troubleshooting requires expertise beyond that of most small railroads because they do not have the resources to hire trained electronic engineers with the necessary expertise to identify the source of ECP system failures. PHMSA and FRA addressed the need for training on small railroads in the RIA on page 220. Because the final rule includes the less burdensome alternatives discussed above, PHMSA and FRA believe that there are effective methods for avoiding the type of training described.

Finally, AAR states that where an interchange agreement requires the small railroads to use existing power, there would be an enormous expense for the small railroad because that railroad would need to equip locomotives with ECP brakes for handling interchanged unit trains. AAR asserts that this is a particularly large problem because most small railroads have older locomotives that are not processor-based and that lack the required space to install an ECP brake system. It estimates it would cost approximately $250,000 to equip a non-processor based locomotive with ECP brakes. For the reasons discussed above, PHMSA and FRA do not anticipate that older locomotives would need to be equipped.

10. Conflict With the Statute Requiring Two-Way EOT Devices

AAR argues that the ECP brake requirement in the final rule is prohibited by 49 U.S.C. 20141. This statute provides that ''[t]he Secretary shall require two-way end-of-train devices (or devices able to perform the same function) on road trains, except locals, road switchers, or work trains, to enable the initiation of emergency braking from the rear of a train.'' The statute further requires the Secretary to establish performance based regulations to govern the use of two-way EOT devices and allows the Secretary ''to allow for the use of alternative technologies that meet the same basic performance requirements.'' *See* 49 U.S.C. 20141(b)(2). AAR contends that PHMSA and FRA's ECP braking requirement is defective because it directs freight railroads to use ECP brake systems instead of two-way EOT devices. This argument is without merit because any HHFUT operating in ECP brake mode must comply with the ECP–EOT requirements in part 232, subpart G. *See* § 174.310(a)(3); 80 FR 26748.

FRA initially issued regulations governing the use of conventional two-way EOT devices in 1997. *See* 62 FR 278 (Jan. 2, 1997). These regulations are in part 232, subpart E, and are targeted at trains with conventional air brakes. Subpart E requires a conventionally braked train to have a two-way EOT device or an alternative technology unless it meets one of the explicit exceptions identified in § 232.407(e). For example, under § 232.407(e), a conventionally braked train is not required to operate with a two-way EOT device if a locomotive or locomotive consist is located at the rear of the train that is capable of making an emergency brake from the rear—as would occur with a lined and operative DP locomotive located at the rear of the train—or when the train does not operate over heavy grade and the speed of the train is limited to 30 mph.[34]

AAR appears to be under the misconception that the final rule fails to comply with 49 U.S.C. 20141 because it foregoes the requirements in part 232, subpart E, for HHFUTs operating in excess of 30 mph. However, the final rule pertaining to ECP brakes does comply with 49 U.S.C. 20141. It mandates compliance with part 232, subpart G, for any HHFUT operating in ECP brake mode. Indeed, subpart G contains EOT device requirements that are specific to trains operating in ECP brake mode. *See* § 232.613.

The ECP–EOT device requirements in section 232.613 were promulgated as part of FRA's ECP regulations in 2008. *See* 73 FR 60512 (Oct. 16, 2008). These regulations were issued, in part, under 49 U.S.C. 20141.[35] *See* 73 FR at 61552. While ECP–EOT devices perform many of the same functions as conventional two-way EOT devices, FRA recognized that ECP–EOT devices also have different features than those required for trains operated using conventional air brakes:

> In addition to serving as the final node on the ECP brake system's train line cable termination circuit and as the system's 'heart beat' monitoring and confirming train, brake pipe, power supply line, and digital communications cable continuity, the ECP–EOT device transmits to the [head end unit or] HEU a status message that includes the brake pipe pressure, the train line cable's voltage, and the ECP–EOT device's battery power level.

See 73 FR 61545. Although FRA noted that the ECP–EOT device operates differently than a conventional two-way EOT device, the ECP–EOT device does ensure that an automatic emergency brake application occurs in the event of a communication breakdown:

> Since the ECP–EOT device—unlike a conventional EOT device—will communicate

[34] *See* 49 CFR 232.407(e), identifying additional exceptions to the two-way EOT requirement for trains with conventional air brakes.

[35] It is worth noting that FRA's ECP regulations were also issued under 49 U.S.C. 20306. This provision allows the Secretary to waive the statutory provisions in 49 U.S.C. ch. 203 ''when those requirements preclude the development or implementation of more efficient railroad transportation equipment or other transportation innovations under existing law.'' FRA held public hearings on October 4, 2007, and October 19, 2007, which included comments and discussion about ECP–EOT devices. Based on the comments received during these public hearings and a related public hearing on January 16, 2007, FRA determined it was appropriate to exercise the Secretary's authority under 49 U.S.C. 20306 to promulgate its ECP regulations.

with the HEU exclusively through the digital communications cable and not via a radio signal, it does not need to perform the function of venting the brake pipe to atmospheric pressure to engage an emergency brake application. However, ECP–EOT devices do verify the integrity of the train line cable and provide a means of monitoring the brake pipe pressure and gradient, providing the basis for an automatic—rather than engineer commanded—response if the system is not adequately charged. In the case of ECP brakes, the brake pipe becomes a redundant—rather than primary—path for sending emergency brake application commands. Under certain communication break downs between the ECP–EOT device, the HEU, and any number of CCDs, the system will self-initiate an emergency brake application.

Id. Section 232.613 requires the ECP–EOT device to send a beacon every second from the rear unit of the train to the controlling locomotive. The EOT beacon works as a kind of fail-safe. It functions virtually identically to the radio signal of a conventional two-way EOT device with one important exception: if the EOT Beacon is lost for six seconds on a train operated in ECP brake mode, then the train goes into penalty brake application, which will brake all cars in the train simultaneously. In contrast, a two-way EOT device may lose communication for up to 16 minutes, 30 seconds, at which point the train speed must be reduced to 30 mph.

Based on these factors, PHMSA and FRA conclude that the ECP brake component of the final rule complies with the requirements of 49 U.S.C. 20141. AAR should be aware that HHFUTs operating in ECP brake mode must have an ECP–EOT or an appropriate alternative, such as an ECP-equipped locomotive, at the rear of the train. This requirement is consistent with FRA's ECP brake regulations at part 232, subpart G.

For the above reasons, AAR's appeal to eliminate the new ECP brake standard of the final rule is denied.

III. Summary

PHMSA denies the appellants' (DGAC, ACC, AAR, AFPM, and Treaty Tribes) appeals on Scope of Rulemaking, Tribal Impacts and Consultation, Retrofit Timeline and Tank Car Reporting Requirements, Thermal Protection for Tank Cars, and Advanced Brake Signal Propagation Systems. We conclude we reasonably determined how to apply new regulations and provided the regulatory analysis to support those decisions. While we understand that shippers, carriers, and tank car manufacturers for Class 3 flammable liquids will face new challenges in the wake of these regulations, we maintain that they are capable of complying with the final rule.

We also deny DGAC's appeal to eliminate or provide further guidance for the Sampling and Testing program. The sampling and testing program is reasonable, justified, necessary, and clear as written. Additionally, we disagree that a delayed compliance date of March 31, 2016 should be provided for implementation of the requirements in § 173.41 for shippers to implement changes for training and documentation.

With respect to Information Sharing/Notification, PHMSA announced in a May 28, 2015, notice that it would extend the Emergency Order applicable to the topic of Information Sharing/Notification indefinitely, while it considered options for codifying the disclosure requirement permanently. Furthermore, on July 22, 2015, FRA issued a public letter instructing railroads transporting crude oil that they must continue to notify SERCs of the expected movement of Bakken crude oil trains through individual States. While the treaty tribes and other stakeholders will have the opportunity to comment on these future regulatory proposals in the course of that rulemaking proceeding, PHMSA will continue to seek opportunities to reach out to the tribes and consultation from tribal leaders.

Issued in Washington, DC on November 5, 2015.

Marie Therese Dominguez,

Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2015–28774 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 101206604–1758–02]

RIN 0648–XE290

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; 2015–2016 Accountability Measure and Closure for King Mackerel in Western Zone of the Gulf of Mexico

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for commercial king mackerel in the western zone of the Gulf of Mexico (Gulf) exclusive economic zone (EEZ) through this temporary final rule. NMFS has determined that the commercial quota for king mackerel in the western zone of the Gulf EEZ will be reached by November 17, 2015. Therefore, NMFS closes the western zone of the Gulf EEZ to commercial king mackerel fishing on November 17, 2015. This closure is necessary to protect the Gulf king mackerel resource.

DATES: The closure is effective at noon, local time, November 17, 2015, until 12:01 a.m., local time, on July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Susan Gerhart, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *susan.gerhart@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, and cobia) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

The commercial quota for the Gulf migratory group king mackerel in the western zone is 1,071,360 lb (485,961 kg) (76 FR 82058, December 29, 2011), for the current fishing year, July 1, 2015, through June 30, 2016.

Regulations at 50 CFR 622.388(a)(1) require NMFS to close the commercial sector for Gulf migratory group king mackerel in the western zone when the quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. Based on the best scientific information available, NMFS has determined the commercial quota of 1,071,360 lb (485,961 kg) for Gulf migratory group king mackerel in the western zone will be reached by November 17, 2015. Accordingly, the western zone is closed to commercial fishing for Gulf migratory group king mackerel effective at noon, local time, November 17, 2015, through June 30, 2016, the end of the current fishing year. The western zone of Gulf migratory group king mackerel is that part of the EEZ between a line extending east from the border of the United States and Mexico and 87°31.1' W. longitude,

which is a line directly south from the state boundary of Alabama and Florida.

Except for a person aboard a charter vessel or headboat, during the closure no person aboard a vessel that has been issued a commercial permit for king mackerel may fish for or retain Gulf migratory group king mackerel in the EEZ in the closed zone (50 CFR 622.384(e)(1)). A person aboard a vessel that has a valid charter vessel/headboat permit for coastal migratory pelagic fish may continue to retain king mackerel in or from the closed zone under the bag and possession limits set forth in 50 CFR 622.382(a)(1)(ii) and (a)(2), provided the vessel is operating as a charter vessel or headboat (50 CFR 622.384(e)(2)). A charter vessel or headboat that also has a commercial king mackerel permit is considered to be operating as a charter vessel or headboat when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew.

During the closure, king mackerel from the closed zone, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to king mackerel from the closed zone that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor (50 CFR 622.384(e)(3)).

Classification

The Regional Administrator, Southeast Region, NMFS, has determined this temporary rule is necessary for the conservation and management of Gulf migratory group king mackerel and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.388(a)(1) and 622.384(e), and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act because the temporary rule is issued without opportunity for prior notice and comment.

This action responds to the best scientific information available. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirements to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule implementing the commercial quota and the associated requirement for closure of the commercial harvest when the quota is reached or is projected to be reached has already been subject to notice and public comment, and all that remains is to notify the public of the closure. Additionally, allowing prior notice and opportunity for public comment is contrary to the public interest because of the need to immediately implement this action to protect the king mackerel stock, because the capacity of the fishing fleet allows for rapid harvest of the quota. Prior notice and opportunity for public comment would require time and could potentially result in a harvest well in excess of the established quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 13, 2015.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–29475 Filed 11–13–15; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

RIN 0648–XE316

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Notification that Northeast Distant gear restricted area (NED) quota is filled.

SUMMARY: NMFS announces that the 25-mt quota available for Atlantic bluefin tuna bycatch (including landings and dead discards) by the Longline category in the Northeast Distant gear restricted area (NED) was filled on November 12, 2015. NMFS reminds vessels fishing in the NED that they now must account for any bluefin bycatch retained or discarded dead using IBQ allocation available to the vessel and that any quota debt remaining at the end of 2015 will carry over to 2016.

DATES: Effective November 18, 2015.

FOR FURTHER INFORMATION CONTACT: Tom Warren or Brad McHale, 978–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of bluefin tuna by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. bluefin tuna quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories per the allocations established in the 2006 Consolidated Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014).

The U.S. bluefin tuna annual quota from the International Commission for the Conservation of Atlantic Tunas (ICCAT) includes, as in previous years, a 25-mt set-aside for bluefin tuna bycatch related to longline fisheries operating in the vicinity of the ICCAT management area boundary. See ICCAT Recommendation 14–05; and 80 FR 52198, (August 28, 2015) (implementing the quota domestically). For management and monitoring purposes, NMFS implements this set-aside in the NED gear restricted area as quota available to Atlantic Longline category permitted vessels. Longline is not a permitted gear for directed fishing on bluefin tuna; any catch must be incidental to fishing for other species. Accounting for this bycatch includes all catch (landings and dead discards). The NED is the Atlantic Ocean area bounded by straight lines connecting the following coordinates in the order stated: 35°00′ N. lat., 60°00′ W. long.; 55°00′ N. lat., 60°00′ W. long.; 55°00′ N. lat., 20°00′ W. long.; 35°00′ N. lat., 20°00′ W. long.; 35°00′ N. lat., 60°00′ W. long.

The IBQ Program and the Northeast Distant Area (NED)

Under Amendment 7 (79 FR 71510, December 2, 2014), new rules were implemented for Longline category vessels fishing in the NED. See 50 CFR 635.15(b)(8). Any bluefin tuna bycatch by permitted vessels fishing with pelagic longline gear in the NED counts toward the ICCAT-allocated separate NED quota (25 mt), until that quota has been filled. During that period, the bluefin tuna accounting requirements of the IBQ Program do not apply to those vessels. Once the NED quota is filled, Longline category permitted vessels may fish or continue to fish in the NED, but the permitted vessels must then abide by the applicable requirements of the IBQ program, which requires individual

vessel accounting for bluefin tuna bycatch using quota allocation available to the vessel (either through its own quota share or leasing allocation from another vessel). Bluefin tuna must be accounted for as described at § 635.15(b)(4) and (5).

Based on Atlantic bluefin tuna dealer data and IBQ system data, as of November 10, 2015, 33,484 lb (15.2 mt) of bluefin tuna has been landed, and 90 lb (<0.1 mt) of bluefin tuna has been discarded dead in the NED; an additional 36 bluefin tuna have been reported as retained through Vessel Monitoring System (VMS) bluefin tuna catch reports. These 36 retained bluefin tuna reported via VMS equate to approximately 17,460 lb (7.9 mt) of additional catch, which brings the total estimated bluefin tuna catch from the NED to 51,034 lb (23.2 mt). Based on this data, NMFS has determined that the 25 mt set-aside will be filled on November 12, 2015.

Because the NED the quota has been reached, vessels are notified that they must account for any bycatch of bluefin tuna (landings and/or dead discards) in the NED using IBQ allocation as specified in the regulations at § 635.15(b)(8). Vessel owners will have to account retroactively for their bluefin tuna bycatch with IBQ to the date that the separate quota was reached. NMFS currently anticipates that date will be November 12, 2015, but will notify relevant vessel owners of the precise date when we have complete NED catch data.

With respect to quota accounting for the fishery as whole, bluefin bycatch (landings and dead discards) from the NED beyond the 25 mt set-aside will count toward the Longline category annual baseline subquota. For 2015, NMFS delayed certain regulatory requirements requiring vessels with pelagic longline gear to have a minimum amount of IBQ quota before departing on fishing trips, thus allowing such vessels to fish with pelagic longline gear even if they have quota debt. However, we specified that quota debt will accrue throughout the 2015 fishing year, and vessels will be responsible for accounting for all of their bluefin bycatch at the end of the year. If, by the end of 2015, a permit holder does not have adequate IBQ allocation to settle their vessel's quota debt, the vessel's allocation will be reduced in the amount equal to the quota debt in the subsequent year or years until the quota debt is fully accounted for. Vessels with a negative balance will have to satisfy the quota debt before departing on any trips in 2016.

NMFS will continue to monitor bluefin tuna bycatch by vessels fishing with pelagic longline gear using VMS and dealer data, as well as monitor the accounting for such catch in the IBQ system, to ensure that vessels are accountable for their bluefin bycatch and that quotas are managed consistent with the 2006 Consolidated HMS FMP and our international quota obligations. For fishery updates, fishermen may call the Atlantic Tunas Information Line at (888) 872–8862 or (978) 281–9260, access the following internet address: *www.hmspermits.gov.*

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: November 12, 2015.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–29400 Filed 11–13–15; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 140214140–5999–01]

RIN 0648–BD92

Fisheries Off West Coast States; Pacific Coast Groundfish Fishery; Seabird Avoidance Measures

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

ACTION: Final rule.

SUMMARY: This final rule implements a Seabird Avoidance Program in the Pacific Coast Groundfish Fishery. The rule was recommended by the Pacific Fishery Management Council (Council) in November 2013 to minimize the take of ESA-listed short-tailed albatross (*Phoebastria albatrus*). A 2012 U.S. Fish and Wildlife Service (USFWS) Biological Opinion (Opinion) required NMFS to initiate implementation of regulations within 2 years that mandate the use of seabird avoidance measures by vessels greater than or equal to 55 feet length overall (LOA) using bottom longline gear to harvest groundfish. The seabird avoidance measures, including streamer lines that deter birds from ingesting baited hooks, are modeled after a similar regulatory program in effect for the Alaskan groundfish fishery.

DATES: Effective on December 18, 2015.

ADDRESSES: Information relevant to this final rule, which includes a final environmental assessment (EA), are available from William W. Stelle, Jr., Regional Administrator, West Coast Region, NMFS, 7600 Sand Point Way NE., Seattle, WA 98115–0070. Electronic copies of this final rule are also available at the NMFS West Coast Region Web site: *http://www.westcoast.fisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Sarah Williams, 206–526–4646; (fax) 206–526–6736; *sarah.williams@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The purpose of this rule is to reduce interactions between ESA-listed seabirds and groundfish longline gear. This final rule amends the regulations governing the Pacific Coast Groundfish Fishery (fishery) to require seabird avoidance measures—specifically, the use of streamer lines and related provisions similar to those currently mandated in the Alaskan groundfish fishery—by vessels 55 ft LOA or greater in the bottom longline fishery.

This rule is needed to minimize takes of endangered short-tailed albatross and comply with a 2012 Biological Opinion (Opinion) issued by the U.S. Fish and Wildlife Service.

In sum, the rule:

- Requires the use of streamer lines in the commercial longline fishery of the Pacific Coast Groundfish Fishery for non-tribal vessels 55 feet in length or greater;
- Requires vessels to deploy one or two streamer lines depending on the type of longline gear being set;
- Requires that streamer lines meet technical specifications and be available for inspection; and
- Allows for a rough weather exemption from using streamer lines for safety purposes. The threshold for the rough weather exemption is a Gale Warning as issued by the National Weather Service.

The rule is designed to be consistent with the requirements of the Opinion and responsive to issues raised through the public process and consultation with experts.

Comments and Responses

NMFS solicited public comment on the proposed seabird avoidance measures (79 FR 53401, September 9, 2014). The comment period ended October 9, 2014. NMFS received seven comment letters from individuals or organizations. The letters are available in their entirety from NMFS (see

ADDRESSES) or at the following web address: *http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dct=PS;D=NOAA-NMFS-2014-0099.* For clarity in responding, comments have been organized into the following categories, which are addressed in turn below: Monitoring, Gear Specification and Performance, Scope, Environmental Assessment, and Other.

Monitoring

Comment 1: Observers or Electronic Monitoring should be used to monitor compliance with performance and materials standards in order for the seabird avoidance regulations to be effective.

Response: NMFS agrees. The West Coast Groundfish Observer Program (WCGOP) developed and implemented a sampling protocol in 2009 and 2010 to characterize the longline fleet and its use of seabird avoidance gear. The protocol was designed to provide data on the types of streamer lines being deployed and the performance of the streamers insofar as it can be determined visually. For example, observers recorded the number of streamer lines deployed; where the streamer lines were deployed relative to sinking hooks; the deployment of towed objects on the end of streamer lines; the extent of streamer lines relative to the water surface; the number of streamers on each line; the color and material of the streamers; the distance between streamers; the distance from the stern to the first streamer; and a range of measurements associated with the design and performance of streamer lines. The information can be used by managers to assess the performance of streamer lines at sea. Observers currently record the type of seabird avoidance gear being used. In 2015, this will include a distinction between single and double streamer lines. Observers also record the catch of seabirds which is the ultimate determinant of the performance of seabird avoidance measures. In response to this comment and the ongoing need to characterize the use of seabird avoidance gear, WCGOP will refine the sampling protocol for implementation in 2016 or earlier as opportunity allows.

Comment 2: NMFS should use either human observers or electronic means to monitor seabird interactions in the at-sea hake fishery because there is a high overlap of fishing areas with albatross occurrence; and, the fleet's practice of continuous offal discharge may attract birds. It is known that bird strikes with trawl cables cause high mortality of albatross in other regions.

Response: As described in the BiOp, seabirds are attracted to offal plumes and can strike trawl cables, sonar cables, or become entangled on nets at or near the surface. Such interactions are unlikely to be detected as they do not show up on the deck to be sampled under normal observer protocols. NMFS agrees with the need to characterize seabird mortality in the at-sea hake fishery and is committed to developing a monitoring plan; however, there are significant issues associated with both the observer program and electronic monitoring that make it premature to choose a specific course of action at this time.

Regarding the observer program, observer duties are carefully prescribed according to priorities developed to support fishery management decisions. The main priority is to monitor catch composition—including seabirds that come up with the trawl. Each processing vessel carries two observers. Observers subsample the catch to collect data used to estimate catch composition. In addition, the observers collect biological data from groundfish, protected species including seabirds, and prohibited species. Observers are required to be in the factory, below deck, for the majority of their sampling. Observation of trawl and sonar cables would occur on deck and take a significant amount of time away from catch composition sampling.

Electronic monitoring is in a developmental stage for West Coast groundfish fisheries and significant research is necessary before it is practicable to apply to seabird monitoring in the at-sea hake fishery. Similar to observers, electronic monitoring is being developed to monitor catch composition. There have not been formal investigations into the effectiveness and practicability of training cameras away from the deck to monitor trawl and sonar cables.

NMFS will pursue a monitoring plan by working through the Council and its appropriate committees, such as the Council's ESA Working Group that was established specifically to implement the Opinion; and, ad hoc committees composed to advise the Council on the development of electronic monitoring. Such committees offer a formal opportunity to engage the Council in monitoring and conservation issues and is the most appropriate opportunity to develop an effective and practicable monitoring plan.

Comment 3: Observers should record wind speed to associate weather data with seabird interactions in order to assess impacts associated with the rough weather exemption.

Response: NMFS agrees. Observers currently record weather conditions using the Beaufort scale for any sighting or take of an ESA-listed species, including short-tailed albatross. Weather observations are currently made at the time the observer encounters the animal which, in longline fisheries, is usually during the retrieval of gear. The weather conditions during retrieval may be different from when the mortality event occurred, which is typically as gear is being set. For this reason, and in response to this comment, NMFS will modify WCGOP sampling protocols so that observers record weather conditions as longlines are being set for at least a subset of hauls. The modified protocol may not be fully effective until 2016 due to program logistics.

Comment 4: NMFS should monitor the free streamer line program to determine if lines are being used properly, ensure plastic components of the streamer lines are not illegally discarded at sea, and to avoid wasteful spending of U.S. tax dollars that are funding the program.

Response: NMFS agrees. Consistent with the response to Comment 1 above, observers are monitoring the performance of streamer lines at sea. Observers also monitor for violations of the International Convention for the Prevention of Pollution from Ships (MARPOL) that prohibits the at-sea disposal of all plastics. Observers document compliance infractions and suspected violations in their logbook and complete a written statement during debriefing.

Gear Specification and Performance

Comment 5: NMFS should exempt the requirement to use streamer lines during longline sets that take place at night. Based on 20 years of personal experience, I have never encountered a seabird on a night set. Requiring streamer lines during night sets imposes a safety risk and inconvenience without reducing seabird mortality.

Response: To address this comment, NMFS conducted an analysis to determine if seabird catch rates differ when the longline gear is set in the dark versus the light. The analysis shows a reduction in the seabird bycatch when the gear is set at night and could provide an option for fishermen to not use streamer lines at night in the future. At this time, NMFS has determined that providing a night-setting exemption is outside the scope of the proposed rule. NMFS received comments from the Council on including an exemption for night setting, including comments from the U.S. Coast Guard representative,

which supported the exemption but requested further investigation into an exemption rather than inclusion in the regulations at this time.

Comment 6: The proposed rule is inadequate and ineffective as a seabird bycatch mitigation measure. Best practices, as adopted by the Agreement on the Conservation of Albatrosses and Petrels (ACAP), do not support only using streamer lines to deter seabirds. Streamer lines should be used in conjunction with other measures such as weighting the line to maximize sink rates; actively deterring birds from baited hooks by using bird scaring lines; and, setting at night.

Response: NMFS disagrees that the proposed rule is inadequate; however, NMFS agrees that the full range of best practices described by ACAP is an important component of effective seabird conservation. NMFS and the Council considered alternatives that would have implemented the full suite of ACAP best practices in the EA (see **ADDRESSES**). The measures described in the comment (other than streamer lines) are being pursued by non-regulatory means. NMFS and partner organizations are working with fishermen to encourage voluntary implementation of measures consistent with ACAP best practices, including sinking hooks quickly, night setting, and managing discharge of offal and bait. Fishermen on the West Coast have a significant incentive to avoid seabirds in order to ensure baited hooks are available to catch fish. A hook with a seabird on it precludes that opportunity and impacts the profitability of fishing operations. For this reason and as analyzed in the EA, NMFS and the Council determined that a non-regulatory approach to the full suite of best practices was the most appropriate at this time. This does not preclude regulatory approaches in the future should monitoring indicate that voluntary efforts are not sufficient. To that end, NMFS has worked to establish the ESA Working Group to consider new information and formulate advice on adaptive management to the Council.

Comment 7: The proposed streamer line specifications are inadequate and ineffective. The specifications used under the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR) should be adopted, including: (1) Minimum of height at stern of 7 m; (2) minimum streamer line length of 150 m and the use of a drogue; (3) no rough weather exemption; and, (4) the aerial extent of streamer lines should be stipulated as a performance standard (100 m is suggested).

Response: NMFS disagrees that the proposed streamer line specifications are inadequate and ineffective. The CCAMLR regulations reflect the development of seabird avoidance measures designed for the specific fisheries and seabird assemblages. The sub-Antarctic fisheries governed under CCAMLR include primarily Patagonia toothfish (*Dissostichus eleginoides*), which is fished with the Spanish method of bottom longlining, where the gear is more buoyant than that used on the West Coast. The majority of the vessels are large (30–50 m) and deploy gear from the stern at speeds of 10–13 knots. The prevalent seabirds incidentally taken are albatrosses and petrels species, many of which dive to foraging depths that are substantially deeper than the North Pacific albatross and other species that occur off the West Coast.

In contrast, West Coast groundfish fisheries target primarily sablefish, which is a demersal species fished with bottom gear consisting of groundlines to which relatively short gangions are attached. In general, vessels deploy gear from the stern. The prevalent seabird species incidentally taken are fulmars, gulls, and albatrosses.

The CCAMLR streamer line specifications are designed to provide more aerial coverage than is necessary or appropriate for West Coast groundfish fisheries. The minimum stern height, line length, and aerial extent specifications cover a greater area because longlines used in those fisheries are more buoyant and extend further behind the vessel than occurs in fisheries covered under this rule, and because the seabird species taken in CCAMLR fisheries dive to deeper depths than those on the West Coast. The specifications in this rule were recommended based on extensive research that demonstrated them to be effective in Alaskan groundfish fisheries, where the targeted fish species, vessels, and seabirds are similar and, in some cases, identical. More information on this research and the effectiveness of the streamer line specification in this final rule is available in the Opinion or EA (see **ADDRESSES**).

NMFS notes however that preliminary research by Washington Sea Grant indicates that some vessels in West Coast groundfish fisheries are using floats on gangions to avoid predation by non-marketable bottom fish (*i.e.,* hagfish). The floats may reduce the effectiveness of these streamer line specifications by keeping baited hooks in the water column past the extent of streamer lines. It is unclear at this time how widespread the use of floats is, how much it influences seabird catch rates, and what alternatives are appropriate if floats are determined to be a significant issue affecting seabird catch rates. Because the research is preliminary, and because the streamer line specifications in this final rule have been demonstrated to be effective in reducing seabird mortality and are required by the Opinion, NMFS is finalizing this rule and will continue to monitor its effectiveness to determine if future changes are warranted. NMFS is also continuing to support Washington Sea Grant in conducting this research and has worked to establish the ESA Working Group to consider new information and formulate advice on adaptive management to the Council.

Comment 8: Vessels should not be permitted to take excessive numbers of seabirds. Vessels should be required to move to night setting for the remainder of the fishing season if seabird bycatch exceeds 0.01 seabirds per 1000 hooks in a set, or until the vessel is able to demonstrate a line sink rate of a minimum of 0.3 m/second to 15 m depth. Applying a performance standard quickly halts lax and ineffective fishing practices.

Response: A system does not currently exist within NMFS to hold individual vessels accountable for seabird mortality in real time. Similarly, it is not feasible for NMFS to monitor and enforce sink rates of longline gear on individual vessels. More importantly, NMFS does not believe such a system is necessary given that the final regulations are designed to effectively reduce seabird bycatch in the fleet where most of the seabirds are taken.

Scope of the Regulations

Comment 9: Vessels smaller than 55 ft should be required to use seabird avoidance measures to minimize the chance that such vessels will take ESA-listed short-tailed albatross and other seabirds.

Response: NMFS agrees that there may be a risk to short-tailed albatross from longline vessels under 55 ft; however, it would be premature to require that they use seabird avoidance gear at this time. The Opinion specifies that this rule apply to larger vessels for the following reasons: (1) Vessels under 55 ft have not been observed to interact with short-tailed albatross; (2) vessels under 55 ft are being encouraged through formal outreach described in the EA (see **ADDRESSES**) to deploy seabird avoidance measures on a voluntary basis; and, (3) NMFS does not have an appropriate technical

specification for streamer lines proven to be safe for smaller vessels. To address the latter, Washington Sea Grant is conducting research to determine safe and effective seabird avoidance measures for vessels under 55 ft. In limiting the requirement specified in the Opinion to vessels 55 ft and over, USFWS further required NMFS to adapt management as appropriate in response to that research and ongoing monitoring. NMFS is committed to review new information as it becomes available to determine if these regulations should be adapted to cover smaller vessels. To that end, NMFS has worked to establish the ESA Working Group to consider new information and formulate advice on adaptive management to the Council.

Comment 10: NMFS should require that seabird avoidance measures be deployed in the at-sea hake fishery because there is a high overlap of fishing areas with albatross occurrence and the fleet's practice of continuous offal discharge that may attract birds. It is known that bird strikes with trawl cables cause high mortality of albatross in other regions.

Response: NMFS agrees that there is a potential threat to seabirds associated with the at-sea hake fishery; however, it is premature to regulate that fishery at this time. As described in the response to Comment 2 above, NMFS will pursue a monitoring plan to assess the level of threat and appropriate responses. Regulating the at-sea hake fishery is outside the scope of this rule, which is focused on implementing requirements stipulated by USFWS in the Opinion. USFWS recognized the potential for interaction between seabirds and the at-sea hake fishery but determined that the focus of seabird avoidance measures should be the longline fleet. In doing so, USFWS further required NMFS to adapt management as appropriate in response to new information. NMFS is committed to reviewing new information as it becomes available to determine if these regulations should be adapted to other fisheries such as the at-sea hake fishery. To that end, NMFS has worked to establish the ESA Working Group to consider new information and formulate advice on adaptive management to the Council.

Environmental Assessment

Comment 11: The EA must analyze whether short-tailed albatross are at higher risk of entanglement during high wind events.

Response: NMFS agrees. The EA, in Section 4.1.1, acknowledges the uncertainty regarding seabird behavior during rough weather and concludes the exemption is not expected to significantly influence the overall reduction in seabird bycatch. NMFS is not aware of additional information pertinent to assessing the effects of rough weather on seabird encounters by longline vessels but will continue to monitor observer data and adapt management as new information becomes available. To that end, NMFS has worked to establish the ESA Working Group to consider new information and formulate advice on adaptive management to the Council.

Comment 12: The EA does not adequately assess the effects of vessels under 55 ft on short-tailed albatross.

Response: NMFS disagrees. Consistent with the response to Comment 9, the EA acknowledges there may be a risk to short-tailed albatross from vessels under 55 ft and incorporates voluntary conservation and ongoing research into analysis of the status quo alternative (See **ADDRESSES**).

Other

Comment 13: The groundfish fishery operates in important seabird foraging habitat as well as critical habitat of leatherback sea turtles and green sturgeon. Streamer lines may have unintended consequences if they are lost overboard. Streamers should be made of plant-based materials in order to minimize the biological risks associated with ingestion by marine animals.

Response: In response to this comment, NMFS consulted with NOAA's Marine Debris Program to determine if there is evidence for streamer lines as marine debris in areas such as Alaska and Hawaii, where there are existing requirements for longline vessels to use them. Streamers (the plastic component of streamer lines) have been observed during shoreline clean-ups in Alaska; however, the quantity relative to other marine debris is very low. Reports from shoreline cleanups in Hawaii have not noted the presence of streamers. Given the low incidence of observed streamers, it would not be reasonable to change design specifications at this time. Streamer lines are constructed of materials, including plastics, sufficient to withstand at-sea conditions. A change in the material specifications would require significant research to ensure streamer lines would continue to function by reducing seabird entanglement. Such research is not practicable at this time. NMFS notes that intentional disposal at sea is unlikely because fishermen are subject to MARPOL, which prohibits the at-sea disposal of plastics.

Comment 14: NMFS should ensure authorization of fisheries complies with the Migratory Bird Treaty Act (MBTA).

Response: NMFS agrees. The final regulations are consistent with the MBTA.

Comment 15: NMFS should provide, and crewmembers should be required to attend, workshops to identify and distinguish short-tailed albatross from other albatrosses and also to safely release live short-tailed albatrosses.

Response: NMFS agrees that education and outreach is an important component of seabird conservation; however, NMFS disagrees that it should be required. NMFS has provided funding for Washington Sea Grant to conduct outreach that has included mailings to all fixed-gear permit holders, port meetings with fishermen, an internet site, and educational exhibits at trade shows. The material includes information on seabird avoidance, species identification, and how to handle hooked albatross. NMFS believes that these efforts have been successful in educating fishermen on issues related to seabird bycatch.

Comment 16: A number of commenters were in support of the proposed regulations.

Response: NMFS acknowledges this comment.

Changes from the Proposed Rule

There are no substantial changes from the proposed rule. NMFS made one modification to re-locate the regulatory text so that it is grouped with other groundfish regulations. The goal of this change is to locate the seabird avoidance program regulations near other programs that apply to multiple sectors of the groundfish fishery.

Classification

Pursuant to section 304(b)(1)(A) of the MSA, the NMFS Assistant Administrator has determined that this final rule is consistent with the Pacific Coast Groundfish FMP, other provisions of the MSA, and other applicable law.

NMFS and the Council prepared a final Environmental Assessment (EA) for this regulation and concluded that there would not be a significant impact on the human environment as a result of this rule. A copy of the EA is available from NMFS (see **ADDRESSES**).

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Regulatory Flexibility Act requires Federal agencies to conduct a full RFAA unless the agency can certify that the proposed and/or final rule would not have a significant economic

impact on a substantial number of small entities.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a public notice that also serves as small entity compliance guide (the guide) was prepared. Copies of this final rule are available from the West Coast Regional Office, and the guide will be posted on the NMFS West Coast Region Web site and emailed to the groundfish fishery listserve. The guide and this final rule will be available upon request.

NMFS issued Biological Opinions under the Endangered Species Act (ESA) on August 10, 1990, November 26, 1991, August 28, 1992, September 27, 1993, May 14, 1996, and December 15, 1999, pertaining to the effects of the Groundfish FMP fisheries on Chinook salmon (Puget Sound, Snake River spring/summer, Snake River fall, upper Columbia River spring, lower Columbia River, upper Willamette River, Sacramento River winter, Central Valley spring, California coastal), coho salmon (Central California coastal, southern Oregon/northern California coastal), chum salmon (Hood Canal summer, Columbia River), sockeye salmon (Snake River, Ozette Lake), and steelhead (upper, middle and lower Columbia River, Snake River Basin, upper Willamette River, central California coast, California Central Valley, south/central California, northern California, southern California). These biological opinions have concluded that implementation of the FMP is not expected to jeopardize the continued existence of any endangered or threatened species under the jurisdiction of NMFS, or result in the destruction or adverse modification of critical habitat.

NMFS issued a Supplemental Biological Opinion on March 11, 2006, concluding that neither the higher observed bycatch of Chinook in the 2005 whiting fishery nor new data regarding salmon bycatch in the groundfish bottom trawl fishery required a reconsideration of its prior ''no jeopardy'' conclusion. NMFS also reaffirmed its prior determination that implementation of the FMP is not likely to jeopardize the continued existence of any of the affected ESUs. Lower Columbia River coho (70 FR 37160, June 28, 2005) and Oregon Coastal coho (73 FR 7816, February 11, 2008) were relisted as threatened under the ESA. The 1999 biological opinion concluded that the bycatch of salmonids in the Pacific whiting fishery were almost entirely Chinook salmon, with little or no bycatch of coho, chum, sockeye, and steelhead.

On December 7, 2012, NMFS completed a biological opinion concluding that the groundfish fishery is not likely to jeopardize non-salmonid marine species including listed eulachon, green sturgeon, humpback whales, Steller sea lions, and leatherback sea turtles. The opinion also concluded that the fishery is not likely to adversely modify critical habitat for green sturgeon and leatherback sea turtles. An analysis included in the same document as the opinion concluded that the fishery is not likely to adversely affect green sea turtles, olive ridley sea turtles, loggerhead sea turtles, sei whales, North Pacific right whales, blue whales, fin whales, sperm whales, Southern Resident killer whales, Guadalupe fur seals, or the critical habitat for Steller sea lions.

West Coast pot fisheries for sablefish are considered Category II fisheries under the Marine Mammal Protection Act (MMPA), indicating occasional interactions. All other West Coast groundfish fisheries, including the trawl fishery, are considered Category III fisheries under the MMPA, indicating a remote likelihood of or no known serious injuries or mortalities to marine mammals. MMPA section 101(a)(5)(E) requires that NMFS authorize the taking of ESA-listed marine mammals incidental to U.S. commercial fisheries if it makes the requisite findings, including a finding that the incidental mortality and serious injury from commercial fisheries will have a negligible impact on the affected species or stock. As noted above, NMFS concluded in its biological opinion for the 2012 groundfish fisheries that these fisheries were not likely to jeopardize Steller sea lions or humpback whales. The eastern distinct population segment of Steller sea lions was delisted under the ESA on November 4, 2013 (78 FR 66140). On September 4, 2013, based on its negligible impact determination dated August 28, 2013, NMFS issued a permit for a period of 3 years to authorize the incidental taking of humpback whales by the sablefish pot fishery (78 FR 54553).

NMFS has reinitiated section 7 consultation on the Pacific Coast Groundfish FMP with respect to its effects on listed salmonids. In the event the consultation identifies either reasonable and prudent alternatives to address jeopardy concerns, or reasonable and prudent measures to minimize incidental take, NMFS would coordinate with the Council to put additional alternatives or measures into place, as required. After reviewing the available information, NMFS has concluded that, consistent with sections 7(a)(2) and 7(d) of the ESA, this action will not jeopardize any listed species, would not adversely modify any designated critical habitat, and will not result in any irreversible or irretrievable commitment of resources that would have the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures.

On November 21, 2012, the U.S. Fish and Wildlife Service (FWS) issued a biological opinion concluding that the groundfish fishery will not jeopardize the continued existence of the short-tailed albatross. The 2012 Opinion evaluated the risks of continued operation of the Pacific Coast groundfish fishery on ESA-listed seabirds, including short-tailed albatross. The 2012 Opinion included a Term and Condition requiring NMFS to promulgate regulations mandating the use of streamer lines by longline vessels 55 feet LOA or greater, patterned on the Alaska streamer line regulations. Accordingly, for the fishery to be exempt from the ESA section 9 prohibition regarding take of a listed species, NMFS must initiate implementation of streamer line regulations by November 21, 2014. The 2012 Opinion anticipates the yearly average take of one short-tailed albatross killed from longline hooks or trawl cables. As the short-tailed albatross population is expanding, it is expected to result in more interactions with the Pacific Coast Groundfish Fisheries. This action would implement one of the Terms and Conditions of the 2012 Opinion and reduce the risk of exceeding the take limits of short-tailed albatross, which in turn would reduce

the risk of economic harm to the fishing industry that could result from the incidental take limit being exceeded. The FWS also concurred that the fishery is not likely to adversely affect the marbled murrelet, California least tern, southern sea otter, bull trout, or bull trout critical habitat.

This final rule does not contain a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA).

This final rule was developed after meaningful collaboration, through the Council process, with the tribal representative on the Council. The regulations have no direct effect on the tribes and were deemed by the Council as ''necessary or appropriate'' to implement the FMP as amended.

List of Subjects in 50 CFR Part 660

Administrative practice and procedure, American Samoa, Fisheries, Fishing, Guam, Hawaiian natives, Indians, Northern Mariana Islands, Reporting and recordkeeping requirements.

Dated: November 10, 2015.

Samuel D. Rauch III,

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

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

PART 660—FISHERIES OFF WEST COAST STATES

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

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

■ 2. In § 660.11, add paragraph (6)(i)(A) and reserved paragraph (6)(i)(B) to the definition of ''Fishing gear'' and add the definition for ''Seabird'' in alphabetical order to read as follows:

§ 660.11 General definitions.

* * * * *

Fishing gear * * *

(6) * * *

(i) * * *

(A) Snap gear means a type of bottom longline gear where the hook and gangion are attached to the groundline using a mechanical fastener or snap.

(B) [Reserved]

* * * * *

Seabird means those bird species that habitually obtain their food from the sea below the low water mark.

* * * * *

■ 3. In § 660.12, add paragraph (a)(15) to read as follows:

§ 660.12 General groundfish prohibitions.

* * * * *

(a) * * *

(15) Fail to comply with the requirements of the Seabird Avoidance Program described in § 660.21 when commercial fishing for groundfish using bottom longline gear.

* * * * *

■ 4. Add § 660.21 to read as follows:

§ 660.21 Seabird Avoidance Program.

This section contains the requirements of the Seabird Avoidance Program.

(a) *Purpose.* The purpose of the Seabird Avoidance Program is to minimize interactions between fishing gear and seabird species, including short-tailed albatross (*Phoebastria albatrus*).

(b) *Applicability.* The requirements specified in paragraph (c) of this section apply to the following fishing vessels:

(1) Vessels greater than or equal to 55 ft (16.8 m) LOA engaged in commercial fishing for groundfish with bottom longline gear as defined in § 660.11 pursuant to the gear switching provisions of the Limited Entry Trawl Fishery, Shorebased IFQ Program as specified in § 660.140(k), or pursuant to Subparts E or F of this Part, except as provided in paragraph (b)(2) of this section.

(2) *Exemptions.* The requirements specified in paragraph (c) of this section do not apply to Pacific Coast treaty Indian fisheries, as described at § 660.50, or to anglers engaged in recreational fishing for groundfish, as described in Subpart G of this Part.

(c) *Seabird Avoidance Requirements*—(1) *General Requirements.* The operator of a vessel described in paragraph (b)(1) of this section must:

(i) Gear onboard. Have onboard the vessel seabird avoidance gear as specified in paragraph (c)(2) of this section.

(ii) Gear inspection. Upon request by an authorized officer or observer, make the seabird avoidance gear available for inspection.

(iii) Gear use. Use seabird avoidance gear as specified in paragraph (c)(2) of this section that meets the standards specified in paragraph (c)(3) of this section while bottom longline and snap gears are being deployed.

(iv) Handling of hooked short-tailed albatross.

(A) Safe release of live short-tailed albatross. Make every reasonable effort to ensure short-tailed albatross brought on board alive are released alive and that, whenever possible, hooks are removed without jeopardizing the life of the bird(s). If the vessel operator determines, based on personal judgment, that an injured bird is likely to die upon release, the vessel operator is encouraged to seek veterinary care in port. Final disposition of an injured bird will be with a Wildlife Rehabilitator. If needed, phone the U.S. Fish and Wildlife Service at 503–231–6179 to assist in locating a qualified Wildlife Rehabilitator to care for the short-tailed albatross.

(B) Dead short-tailed albatross must be kept as cold as practicable while the vessel is at sea and frozen as soon as practicable upon return to port. Carcasses must be labeled with the name of vessel, location of hooking in latitude and longitude, and the number and color of any leg band if present on the bird. Leg bands must be left attached to the bird. Phone the U.S. Fish and Wildlife Service at 503–231–6179 to arrange for the disposition of dead short-tailed albatross.

(C) All hooked short-tailed albatross must be reported to U.S. Fish and Wildlife Service Law Enforcement by the vessel operator by phoning 360–753–7764 (WA); 503–682–6131 (OR); or 916–414–6660 (CA) as soon as practicable upon the vessel's return to port.

(D) If a NMFS observer is on board at the time of a hooking event, the observer shall be responsible for the disposition of any captured short-tailed albatross and for reporting to U.S. Fish and Wildlife Service Law Enforcement Otherwise, the vessel operator shall be responsible.

(2) *Gear Requirements.* The operator of a vessel identified in paragraph (b)(1) of this section must comply with the following gear requirements:

(i) Snap gear. Vessels using snap gear as defined at § 660.11 must deploy a minimum of a single streamer line in accordance with the requirements of paragraphs (c)(3)(i) through (ii) of this section, except as provided in paragraph (c)(2)(iii) of this section.

(ii) Bottom longline. Vessels using bottom longline gear must deploy streamer lines in accordance with the requirements of paragraphs (c)(3)(i) and (iii) of this section, except as provided in paragraph (c)(2)(iii) of this section.

(iii) Weather Safety Exemption. Vessels are exempted from the requirements of paragraph (c)(1)(iii) of this section when a National Weather Service Gale Warning is in effect. This exemption applies only during the time and within the area indicated in the National Weather Service Gale Warning.

(3) *Gear performance and material standards.* (i) Material standards for all streamer lines. All streamer lines must:

(A) Have streamers spaced a maximum of every 16 ft 5 in (5 m).

(B) Have individual streamers that hang attached to the mainline to 10 in (0.25 m) above the waterline in the absence of wind.

(C) Have streamers constructed of material that is brightly colored, UV-protected plastic tubing or 3/8 inch polyester line or material of an equivalent density.

(ii) Snap gear streamer line standards. For vessels using snap gear, a streamer line must:

(A) Be a minimum length of 147 ft 7 in (45 m).

(B) Be deployed so that streamers are in the air a minimum of 65 ft 7 in (20 m) aft of the stern and within 6 ft 7 in (2 m) horizontally of the point where the main groundline enters the water before the first hook is set.

(iii) Bottom longline streamer line standards. Vessels using bottom longline gear but not snap gear must use paired streamer lines meeting the following requirements:

(A) Streamer lines must be a minimum length of 300 feet (91.4 m).

(B) Streamer lines must be deployed so that streamers are in the air a minimum of 131 ft (40m) aft of the stern for vessels under 100 ft (30.5 m) LOA and 197 ft (60m) aft of the stern for vessels 100 ft (30.5 m) or over.

(C) At least one streamer line must be deployed in accordance with paragraph (c)(3)(iii)(B) before the first hook is set and a second streamer line must be deployed within 90 seconds thereafter.

(D) For vessels deploying bottom longline gear from the stern, the streamer lines must be deployed from the stern, one on each side of the main groundline.

(E) For vessels deploying bottom longline gear from the side, the streamer lines must be deployed from the stern, one over the main groundline and the other on one side of the main groundline.

■ 5. In § 660.140, revise paragraph (k)(1)(iv) to read as follows:

§ 660.140 Shorebased IFQ Program.

* * * * *

(k) * * *

(1) * * *

(iv) The vessel must comply with prohibitions applicable to the limited entry fixed gear fishery as specified at § 660.212, gear restrictions applicable to limited entry fixed gear as specified in §§ 660.219 and 660.230(b), and management measures specified in § 660.230(d), including restrictions on the fixed gear allowed onboard, its usage, and applicable fixed gear groundfish conservation area restrictions, except that the vessel will not be subject to limited entry fixed gear trip limits when fishing in the Shorebased IFQ Program. Vessels using bottom longline and snap gears as defined at § 660.11 are subject to the requirements of the Seabird Avoidance Program described in § 660.21.

* * * * *

■ 6. In § 660.230, add paragraph (b)(5) to read as follows:

§ 660.230 Fixed gear fishery-management measures.

* * * * *

(b) * * *

(5) Vessels fishing with bottom longline and snap gears as defined at § 660.11 are subject to the requirements of the Seabird Avoidance Program described in § 660.21.

* * * * *

■ 7. In § 660.330, revise paragraph (b)(2)(i) to read as follows:

§ 660.330 Open access fishery-management measures.

* * * * *

(b) * * *

(2) * * *

(i) Fixed gear (longline, trap or pot, set net and stationary hook-and-line gear, including commercial vertical hook-and-line gear) must be attended at least once every 7 days. Vessels fishing with bottom longline and snap gears as defined at § 660.11 are subject to the requirements of the Seabird Avoidance Program described in § 660.21.

* * * * *

[FR Doc. 2015–29249 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 80, No. 222

Wednesday, November 18, 2015

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2015–0186]

RIN 3150–AJ65

List of Approved Spent Fuel Storage Casks: NAC International, Inc., MAGNASTOR® Cask System; Certificate of Compliance No. 1031, Amendment Nos. 0–3, Revision 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel storage regulations by revising the NAC International, Inc. (NAC), MAGNASTOR® Cask System listing within the ''List of approved spent fuel storage casks'' to include Revision 1 to Amendment Nos. 0 (the initial Certificate), 1, 2 and 3 to Certificate of Compliance (CoC) No. 1031. Revision 1 to Amendment Nos. 0–3 to CoC No. 1031 makes changes to the Technical Specifications (TSs), including correcting a typographical error in two actual boron loadings in TS 4.1.1(a), and revising the decay times in Tables B2–4 (for Amendment Nos. 0 and 1) and B2–5 (for Amendment Nos. 2 and 3) in Appendix B of the TSs for minimum additional decay time required for spent fuel assemblies that contain nonfuel hardware.

DATES: Submit comments by December 18, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0186. Address questions about NRC dockets to Carol Gallagher, telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at (301) 415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Solomon Sahle, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3781; email: *Solomon.Sahle@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0186 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–2015–0186.
- *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, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2015–0186 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Procedural Background

This proposed rule is limited to the changes contained in Revision 1 to Amendment Nos. 0–3, to CoC No. 1031 and does not include other aspects of the NAC MAGNASTOR® Cask System. Because the NRC considers this action noncontroversial and routine, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register.** Adequate protection of public health and safety continues to be ensured. The direct final rule will become effective on February 1, 2016. However, if the NRC receives significant adverse comments on this proposed rule by December 18, 2015, then the NRC will publish a document that withdraws the direct final rule. If the direct final rule is withdrawn, the NRC will address the comments

received in response to these proposed revisions in a subsequent final rule. Absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

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

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

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

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

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

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

(3) The comment causes the NRC staff to make a change (other than editorial) to the rule, CoC, or TSs.

For additional procedural information and the regulatory analysis, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register.**

III. Background

Section 218(a) of the Nuclear Waste Policy Act (NWPA) of 1982, as amended, requires that ''the Secretary [of the U.S. Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [U.S. Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the NWPA states, in part, that ''[the Commission] shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule which added a new subpart K in part 72 of title 10 of the *Code of Federal* Regulations (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L within 10 CFR part 72 entitled, ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs.

The NRC issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC MAGNASTOR® Cask System design to add Amendment No. 0 to the list of NRC-approved cask designs in 10 CFR 72.214 as CoC No.1031. Subsequently on June 15, 2010 (75 FR 33678), the NRC issued a final rule adding Amendment No. 1 to CoC No. 1031 to the list of NRC-approved cask designs in 10 CFR 72.214. Similar final rules were issued on November 14, 2011 (76 FR 70331), and June 25, 2013 (78 FR 37927), to add Amendment Nos. 2 and 3 to CoC No. 1031, respectively, to the list of NRC-approved cask designs in 10 CFR 72.214.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document	ADAMS Accession No.
Proposed CoC No. 1031, Amendment No. 0, Revision 1	ML15180A230.
Proposed CoC No. 1031 Amendment No. 0, Revision 1, TS Appendix A	ML15180A238.
Proposed CoC No. 1031 Amendment No. 0, Revision 1, TS Appendix B	ML15180A270.
Proposed SER for CoC No. 1031 Amendment No. 0, Revision 1	ML15180A281.
Proposed CoC No. 1031, Amendment No. 1, Revision 1	ML15180A161.
Proposed CoC No. 1031 Amendment No. 1, Revision 1, TS Appendix A	ML15180A164.
Proposed CoC No. 1031 Amendment No. 1, Revision 1, TS Appendix B	ML15180A192.
Proposed SER for CoC No. 1031 Amendment No. 1, Revision 1	ML15180A220.
Proposed CoC No. 1031, Amendment No. 2, Revision 1	ML15180A114.
Proposed CoC No. 1031, Amendment No. 2, Revision 1, TS Appendix A	ML15180A119.
Proposed TS Amendment No. 2, Revision 1, TS Appendix B	ML15180A128.
Proposed SER for CoC No. 1031 Amendment No. 2, Revision 1	ML15180A141.
Proposed CoC No. 1031, Amendment No. 3, Revision 1	ML15180A033.
Proposed CoC No. 1031 Amendment No. 3, Revision 1, TS Appendix A	ML15180A077.
Proposed CoC No. 1031 Amendment No. 3, Revision 1, TS Appendix B	ML15180A087.
Proposed SER for CoC No. 1031 Amendment No. 3, Revision 1	ML15180A092.

The NRC may post materials related to this document, including public comments, on the Federal Rulemaking Web site at *http://www.regulations.gov* under Docket ID NRC–2015–0186. The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2015–0186); (2) click the ''Sign up for Email Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Criminal penalties, Hazardous waste, Indians,

Intergovernmental relations, Manpower training programs, Nuclear energy, Nuclear materials, Occupational safety and health, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is proposing to adopt the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1032 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1031.

Initial Certificate Effective Date: February 4, 2009, superseded by Initial Certificate, Revision 1, on February 1, 2016.

Initial Certificate, Revision 1, Effective Date: February 1, 2016.

Amendment Number 1 Effective Date: August 30, 2010, superseded by Amendment Number 1, Revision 1, on February 1, 2016.

Amendment Number 1, Revision 1, Effective Date: February 1, 2016.

Amendment Number 2 Effective Date: January 30, 2012, superseded by Amendment Number 2, Revision 1, on February 1, 2016.

Amendment Number 2, Revision 1, Effective Date: February 1, 2016.

Amendment Number 3 Effective Date: July 25, 2013, superseded by Amendment Number 3, Revision 1, on February 1, 2016.

Amendment Number 3, Revision 1, Effective Date: February 1, 2016.

Amendment Number 4 Effective Date: April 14, 2015.

Amendment Number 5 Effective Date: June 29, 2015.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the MAGNASTOR® System.

Docket Number: 72–1031.

Certificate Expiration Date: February 4, 2029.

Model Number: MAGNASTOR®.

* * * * *

Dated at Rockville, Maryland, this 5th day of November, 2015.

For the Nuclear Regulatory Commission.

Glenn M. Tracy,

Acting Executive Director for Operations.

[FR Doc. 2015–29423 Filed 11–17–15; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[Docket No. EERE–2015–BT–CRT–0013]

RIN 1904–AD53

Energy Conservation Program: Exempt External Power Supplies Under the EPS Service Parts Act of 2014

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Energy (DOE) is proposing to codify provisions of the EPS Service Parts Act of 2014 that exempt from energy conservation standards certain external power supplies (EPSs) made available by a manufacturer as a service or spare part. Consistent with that Act, DOE is proposing to require annual reports of the total number of exempt EPS units sold as service and spare parts that do not meet the relevant energy conservation standards.

DATES: DOE will accept comments, data, and information regarding this notice of proposed rulemaking no later than December 18, 2015. See section V, ''Public Participation,'' for details.

ADDRESSES: Any comments submitted must identify the NOPR for Exempt External Power Supplies Under the EPS Service Parts Act of 2014, and provide docket number EERE–2015–BT–CRT–0013 and/or regulatory information number (RIN) number 1904–AD53. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: EPSServiceParts2015CRT0013@ee.doe.gov.* Include the docket number and/or RIN in the subject line of the message.

3. *Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC, 20585–0121. If possible, please submit all items on a CD. It is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Program, 950 L'Enfant Plaza SW., Suite 600, Washington, DC, 20024. Telephone: (202) 586–2945. If possible, please submit all items on a CD. It is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section V of this document (Public Participation).

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at regulations.gov. All documents in the docket are listed in the regulations.gov index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

A link to the docket Web page can be found at: *http://www1.eere.energy.gov/buildings/appliance_standards/product.aspx?productid=23.* This Web page will contain a link to the docket for this notice on the regulations.gov site. The regulations.gov Web page will contain simple instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through regulations.gov.

For further information on how to submit a comment, review other public comments and the docket, or to request a public meeting, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information may be sent to Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121.

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I. Authority and Background

Authority

Title III of the Energy Policy and Conservation Act of 1975 (42 U.S.C. 6291, *et seq.;* ''EPCA'' or, in context, ''the Act'') sets forth a variety of provisions designed to improve energy efficiency. (All references to EPCA refer to the statute as amended through the Energy Efficiency Improvement Act of 2015, Pub. L. 114–11 (April 30, 2015).) Part B of title III, which for editorial reasons was re-designated as Part A upon incorporation into the U.S. Code (42 U.S.C. 6291–6309, as codified), establishes the ''Energy Conservation Program for Consumer Products Other Than Automobiles.'' External power supplies are among the products affected by these provisions.

Background

Section 301 of EISA 2007 established minimum energy conservation standards for Class A external power supplies (EPSs) manufactured on or after July 1, 2008. (42 U.S.C. 6295(u)(3)(A)). See 42 U.S.C. 6291(36)(C)(i)–(ii). EISA 2007 exempts Class A EPSs from meeting these statutorily-prescribed standards if the devices are manufactured before July 1, 2015, and made available by the manufacturer as service parts or spare parts for end-use consumer products that were manufactured prior to July 1, 2008. (42 U.S.C. 6295(u)(3)(B)) Congress created this limited (and temporary) exemption as part of a broad range of amendments to EPCA under EISA 2007. The provision did not grant DOE with the authority to expand or extend the length of this exemption and Congress did not grant DOE with the general authority to exempt any already covered product from the requirements set by Congress.

After releasing a preliminary analysis and issuing a proposed set of energy conservation standards, DOE published a final rule prescribing new standards for non-Class A EPSs and amended standards for some Class A EPSs—namely, those EPSs that met what DOE has termed as ''direct operation'' EPSs. See 79 FR 7846 (Feb. 10, 2014). (A direct operation EPS is an external power supply that can operate a consumer product that is not a battery charger without the assistance of a battery. See 10 CFR 430.2.) These new standards apply to products manufactured on or after February 10, 2016. At that time, DOE did not have the authority to provide manufacturers with an exemption for EPSs that were made available as service or spare parts to end-use consumer products that were manufactured prior to the compliance date of these new standards. Accordingly, despite requests from some commenters who responded to DOE's proposed standards by asking for such an exemption, no such relief was provided as part of the final rule.

On December 18, 2014, the EPS Service Parts Act of 2014, Public Law 113–263 (Dec. 18, 2014) (''Service Parts Act'') was enacted. That law provided manufacturers with an exemption for EPSs that are made available as service and spare parts for end-use products manufactured before February 10, 2016. To be exempt from the new standards under the Service Parts Act, an EPS must meet four separate criteria. Specifically, the EPS must be: (i) Manufactured during the period beginning on February 10, 2016, and ending on February 10, 2020; (ii) marked in accordance with the External Power Supply International Efficiency Marking Protocol; (iii) compliant, where applicable, with the standards for Class A EPSs and certified to DOE as meeting at least International Efficiency Level IV; and (iv) made available by the manufacturer as a service part or spare part for an end-use product manufactured before February 10, 2016.

Additionally, the Service Parts Act permits DOE to require manufacturers of an EPS that is exempt from the 2016 standards to report to DOE the total number of EPS units shipped annually that are made available as service and spare parts and do not meet those standards. See 42 U.S.C. 6295(u)(5)(A)(ii). DOE may also limit the applicability of the exemption if the Secretary determines that the exemption is resulting in a significant reduction of the energy savings that would result were there no exemption to the new standards. See 42 U.S.C. 6295(u)(5)(A)(iii). Finally, the statute authorizes DOE to provide a similar exemption from future EPS conservation standards.

II. Summary of the Notice of Proposed Rulemaking

DOE is proposing to incorporate the statutory provisions described above into its regulations. DOE is also providing some clarification on the circumstances under which EPSs would be considered spare or service parts. DOE also proposes to require that importers and domestic manufacturers annually report to DOE the total units of exempt EPSs sold as service and spare parts that do not meet the 2016 standards.

III. Discussion

A. Codifying the Exemption in the CFR

DOE is proposing to incorporate the provisions of the Service Parts Act into 10 CFR 430.32. This would help ensure that the regulations reflect the statutory exemption and that interested parties are able to readily access the content of this new statutory provision. It also ensures consistency with the similar exemption to the Class A EPS standards provided by Congress within EISA 2007, which was codified in the CFR.

B. Service or Spare Part EPSs

The Service Parts Act provides an exemption for certain EPSs that are made available by manufacturers as service or spare parts. Most end-use products that use EPSs are sold with the EPS that is necessary to operate that product. In such a case, the EPS that is sold with the end-use product would not be considered to be an EPS made available as a spare or service part. However, any EPS that is sold separately from an end-use product, including an EPS made available as a replacement for, or in addition to, the EPS originally sold with an end-use product would be considered an EPS

made available as a service or spare part.

Further, to clarify the application of this statutory exemption, only those EPSs that are made available as service or spare parts for end-use products that were manufactured before February 10, 2016 (the date that manufacturers must comply with the new and amended standards for direct operation EPSs) qualify for the Service Parts Act's exemption. If an EPS is made available as a service part or spare part for any end-use product that continues to be manufactured after February 10, 2016, or is sold with any end-use product manufactured after that date, that EPS would not be eligible for this exemption. Congress specifically limited the application of the exemption to those EPSs that the manufacturer makes available for an end-use product that constitutes the primary load of that end-use product so long as it was manufactured prior to February 10, 2016. See 42 U.S.C. 6295(u)(5)(A).

Furthermore, DOE recognizes that many EPSs, like those that use an industry standard communication protocol such as the universal serial bus (USB), may be capable of operating many different end-use products. If the EPS is capable of operating multiple end-use products, some of which were manufactured before February 10, 2016, and some of which were manufactured after February 10, 2016, then that EPS would also not be eligible for the service and spare part exemption since the EPS can operate an end-use product manufactured after February 10, 2016. In order to clarify which EPSs are eligible for the exemption, DOE is proposing to clarify that this exemption would apply to an EPS basic model that a manufacturer makes available only as a service part or a spare part for an end-use product that was manufactured before February 10, 2016, and would not apply to an EPS basic model that a manufacturer makes available as a service part or spare part for end-use products that continue to be manufactured after February 10, 2016. Specifically, an EPS would be exempt from the 2016 Level VI standard if, among other criteria, it is made available by the manufacturer only as a service part or a spare part for an end-use product, and only if the end-use product was manufactured before February 10, 2016.

DOE seeks comment regarding how manufacturers produce spare or service parts as compared to how manufacturers produce EPS units provided with a new product. For example, do manufacturers typically produce a single EPS basic model that is both sold independently as a service/spare part for a given end-use product and packaged with a new end-use product? If a manufacturer typically produces a single EPS basic model, are those EPSs produced as a spare or service part labelled differently from those packaged with a new product?

C. Sales Reporting Requirements

Additionally, the Service Parts Act permits DOE to require manufacturers of an EPS that is exempt from the 2016 standards to report to DOE the total number of EPS units shipped annually that are made available as service and spare parts and do not meet those standards. See 42 U.S.C. 6295(u)(5)(A)(ii). Consistent with that authority, DOE is proposing that importers and domestic manufacturers of EPSs that are exempt under the Service Parts Act report to DOE annually the total number of exempt EPS units sold that do not meet the amended standard. DOE considers the ''shipments'' referred to in the statute to be the units sold by either the importer or the domestic manufacturer. Because importers would have both incoming and outgoing shipments, DOE considers the ''units sold'' to be clearer than ''units shipped.'' DOE requests comment on this phrasing.

Many of the EPSs involved are Class A EPSs and continue to be subject to the current Class A EPS standards (*i.e.* Level IV) set forth in 10 CFR 430.32(w)(1)(i) and associated certification requirements. Manufacturers of any basic model of such a Class A EPS must, therefore, submit an annual certification report to DOE as required under 10 CFR part 429. For these EPSs, submission of an annual certification report to DOE is required to qualify for the exemption. In addition to the annual certification report requirement for these EPSs, DOE is proposing to require each importer or domestic manufacturer to include in its annual certification report information the number of units of each individual model of exempt EPS it sold in the preceding year that do not meet the 2016 standards. The Service Parts Act authorizes DOE to limit the applicability of the service and spare part exemption if DOE determines that the exemption is resulting in a significant reduction of the energy savings that would otherwise result from the final rule. In assessing whether such a change would be needed, DOE plans to use the reported information to evaluate the exemption's impacts on energy savings.

Similarly, DOE is proposing to require each importer or domestic manufacturer of non-Class A EPSs that are exempted by the Service Parts Act and do not meet the 2016 standards to submit an annual report of the corresponding number of units of each individual model of such EPS that the importer or domestic manufacturer sold in the prior year. Examples of these kinds of non-Class A EPSs include multiple-voltage EPSs, high-power EPSs, and some EPSs used to operate end-use products that are motor-driven. Under DOE's February 2014 final rule, these EPSs, unless exempt, are required to meet the Level VI standards starting in 2016. These non-class A EPSs would not be certified under the provisions of 10 CFR 429.12 (General requirements applicable to certification reports), if they are exempt. Therefore, consistent with the Service Parts Act, DOE is proposing to require that importers and domestic manufacturers report the total number of units sold in the year preceding the report. Specifically, DOE is proposing to add this reporting requirement to 10 CFR 429.37, with the product-specific certification requirements.

DOE proposes that the reporting period for the sales information be from August 1 through July 31 of each year. This would allow importers and domestic manufacturers time to compile sales information and report the number of units sold and to align the submittal date with the annual certification report deadline of September 1 for Class-A EPSs. DOE seeks comment on this proposed reporting requirement.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

This rulemaking is not significant for purposes of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential

impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *http://energy.gov/gc/office-general-counsel.*

For manufacturers of EPSs, the Small Business Administration (SBA) has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. 65 FR 30836, 30848 (May 15, 2000), as amended at 65 FR 53533, 53544 (Sept. 5, 2000) and codified at 13 CFR part 121. The size standards are listed by North American Industry Classification System (NAICS) code and industry description and are available at *http://www.sba.gov/content/summary-size-standards-industry.* EPS manufacturing is classified under NAICS 335999, ''All Other Miscellaneous Electrical Equipment and Component Manufacturing.'' The SBA sets a threshold of 500 employees or less for an entity to be considered as a small business for this category.

As a preliminary matter, DOE notes that there are no domestic manufacturers of EPSs. Consequently, there are no small business impacts to evaluate for purposes of the Regulatory Flexibility Act.

Notwithstanding the absence of domestic EPS manufacturers, DOE 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 would incorporate into DOE's regulations a statutorily-prescribed exemption affecting EPSs that manufacturers make available as service or spare parts. The exemption allows manufacturers to maintain and distribute supplies of replacement parts for older equipment without needing to meet the EPS energy conservation standards that will apply starting in 2016. This exemption provides manufacturers flexibility in meeting their warranty and contract obligations in cases where service or spare parts require an EPS. It also relieves manufacturers of the burdens of redesigning and certifying EPSs used for end-use products that are no longer manufactured starting in 2016, which DOE anticipates will save these manufacturers from any significant expenses that would otherwise be used to solely support products that are no longer in production.

Consistent with its prior incorporation of the previous statutory exemption added by Congress for Class A EPSs made available as service and spare parts, see 10 CFR 430.32(w)(2) (2015), DOE expects any potential impact from its proposal to be minimal.

For these reasons, DOE certifies that the proposed rule would 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 will transmit the certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the SBA for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

This rule proposes to revise an existing information collection. This information collection request contains:

(1) OMB Control Number: 1910–1400.

(2) Information Collection Request Title: Certification Reports, Compliance Statements, Application for a Test Procedure Waiver, and Recordkeeping for Consumer Products and Commercial/Industrial Equipment Subject to Energy or Water Conservation Standards.

(3) Type of Request: Revision of a Currently Approved Collection.

(4) Purpose: Today's notice would require external power supply manufacturers to report the number of exempt EPS units sold as part of the annual certification report, which is already required. The annual certification report must be submitted via CCMS, an electronic system for recording and processing certification submissions.

Manufacturers of EPSs must certify to DOE that their products comply with any applicable energy conservation standards. In certifying compliance, manufacturers must test their products according to the DOE test procedures for EPSs including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including external power supplies. See 10 CFR part 429, subpart B. The collection-of-information requirement for certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (PRA). This requirement has been approved by OMB under OMB Control Number 1910–1400. Public reporting burden for the proposed certification requirement is estimated to average 30 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

In today's notice, DOE is proposing to require external power supply manufacturers to provide the total number of exempt EPS units sold as service and spare parts for each basic model for which the manufacturer is claiming exemption from the current standards. The following are DOE estimates of the increased time (over the existing approved information collection) for manufacturers to collect, organize and store the data required by today's notice of proposed rulemaking.

Affected Public: Manufacturers of external power supplies that are claiming the spare parts exemption.

Estimated Number of Impacted Manufacturers: 1028.

Estimated Time per Record: 4 minutes.

Estimated Total Annual Burden Hours: 69 hours.

Estimated Total Annual Cost to the Manufacturers: $500.

This revision would yield the following totals for the information collection:

(5) Annual Estimated Number of Respondents: 3028

(6) Annual Estimated Number of Total Responses: 20,000

(7) Annual Estimated Number of Burden Hours: 68,069 hours

(8) Annual Estimated Reporting and Recordkeeping Cost Burden: $6,800,500

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

D. Review Under the National Environmental Policy Act of 1969

DOE has determined that this proposal, which would incorporate a recently-enacted exemption into the CFR for EPSs sold as spare or service parts, falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321, *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this proposed rule would adopt changes to the manner in which certain covered equipment would be certified and/or reported, which would not affect the amount, quality or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this

rulemaking is covered by Categorical Exclusion A6 (Procedural Rulemaking) under 10 CFR part 1021, subpart D. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of today's proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a)–(b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/office-general-counsel*. DOE examined this proposed rule according to UMRA and its statement of policy and determined that the proposed rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

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

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988), that this proposed regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on

energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This proposed regulatory action to amend the existing certification requirements for EPSs sold as spare parts is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition. This proposal to amend the certification requirements for all covered consumer products does not propose the use of any commercial standards.

V. Public Participation

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

VI. Approval of the Office of the Secretary

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

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Reporting and recordkeeping requirements.

10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Small businesses.

Issued in Washington, DC, on November 10, 2015.

Kathleen B. Hogan,

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

For the reasons stated in the preamble, DOE is proposing to amend parts 429 and 430 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317.

■ 2. Section 429.37 is amended by adding paragraphs (b)(3) and (c) to read as follows:

§ 429.37 External power supplies.

* * * * *

(b) * * *

(3) Pursuant to § 429.12(b)(13), a certification report for external power supplies that are exempt from the energy conservation standards at § 430.32(w)(1)(ii) pursuant to § 430.32(w)(2) must include the following additional product-specific information: The number of units of each individual model of exempt external power supplies sold during the most recent 12-calendar-month period ending on July 31.

(c) *Exempt External Power Supplies.* For each individual model of external power supply that is exempt from energy conservation standards pursuant to § 430.32(w)(2) and has not been certified pursuant to § 429.12(a) as compliant with an applicable standard, the importer or domestic manufacturer must, no later than September 1, 2017, and annually thereafter, submit a report providing the following information:

(1) The importer or domestic manufacturer's name and address;

(2) The brand name;

(3) The model number;

(4) The average active mode efficiency as a percentage (%);

(5) No-load mode power consumption in watts (W);

(6) The nameplate output power in watts (W);

(7) The nameplate output current in aperes (A); and

(8) The number of units sold during the most recent 12-calendar-month period ending on July 31. The report must be submitted to DOE in accordance with the submission procedures set forth in § 429.12(h).

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 3. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 4. Section 430.32 is amended by revising paragraph (w)(2) to read as follows:

§ 430.32 Energy and water conservation standards and their compliance dates.

* * * * *

(w) * * *

(2) A basic model of external power supply is not subject to the energy conservation standards of paragraph (w)(1)(ii) of this section if the external power supply—

(i) Is manufactured during the period beginning on February 10, 2016, and ending on February 10, 2020;

(ii) Is marked in accordance with the External Power Supply International Efficiency Marking Protocol, as in effect on February 10, 2016;

(iii) Meets, where applicable, the standards under paragraph (w)(1)(i) of this section, and has been certified to the Secretary as meeting those standards; and

(iv) Is made available by the manufacturer only as a service part or a spare part for an end-use product that—

(A) Constitutes the primary load; and

(B) Was manufactured before February 10, 2016.

* * * * *

[FR Doc. 2015–29303 Filed 11–17–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. FDA–2014–N–1021]

RIN 0910–AH00

Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to establish requirements concerning ''gluten-free'' labeling for foods that are fermented or hydrolyzed or that contain fermented or hydrolyzed ingredients. These additional requirements for the ''gluten-free'' labeling rule are needed to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to fermented or hydrolyzed foods labeled as ''gluten-free.'' There is uncertainty in interpreting the results of current gluten test methods for fermented and hydrolyzed foods on a quantitative basis that equates the test results in terms of intact gluten. Thus, we propose to evaluate compliance of such fermented and hydrolyzed foods that bear a ''gluten-free'' claim with the gluten-free labeling rule based on records that are made and kept by the manufacturer of the food bearing the ''gluten-free'' claim and made available to us for inspection and copying. The records would need to provide adequate assurance that the food is ''gluten-free'' in compliance with the gluten-free food labeling final rule before fermentation or hydrolysis. In addition, the proposed rule would require the manufacturer of fermented or hydrolyzed foods bearing the ''gluten-free'' claim to document that it has adequately evaluated the potential for gluten cross-contact and, if identified, that the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process. Likewise, manufacturers of foods that contain fermented or hydrolyzed ingredients and bear the ''gluten-free'' claim would be required to make and keep records that demonstrate with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with the gluten-free food labeling final rule. Finally, the proposed rule would state that we would evaluate compliance of distilled foods by

verifying the absence of protein using scientifically valid analytical methods that can reliably detect the presence of protein or protein fragments in the distilled food.

DATES: Submit either electronic or written comments on the proposed rule by February 16, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by December 18, 2015.

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–2014–N–1021 for Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods. 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 comments on information collection issues to the Office of Management and Budget in the following ways:

• Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods.

FOR FURTHER INFORMATION CONTACT: *With regard to the proposed rule:* Carol D'Lima, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2371, FAX: 301–436–2636.

With regard to the information collection issues: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of the Rule

Need for the rule: Celiac disease, a hereditary, chronic inflammatory disorder of the small intestine, has no cure, but individuals who have this disease are advised to avoid all sources of gluten in their diet to protect against adverse health effects associated with the disease. In the **Federal Register** of August 5, 2013 (78 FR 47154), we published a final rule that defines the term ''gluten-free'' and establishes requirements for the voluntary use of that term in food labeling. The final rule (now codified at § 101.91 (21 CFR 101.91)) is intended to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled. The regulation provides that ''[w]hen compliance with [the rule] is based on an analysis of the food, the FDA will use a scientifically valid method that can reliably detect the presence of 20 parts per million (ppm) gluten in a variety of food matrices, including both raw and cooked or baked products'' (§ 101.91(c)). We established this 20 ppm limit for intact gluten considering multiple factors, including currently available analytical methods and the needs of individuals with celiac disease, as well as factors such as ease of compliance and enforcement, stakeholder concerns, economics, trade issues, and legal authorities. Although test methods for the detection of gluten fragments in fermented and hydrolyzed foods have advanced, there is still uncertainty in interpreting the results of these test methods on a quantitative basis that equates the test results to an equivalent amount of intact gluten. Thus, alternative means are necessary to verify compliance with the provisions of the rule for fermented and hydrolyzed foods, such as cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine, or hydrolyzed plant proteins used to improve flavor or texture in processed foods such as soups, sauces, and seasonings.

Legal authority: Consistent with section 206 of the Food Allergen

Labeling and Consumer Protection Act (FALCPA) and sections 403(a)(1), 201(n), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(a)(1), 321(n), and 371(a)), we are proposing requirements to permit the voluntary use of the term ''gluten free'' in the labeling of foods that are fermented, hydrolyzed, or distilled, or that contain fermented, hydrolyzed, or distilled ingredients.

Major provisions of the rule: The proposed rule would amend § 101.91(c) to provide alternative means for us to verify compliance based on records that are maintained by the manufacturer of the food bearing the ''gluten-free'' claim and made available to us for inspection and copying. We propose that, for foods fermented or hydrolyzed by the manufacturer and bearing the ''gluten-free'' claim, the records must demonstrate adequate assurance that the food is ''gluten-free'' in compliance with § 101.91(a)(3) before fermentation or hydrolysis. Such adequate assurance can include test results, certificates of analysis (CoAs), or other appropriate verification documentation for each of the ingredients used in the food. Alternatively, adequate assurance can include test results of the food before fermentation or hydrolysis of the food.

In addition, the proposed rule would require the manufacturer to document that any potential for gluten cross-contact has been adequately assessed, and where such a potential has been identified, that the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

Further, for foods containing one or more fermented or hydrolyzed ingredients and bearing the ''gluten-free'' claim, manufacturers would have to make and keep records demonstrating with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with § 101.91(a)(3) including, but not limited to, CoAs or other appropriate verification documentation from the ingredient suppliers and/or results of testing conducted by the ingredient suppliers.

The proposed rule also would require the manufacturer to retain the records for at least 2 years after introduction or delivery for introduction of the food into interstate commerce. The proposed rule would allow these records to be kept as original records, as true copies or as electronic records, and manufacturers would have to make the records available to us for inspection and copying, upon request, during an inspection. The records would need to be reasonably accessible to FDA during an inspection at each manufacturing facility (even if not stored on site) to determine whether the food has been manufactured and labeled in compliance with § 101.91. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible. The proposed rule would provide that we would evaluate compliance of distilled foods, such as distilled vinegar, by verifying the absence of protein using scientifically valid analytical methods that can reliably detect the presence of protein or protein fragments in the food.

Costs and benefits: Full compliance with the proposed rule, if finalized, would have annualized costs of about $9 million per year and annual health benefits of about $41 million per year, for net benefits of $32 million a year:

ANNUAL COST AND BENEFIT OVERVIEW

Costs	Testing of Foods	$3,000,000
	Standard Operating Procedure Development	1,500,000
	Labeling (changes for non-compliant products)	300,000
	Paperwork	3,900,000
Benefits	Health Gains for Individuals with Celiac Disease	41,000,000
Net Benefits		32,000,000

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I. Background

A. Why do we need this proposed rule?

Celiac disease is a hereditary, chronic inflammatory disorder of the small intestine triggered by the ingestion of certain proteins referred to as gluten occurring in wheat, rye, barley, and crossbreeds of these grains. The main protein of wheat gluten is gliadin; the similar proteins of rye and barley are termed secalin and hordein, respectively. Both of the major protein fractions of gluten, gliadins and glutenins, are active in celiac disease. All the gliadins and glutenins subunits are reported to be harmful for individuals with celiac disease (Ref. 1). Celiac disease has no cure, and individuals who have this disease are advised to avoid all sources of gluten in their diet to protect against adverse health effects associated with the disease.

Under section 206 of FALCPA, in the **Federal Register** of August 5, 2013, we published a final rule that defines the term ''gluten-free'' and establishes requirements as to the voluntary use of that term in food labeling. The final rule (now codified at 21 CFR 101.91) is intended to help ensure that individuals with celiac disease are not misled and receive truthful and accurate information with respect to foods labeled as ''gluten-free.'' The final rule does not require manufacturers who label their foods as ''gluten-free'' to test those foods for the presence of gluten

although they may choose to do so to ensure that the food does not contain 20 ppm or more gluten. The regulation provides that ''[w]hen compliance with [the rule] is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products'' (§ 101.91(c)). We may conduct such testing to verify that foods labeled ''gluten free'' meet the criteria for ''gluten-free'' labeling, including the part of the ''gluten-free'' definition that states that ''[a]ny unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten (*i.e.,* below 20 mg gluten per kg of food)'' (§ 101.91(a)(3)(ii)).

In comments we received in response to the proposed rule that appeared in the **Federal Register** of January 23, 2007 (72 FR 2795), and to a related notice we published in the **Federal Register** of August 3, 2011 (76 FR 46671), we became aware that fermented or hydrolyzed foods, some of which are labeled as ''gluten-free,'' cannot be tested for a quantitative measure of intact gluten using currently available analytical methods. In the notice that we published in the **Federal Register** of August 3, 2011 (76 FR 46671 at 46673), we stated that FDA recognized that for some food matrices (*e.g.,* fermented or hydrolyzed foods) there were no currently available validated methods that could be used to accurately determine if they contained <20 ppm gluten. FDA also stated that we were considering whether to require manufacturers of such foods to have a scientifically valid method that would reliably and consistently detect gluten at 20 ppm or less before including a ''gluten-free'' claim in the labeling of their foods. FDA requested comments on this proposed approach as well as on whether FDA also should require these manufacturers to maintain records on test methods, protocols, and results and to make these records available to FDA upon inspection.

The notice explained that we interpret the term ''scientifically valid method'' to mean a method that is ''accurate, precise, and specific for its intended purpose and where the results of the method evaluation are published in the peer-reviewed scientific literature. In other words, a scientifically valid test is one that consistently and reliably does what it is intended to do'' (id.).

As of November 18, 2015, we know of no scientifically valid analytical method effective in detecting and quantifying with precision the gluten protein content in fermented and hydrolyzed foods in terms of equivalent amounts of intact gluten proteins. Without reference standards associated with the production of fermented and hydrolyzed products, such quantification is uncertain and potentially inaccurate (Ref. 2). Thus, we need other means to verify compliance for these foods.

B. What are fermented or hydrolyzed foods?

A fermented food is one that has undergone fermentation—a process that typically involves the conversion of complex organic compounds, especially sugars and other carbohydrates, to simpler compounds such as lactic acid and ethyl alcohol. Fermentation has long been used to preserve or produce foods with characteristic flavors or textures. During fermentation, proteins such as gluten break apart into smaller groups of amino acids known as peptides. Examples of foods that are subject to fermentation during manufacturing are cheese, yogurt, vinegar, sauerkraut, pickles, green olives, beers, and wine.

A hydrolyzed food is one in which a food's chemical components—such as proteins—are broken into smaller organic compounds by reaction with water. These reactions are often accelerated by enzymes. One common application of hydrolysis in food manufacturing is the hydrolysis of plant proteins—such as soy protein. Hydrolyzed soy proteins are often used as an ingredient to increase digestibility of the protein, to enhance flavor, or to improve texture in processed foods such as soups, sauces, and seasonings. There are many different types of fermented or hydrolyzed foods as well as food products that contain fermented or hydrolyzed ingredients (Ref. 3). Examples of foods that use hydrolyzed plant proteins as flavor enhancers include soups, chili, sauces, gravies, stews, dips, and some snacks like potato chips and pretzels.

C. Why are there no appropriate analytical methods to quantify intact gluten in fermented or hydrolyzed foods?

1. Background on Analytical Methods for Gluten

As discussed in the preamble to our final rule (78 FR 47154 at 47165), we routinely rely upon scientifically valid methods in our enforcement programs on food labeling. When we established the requirement that foods bearing the ''gluten-free'' claim contain less than 20 ppm of intact gluten, we were referring to intact gluten as measured by sandwich ELISA-based methods. (ELISA stands for an enzyme-linked immunosorbent assay.) The sandwich ELISA-based methods can both detect and quantify specific amino acid sequences, known as epitopes, with the requirement that at least two epitopes be present in a single strand of amino acids in order to mediate the binding of two antibodies (hence, the concept of a sandwich). Advantages of sandwich ELISA-based methods are an increased specificity associated with the requirement that two antibodies bind the antigen (especially if the two antibodies recognize different epitopes) and a high sensitivity. As a result, the sample does not have to be extensively purified before analysis (Ref. 4).

Sandwich ELISA-based methods are appropriate for foods in which the gluten is not subject to fermentation or hydrolysis and remains intact. However, as we discuss in the next section, sandwich ELISA-based methods are not effective in detecting and quantifying gluten proteins that are no longer intact as a result of fermentation or hydrolysis.

2. Challenges in Quantifying Gluten in Fermented and Hydrolyzed Foods

Proteins can be broken into smaller fragments called peptides. Unless the proteins are sufficiently broken down so as to eliminate all immunopathogenic elements (*e.g.,* strands of amino acids that cause a celiac response), the fermented or hydrolyzed gluten can be harmful to people with celiac disease (Ref. 5). Compared to other processing methods that physically remove the gluten to produce non-protein containing ingredients (*e.g.,* wheat starch), fermentation, hydrolysis, or enzymatic processing methods that chemically break down gluten peptides may not completely remove the immunotoxic potential of these peptides. Small gluten peptides resulting from these processes and remaining in the finished food could still contain sequences of amino acids which potentially cause adverse reactions in people with celiac disease. We invite comments, including scientific data, on any studies that have been conducted to demonstrate whether any fermentation or hydrolytic processes sufficiently break down gluten into peptides that are harmless to persons with celiac disease.

The principal limitation of the sandwich ELISA-based methods is that they need at least two epitopes recognized by the antibodies used in the assay to be present in the same continuous amino acid strand. However, in fermented or hydrolyzed foods, gluten proteins are typically fragmented

into peptides. Although these peptides may remain immunologically active and be of potential concern to people with celiac disease, the antibodies used in the ELISA-based methods may be unable to recognize the peptides. This affects how one might detect and quantify gluten, such that the quantity of gluten reported may be incorrect (Ref. 6). Thus, sandwich ELISA-based methods are not appropriate analytical methods for detecting and quantifying gluten content in fermented or hydrolyzed products.

Competitive ELISA-based methods that recognize a single epitope have been developed and may overcome the detection problems encountered with the sandwich ELISA-based assays in hydrolyzed or fermented food. Although some studies have validated the reproducibility of competitive ELISA-based test methods (Ref. 7), there is uncertainty about whether these methods can quantify the amount of protein from which those fragments were generated by hydrolysis (Ref. 2). This uncertainty creates problems in equating these test results to an equivalent amount of intact gluten in the fermented or hydrolyzed product. Further, without an appropriate reference standard to gauge the response, one cannot interpret the results on a quantitative basis that equates the response to a specific amount of intact gluten. As of November 18, 2015, we are not aware of any methods for which there is an appropriate reference standard to gauge the response for detection and quantification, with precision, of the gluten content in terms of intact gluten in fermented and hydrolyzed foods.

In addition to ELISA-based methods, mass spectrometry (MS) holds significant potential for analysis of hydrolyzed gluten because of its unique capabilities for protein and peptide analysis. In general, MS can provide accurate measurement of peptide molecular weights and identification of peptide primary amino acid sequences. Qualitative methods can be used to determine the identity of the peptides, with quantitative methods able to determine peptide concentrations. As applied to hydrolyzed gluten analysis, MS analysis may be able to identify and quantify the gluten protein fragment peptides that result from food processing. Therefore, for hydrolyzed food, MS could identify gluten and measure gluten fragment concentrations with high sensitivity and molecular specificity. However, without an appropriate hydrolyzed gluten reference standard that would enable interpretation of the test results in terms of intact gluten, as well as the ability to analyze for all potential peptides, MS analysis would not be able to provide a quantitative measure of intact gluten. Therefore, methods are needed that can not only detect gluten protein hydrolysis fragments, but also quantify the source gluten proteins. We invite comment on any additional research into methods that can be used to quantify the gluten protein content in fermented or hydrolyzed foods in terms of intact gluten, including the use of ELISA-based methods and MS testing, as well as any data and information on appropriate reference standards for such test methods.

D. Is it feasible, and under what circumstances, can foods be processed to remove gluten?

In some cases, it is possible to remove or separate the gluten protein portion of an ingredient derived from a gluten-containing grain. For example, in processing food starch from various grain sources including wheat, the starch is extracted and refined from the grains by wet grinding, washing, and sieving to separate the protein components from the starch. This starch material can be dried or used in further processing. However, some gluten may remain in these ingredients even after they have been processed to remove gluten. Variations in the processing could result in different trace amounts of gluten remaining in the starch. Therefore, § 101.91(a)(3)(i)(A)(*3*) provides that the use of such ingredients must not result in the presence of 20 ppm or more gluten in the finished food (*i.e.,* 20 mg or more gluten per kg of food).

Our regulations do not allow for processing a food (as opposed to the food's ingredients) to remove gluten. Section 101.91(a)(3)(i)(A)(*1*) requires that the food bearing the claim in its labeling not contain an ingredient that is a gluten-containing grain (*e.g.,* spelt wheat). The intent behind § 101.91(a)(3)(i)(A)(*1*) was to ensure that the food, as consumed, contains as little gluten as possible. This approach is consistent with other international standards (see Codex Standard 118–1979, section 2.1.1 (Ref. 8)).

Nevertheless, we have heard arguments that we should allow the use of a ''gluten-free'' label on foods where the food, rather than the food's ingredients, has been processed to remove gluten. We have not received sufficient information regarding any specific processes to remove gluten to determine whether any processes identified would impact our rationale. Thus, we invite comment and data on the feasibility and circumstances under which a food can be processed to remove gluten and the methods by which the absence of gluten can be determined.

E. Can beer be labeled ''gluten-free''?

Some comments submitted in response to the 2007 proposed rule and the 2011 notice wanted us to allow beers subject to FDA labeling regulations to be labeled ''gluten-free'' if the beers contained less than 20 ppm gluten, regardless of whether the beer was made from a gluten-containing grain. Other comments favored prohibiting the use of a ''gluten-free'' claim on the label of beers made from gluten-containing ingredients but whose manufacturers claim were later ''reduced'' in gluten by the processing methods.

The comments favoring the use of ''gluten-free'' labeling on beers made from gluten-containing grains argued that the beers can be processed to remove gluten. As with other foods, beers that have been made using a gluten-containing grain do not meet the gluten-free definition. Thus, beers made from gluten-containing grains cannot bear a ''gluten-free'' claim. However, as with other foods, if the gluten-containing grain has been processed to remove gluten in accordance with the provisions in the ''gluten-free'' definition prior to making beer, the beer may be eligible to make the claim under the provisions of this proposed rule. Regarding the commenters' assertion that beers made from gluten containing grains can be processed to remove gluten, we are not aware of any scientifically valid way to evaluate such a claim, and there is inadequate evidence concerning the effectiveness of the commenters' gluten removal process.

Gluten can be at least partially broken down by several processes, including fermentation. However, as we explained in section I.C.1., the presence or absence of gluten broken down in this way cannot be reliably detected with sandwich ELISA-based methods. We are interested in learning more about the efficacy of competitive ELISA-based methods (*e.g.,* the R5 or G12 competitive ELISA-based methods), given the beer industry's practice of adding enzymes to the beer to prevent the problem of cloudiness or ''haze,'' which can occur as a result of residual protein substances extracted from grain during the brewing and fermentation process. The enzyme hydrolyzes or breaks down gluten proteins at proline residues. As a result, adding these haze control enzymes may generate peptides that are not detectable

using the commercially available competitive ELISA-based methods that rely on the presence of proline in the epitopes (Refs. 9 and 10). However, it is uncertain that cleavage at proline residues totally eliminates the concern for people with celiac disease because there may be immunopathogenic protein fragments still present.

FDA recently completed a study on the effectiveness of proline endopeptidase (PEP), an enzyme that the beer industry uses to remove cloudiness in beer, using sorghum beer spiked with gluten as a model system. The study examined the hydrolysis of gluten and some of the protein fragments reported to affect people with celiac disease. The results indicated that fermentation of beer resulted in a gradual reduction in detectable gluten concentration, and addition of PEP increased the reduction in the detectable gluten concentration. However, differences in peptide profiles between the beer and the calibration standards may lead to inaccurate quantitation of gluten in the final product (Ref. 11). Due to the lack of clinical data and a comprehensive understanding of celiac disease, it is not known if immunopathogenic compounds remain after the use of the enzyme. Hydrolyzed gluten may contain protein fragments that can trigger reactions in people with celiac disease which are not recognized by the ELISA methods used or identified by the MS analysis. For example, Western Blot testing showed that high molecular weight glutenins were less susceptible than the low molecular weight fraction of gluten to the action of PEP during the fermentation of beer. Additional data on the effect of PEP, and possibly clinical evidence, are needed before conclusions can be drawn regarding the effectiveness of PEP in breaking down gluten in a manner that renders the beer, or other foods containing gluten, safe for consumption by people with celiac disease.

We are interested in receiving comment, including scientific research regarding whether beer derived from gluten-containing grains that may still contain protein fragments from gluten can be shown by scientifically valid analytic methods to equate to intact gluten on a quantitative basis. We are also interested in scientific research regarding how we can use such test methods to determine that beer derived from gluten-containing grains contains the equivalent of less than 20 ppm intact gluten proteins, including any data and information regarding quantification of gluten fragments and determining appropriate calibration or reference standards. We also invite comment, including data and any information, on scientific research and methods to determine if a specific enzymatic treatment (or other treatments, if known) of beer derived from gluten-containing grains can modify proteins or protein fragments such that they are present at levels equivalent to less than 20 ppm intact gluten protein.

We note that the labeling of beer is subject to oversight by two separate Federal Agencies. As we explained in the preamble to the final rule (78 FR 47154 at 47165), the Treasury Department's Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for the issuance and enforcement of regulations with respect to the labeling of beers that are malt beverages under the Federal Alcohol Administration Act (FAA Act). Certain other beers do not meet the definition of a malt beverage under the FAA Act (27 U.S.C. 211(a)(7)); those beers are subject to FDA's labeling requirements. We are working with TTB on the issues associated with ''gluten-free'' labeling of beer to promote consistency in our approach, while taking into consideration the differences in the statutes administered by FDA and TTB, respectively.

As we noted in the preamble to the final rule (78 FR 47154 at 47166) beer manufacturers whose beers are subject to FDA's labeling requirements that make beer from a gluten-containing grain or from non-gluten-containing grains are not precluded from using other statements on the label, such as a gluten statement consistent with the TTB Policy on Gluten Content Statements in the Labeling and Advertising of Wine, Distilled Spirits, and Malt Beverages, about processing of beers to reduce gluten. However, such statements must be truthful and not misleading. Beers bearing statements related to the gluten processing or content other than ''gluten free'' are still subject to sections 403(a)(1) and 201(n) of the FD&C Act.

F. Can a distilled food be labeled ''gluten-free''?

The preamble to the final rule (78 FR 47154 at 47174) noted that we had received comments expressing concern that distilled vinegar, as a food product or ingredient, could contain gluten and wanted us to not allow distilled vinegar to be labeled as ''gluten-free.'' We indicated that we would consider the comments received on distilled foods, including distilled vinegar, in this proposed rule.

The process of distillation involves heating a liquid such that components with lower boiling points are vaporized and recovered separate from components with higher boiling points. The remaining compounds, whose boiling points were too high to undergo vaporization, are left behind (Ref. 12). We are aware of two commonly used distilled foods subject to FDA labeling regulations; distilled vinegar and distilled water. Of these, distilled water is inherently gluten-free.

There are several different types of vinegars, and not all of them are distilled, as discussed in the Food and Drug Administration, Compliance Policy Guide Sec. 525.825, ''Vinegar Definitions—Adulteration With Vinegar Eels'' (Ref. 13). Some examples of these include cider vinegar (also known as apple vinegar or simply ''vinegar''), wine vinegar (also known as grape vinegar), malt vinegar, sugar vinegar, and glucose vinegar. All vinegars are made by alcoholic and subsequent acetous fermentation, but can be derived from different substances. Cider vinegar is made from the juice of apples; whereas, wine vinegar is made from the juice of grapes. In addition, some vinegars may be made from gluten-containing grains, such as malt vinegar, which is the product made by the alcoholic and subsequent acetous fermentation, without distillation, of an infusion of barley malt or cereals whose starch has been converted by malt.

Distilled vinegar is commonly made from ethanol derived from corn or sugar cane, but, to a lesser extent, other raw materials can be used to derive the ethanol used to make distilled vinegar. Distilled vinegar (also known as spirit vinegar or grain vinegar) is made by the acetous fermentation of dilute distilled alcohol. The alcohol derived from the initial alcohol fermentation undergoes distillation followed by acetous fermentation. Because distillation is a purification process, separating volatile components like alcohol and flavors from non-volatile materials like proteins and sugars, it is unlikely that gluten (or *any* other protein or protein fragments) is present in distilled vinegar if the distillation process is conducted following good manufacturing practices specific to distillation. Although we are not aware of any analytical methods that can be used to reliably detect and accurately quantify the presence of gluten in distilled vinegar, we are aware of analytical methods that could be used to detect the presence of protein and protein fragments as a means for manufacturers to ensure the absence of protein (and thus gluten). We discuss how the proposed rule addresses these methods in section II.D.

Vinegars that are made from gluten-containing grains but are not further processed by distillation may not bear the gluten-free claim under § 101.91(b). For example, some malt vinegars are the product of fermentation, without distillation, of an infusion of barley malt or cereals whose starch has been converted to malt (Ref. 14). Because these types of malt vinegar are derived from gluten-containing grains that have not been distilled or otherwise processed to remove gluten, they may not be used as ingredients in a food bearing a ''gluten-free'' claim or bear such a claim themselves as provided in § 101.91(a)(3)(i)(A)(*2*). Distilled vinegars that are made from gluten-containing grains are first subjected to an alcohol fermentation process followed by distillation and finally an acetous fermentation process of the distilled, diluted alcohol. Distillation in this case is considered as the ''process to remove gluten'' from the ingredient alcohol, which has been derived from the fermentation of the sugars in the grains, and which is then further fermented to produce vinegar. Distilled vinegars that meet the definition of gluten-free may bear the ''gluten-free'' claim under § 101.91(b). Thus, when a food or ingredient bearing the ''gluten-free'' claim is distilled, we will evaluate compliance by verifying the absence of protein in the food or ingredient using a scientifically valid method that can reliably detect the presence or absence of protein or protein fragments in the food. When choosing a method that will verify the absence of protein, among the factors that need to be considered is the sensitivity of the test method for this purpose, such as a limit of detection as close to zero as possible.

G. How do I evaluate gluten cross-contact?

As we noted in the preamble to the final rule, ''[i]n the context of this rule, [gluten] cross-contact occurs when a food without gluten comes in contact with a gluten-containing food or ingredient, resulting in the presence of gluten in the food not intended to contain gluten'' (78 FR 47154 at 47173). We recognize that the supply chain for raw materials, ingredients, and intermediate products used in the food industry can be complex and involve many suppliers outside the manufacturer's immediate control. Thus, for raw materials, ingredients, and intermediate products, the potential for cross-contact with gluten-containing sources may exist.

For example, official regulatory standards, notably the U.S. Department of Agriculture's Grain Inspection, Packers and Stockyards Administration's (GIPSA's) Federal Grain Inspection Service (FGIS), allow for the adventitious presence of other grains. The FGIS is intended to provide farmers, grain handlers, processors, exporters, and international buyers with information that accurately and consistently describes the quality and quantity of grain being bought and sold (Ref. 15). However, the GIPSA definitions for soybeans, canola, flaxseed, sunflower seeds, corn, and oats, by virtue of their allowance of ''other grains,'' do not prohibit the presence of gluten-containing grains.

The ''other grains'' for which standards exist under the United States Grain Standards Act (Pub. L. 64–90) include barley, rye, triticale, and wheat (see 7 CFR 810.201 (definition of barley), 810.1201 (definition of rye), 810.2001 (definition of triticale), and 810.2201 (definition of wheat)), and these are gluten-containing grains. Therefore, records demonstrating assurance for raw materials such as grains, legumes, and seeds may include certificates of analysis or test results drawn from more frequent sampling or more lots of these source materials.

Conversely, there are certain fermented or hydrolyzed foods, such as those fermented or hydrolyzed from vegetable, meat, and dairy ingredients, that have a low probability of cross contact with gluten-containing grains because the source ingredients for these foods are inherently free of gluten and are less likely to come into contact with gluten-containing grains before being processed. Examples of such foods include cheese, yogurt, some vinegars, sauerkraut, pickles, green olives, meats, and wine. Through the use of manufacturing practices that can prevent gluten cross-contact situations, these fermented or hydrolyzed foods made from source ingredients that are inherently free of gluten may present less potential for the presence of gluten.

Given the variety of fermented or hydrolyzed foods and different manufacturing processes for foods fermented or hydrolyzed by the manufacturer and bearing the ''gluten-free'' claim, we believe that decisions as to how to adequately evaluate any potential for gluten cross-contact during the manufacturing process are best left to manufacturers and their manufacturing operations. Likewise, the manufacturer must determine what measures they should take to prevent the introduction of gluten into the food during the manufacturing process. Manufacturers must keep records adequately evaluating the potential for gluten cross-contact and documenting the measures used to prevent the introduction of gluten into the food during the manufacturing process.

We invite comment on the potential for source ingredients used in fermentation (*i.e.,* milk in yogurt) to come in contact with gluten-containing grains, and on manufacturing practices that can prevent risk of gluten cross contact.

H. Can a fermented or hydrolyzed food be concentrated or dried?

As we explained in the preamble to the final rule (78 FR 47154 at 47159), 20 ppm gluten is a concentration level rather than an absolute quantity of gluten in a food. If a food's ingredients are all below 20 ppm gluten, the food containing those ingredients will have a gluten concentration less than 20 ppm.

When water or other liquid is removed from a food, for example a soup or sauce, or the product is dried, the relative concentration of the material dissolved or suspended in the product increases as the water or dissolving material is removed. In the case of gluten in a product, we are aware that the relative concentration of gluten could increase if water or other liquid is removed. Given the limitations of gluten testing and the variety of processes involved in concentration or drying of fermented or hydrolyzed ingredients, there could be uncertainty in the determination of the amount of gluten contained in these materials. For this reason, and because methods that can reliably detect the presence of 20 ppm intact gluten in fermented or hydrolyzed foods are not currently available, we are considering several regulatory options regarding records for fermented or hydrolyzed foods or ingredients that are concentrated or dried.

One option would be to require the manufacturer of a food bearing the ''gluten-free'' claim to document that the food or ingredient is not concentrated or dried after fermentation or hydrolysis. This would preclude fermented or hydrolyzed foods or ingredients that are concentrated or dried from being in foods bearing the ''gluten-free'' claim and reduce the number of such foods labeled as ''gluten-free'' in the marketplace.

Another option would require the manufacturer of a food bearing the ''gluten-free'' claim to make and keep records documenting that the concentrated or dried fermented or hydrolyzed ingredients used in a food bearing the ''gluten-free'' claim comply with § 101.91(a)(3). This, in turn, could cause manufacturers to request records from the ingredient supplier indicating

the gluten content of the materials used in the ingredient prior to fermentation or hydrolysis, and specific information as to how the final gluten concentration of the ingredient is determined after concentration or drying.

We invite comment on these two possible options, how the options could be modified, whether another option exists, or whether it is necessary to address concentrated or dried ingredients in this regulation. We also invite comment on the potential for fermented or hydrolyzed foods made from ingredients that are concentrated or dried to contain less than 20 ppm gluten in their concentrated or dried form, how this gluten content could be verified and the potential costs associated with a new option.

II. What does the proposed rule say?

Currently, § 101.91(c) states that when compliance with § 101.91(b) (which pertains to requirements for ''gluten-free'' labeling) is based on an analysis of the food, we will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices.

The proposed rule would amend § 101.91(c) to provide alternative means for us to verify compliance for fermented or hydrolyzed foods for which appropriate scientifically valid methods that can reliably detect and quantify the presence of 20 ppm intact gluten are not currently available. If the food or the ingredients used in a food fermented or hydrolyzed by the manufacturer contained less than 20 ppm of intact gluten before fermentation or hydrolysis, then the resulting fermented or hydrolyzed food also would contain less than 20 ppm intact gluten as long as gluten was not introduced during the fermentation or hydrolysis process. For these reasons, the proposed rule would require that the manufacturer of fermented or hydrolyzed foods bearing the ''gluten-free'' claim make and keep records regarding the food demonstrating adequate assurances that the food is ''gluten-free'' in compliance with § 101.91(a)(3) before fermentation or hydrolysis and that gluten has not been introduced during the manufacturing process. Likewise, for foods containing one or more fermented or hydrolyzed ingredients and bearing the ''gluten-free'' claim, the manufacturer would be required to make and keep records demonstrating with adequate assurance that the fermented or hydrolyzed ingredients are ''gluten-free'' in compliance with § 101.91(a)(3).

We would expect that, in some cases, this adequate assurance would include test results or a certificate of analysis for the food or ingredients before fermentation or hydrolysis. Other verification procedures may be appropriate in some circumstances. We expect that the accuracy and reliability of any certificate of analysis would be verified based on initial qualification and periodic requalification of the supplier through testing of the ingredient with sufficient frequency to ensure the material contains less than 20 ppm gluten. Likewise we expect that the ingredients used would be tested with sufficient frequency to ensure the material contains less than 20 ppm gluten.

The content of the records demonstrating adequate assurance that source materials are in compliance with § 101.91(a)(3) before fermentation or hydrolysis may depend on the potential for gluten cross-contact. For example, as discussed in section I.G., a manufacturer of a grain product, such as corn breakfast cereal, may keep different records than a manufacturer of a fruit-flavored yogurt product.

Specifically, the proposed rule would renumber § 101.91(c) as § 101.91(c)(1) and would create new paragraphs (c)(2), (c)(3), and (c)(4) to explain that, when an appropriate method to verify compliance with the gluten-free regulation is not available because the food is fermented or hydrolyzed or contains one or more ingredients that are fermented or hydrolyzed, the manufacturer of the food bearing the ''gluten-free'' claim must make and keep certain records. Proposed § 101.91(c)(5) would describe how FDA would evaluate compliance for distilled foods.

A. For foods fermented or hydrolyzed by the manufacturer, what records must be kept? What must the records demonstrate? (Proposed § 101.91(c)(2))

Due to the unavoidable presence of gluten that may occur through gluten cross-contact in food ingredients or during manufacturing, the proposed rule would require that the manufacturer of foods fermented or hydrolyzed by the manufacturer and bearing the ''gluten-free'' claim make and keep records. The records are to provide adequate assurance that the food or its ingredients are ''gluten-free'' in compliance with § 101.91(a)(3) before fermentation or hydrolysis and that gluten is not introduced during the manufacturing process. If the food or its ingredients comply with § 101.91(a)(3) before fermentation or hydrolysis, and gluten is not introduced during the manufacturing process, the resulting fermented or hydrolyzed food should meet the definition of ''gluten-free.''

1. What records must be kept regarding food before fermentation or hydrolysis? (Proposed § 101.91(c)(2)(i))

The records described in proposed § 101.91(c)(2)(i) must provide adequate assurance that the food or its ingredients comply with § 101.91(a)(3) before fermentation or hydrolysis. Thus, the records must provide adequate assurance that the ingredients are not gluten-containing grains (*e.g.,* spelt wheat), and are not derived from a gluten-containing grain that has not been processed to remove gluten (*e.g.,* wheat flour) or not derived from a gluten-containing grain that has been processed to remove gluten (*e.g.,* wheat starch), if the use of that ingredient results in the presence of 20 ppm or more gluten in the food. Further, the records must provide adequate assurance that any unavoidable presence of gluten in the food is below 20 ppm gluten.

The assurances could include records of test results conducted by the manufacturer or an ingredient supplier, CoAs, or other appropriate verification documentation for the food itself or each of the ingredients used in the food. We would expect manufacturers of fermented or hydrolyzed foods that bear the ''gluten-free'' claim, as part of their routine operations, to test their food or ingredients with sufficient frequency to ensure that the gluten level in the food or in each ingredient is below 20 ppm before fermentation or hydrolysis. This testing could include a single record from testing the food before fermentation or hydrolysis (*i.e.* testing milk before fermentation into yogurt), or could include separate test result records regarding each ingredient, depending on the type of food being produced.

Alternatively, as we noted in the preamble to the final rule (78 FR 47154 at 47167), manufacturers, as part of routine operations, may rely on records, such as CoAs, from their suppliers to determine that each ingredient is below 20 ppm gluten. A CoA is a document indicating specified test results performed on product(s) by a qualified laboratory that has certified these test results. A CoA should be based on initial qualification and periodic requalification of the supplier with sufficient frequency through review of the supplier's documentation and practices.

Similarly, other appropriate verification documentation could provide adequate assurance that a manufacturer has adequately ensured the food or ingredients comply with § 101.91(a)(3). We tentatively conclude

that it is appropriate to allow a manufacturer to use any means of verification that it can develop, as long as the manufacturer can document that such verification provides adequate assurance that the ingredients comply with § 101.91(a)(3). We anticipate that most manufacturers will receive at least some ingredients from outside suppliers. For ingredients that they receive from outside suppliers, manufacturers may document a visit to a supplier's facility, review a supplier's records, and review written documentation from a supplier to verify the compliance of the ingredients they receive. We invite comment on other ingredient verification methods that may be appropriate.

The proposed rule would not specify the types of records to be kept, so the manufacturer could, for example, create the records itself regarding the ingredients that it uses or, if it obtains ingredients from a supplier, maintain records or CoAs it obtains from a supplier. The types of records may also vary based on the type of food or ingredients used. For example, a manufacturer of fermented or hydrolyzed foods from non-gluten-containing grains, legumes, or seeds that are susceptible to cross-contact with gluten-containing grains bearing the ''gluten-free'' claim may be more likely to choose to obtain a CoA from the ingredient suppliers or test the ingredients before fermentation and maintain records of the test results. A manufacturer of products bearing the ''gluten-free'' claim made from inherently gluten-free ingredients, such as milk, or fruit, that have a low probability of cross-contact with gluten-containing grains, may be more likely to use other appropriate verification documentation.

2. What records must be kept to address gluten cross-contact? (Proposed § 101.91(c)(2)(ii) and (iii))

As we discussed in the preamble to the final rule (78 FR 47154 at 47173), we expect foods bearing the ''gluten-free'' claim to be manufactured using whatever controls are necessary to prevent cross-contact with all gluten sources and to ensure that any amount of gluten that may be present in the food from gluten cross-contact is as low as possible and that the food has less than 20 ppm gluten.

To help address potential gluten cross-contact during the manufacturing process, proposed § 101.91(c)(2)(ii) and (iii) would require that a manufacturer wishing to use a ''gluten-free'' claim on a product that they ferment or hydrolyze make and keep records that provide adequate assurance that:

- The manufacturer has adequately evaluated their processing for any potential for gluten cross-contact during the manufacturing process; and
- where the potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

We expect manufacturers of foods bearing the ''gluten-free'' claim to take proper precautions to reduce the potential for gluten cross-contact of food, food ingredients, or food-contact surfaces. This may include careful examination of all phases of their operations, including, for example, transportation and storage of ingredients and finished products and the use of additional manufacturing controls that can prevent gluten cross-contact situations. For example, manufacturers may use physical barriers (such as walls, curtains, or distance) or air handling as a means of isolating the production line and by cleaning and sanitizing equipment between production runs.

In order to provide adequate assurance that they have evaluated their processing for the potential for gluten cross-contact, we expect manufacturers to document their determination regarding the potential for gluten cross-contact as well as the reasoning and/or support for their determination. In order to provide adequate assurance that they have implemented measures to prevent the introduction of gluten during the manufacturing process, we expect manufacturers to document the measures they are using as well as how they determined what measures to use and how those measures prevent gluten cross-contact. Again, the types of records that would provide adequate assurance for ingredients with a high likelihood of gluten cross-contact, such as grains and legumes, may vary from those expected for ingredients with a lower likelihood of gluten cross-contact, such as dairy.

B. For foods that contain one or more fermented or hydrolyzed ingredients, what records must be kept? What must the records demonstrate? (Proposed § 101.91(c)(3))

When a scientifically valid method is not available that equates the test results in terms of intact gluten because the food contains one or more ingredients that are fermented or hydrolyzed, proposed § 101.91(c)(3) would require the manufacturer of such foods bearing the claim to make and keep records providing adequate assurance that that the fermented or hydrolyzed ingredients are ''gluten-free.'' When the entire food is not hydrolyzed or fermented, the analytical methods discussed in the current ''gluten-free'' regulation at § 101.91(c) would be able to detect intact gluten that had been introduced through the manufacturing process or through ingredients that were not hydrolyzed or fermented. Therefore, we are only proposing to require records regarding the specific ingredients that have been fermented or hydrolyzed.

For an ingredient that was fermented or hydrolyzed by a supplier, one way for the manufacturer of a food bearing the ''gluten-free'' claim to provide adequate assurance that the ingredient is ''gluten-free'' would be to obtain records from that supplier supporting that the ingredient meets the definition of ''gluten-free,'' including that the ingredient was manufactured or processed to avoid gluten cross-contact and to contain less than 20 ppm gluten. Adequate assurance regarding the ingredients fermented or hydrolyzed by an ingredient supplier can include documentation regarding the supplier's manufacturing procedures, records of test results from tests conducted by the ingredient supplier on the components of the ingredient before fermentation or hydrolysis, CoAs, or other appropriate documentation provided by the ingredient supplier for the fermented or hydrolyzed ingredient. As discussed previously in section II.A.1, the types of records that would provide adequate assurance for ingredients with a high likelihood of gluten cross-contact, such as grains and legumes, may vary from those expected for ingredients with a lower likelihood of gluten cross-contact, such as dairy.

Manufacturers may wish to verify the accuracy and reliability of these records by checking whether and how the supplier of the ingredient documents that the components used in the fermented or hydrolyzed ingredient each meet the definition of ''gluten-free,'' including that the supplier manufactured or processed the ingredient to avoid gluten cross-contact and contain less than 20 ppm gluten before fermentation or hydrolysis. In addition, manufacturers may wish to verify records documenting the supplier's manufacturing or processing with regard to concentration.

C. How must records be maintained and made available? (Proposed § 101.91(c)(4))

Proposed § 101.91(c)(4) would establish the timeframe for keeping

records and making them available to FDA. In brief, the proposed rule would:

- Require the records be retained for 2 years after introduction or delivery for introduction of the food into interstate commerce;
- allow records to be kept as original records, true copies, or as electronic records; and
- state that the records must be available to FDA for examination and copying during an inspection upon our request.

Proposed § 101.91(c)(4) would establish a minimum 2-year recordkeeping period because we consider 2 years to be a reasonable period of time for most foods to be available for purchase in the marketplace. Such a time period is consistent with other FDA regulations, but we invite comment on whether we should use a different recordkeeping period. In addition, the records may be kept in any format, paper or electronic, provided they contain all the necessary information. Paper records can include true copies such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records. All electronic records maintained under § 101.91 would need to comply with part 11 (21 CFR part 11). The use of electronic records is voluntary and thus, a paper record system could be used to comply with the proposed recordkeeping requirements. The proposed requirements for electronic records extend to electronic signatures. We issued final guidance for industry on this topic. The guidance, entitled ''Part 11, Electronic Records; Electronic Signatures Scope and Application,'' sets out our enforcement policies with respect to certain aspects of part 11. The guidance is available at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm.* This guidance would apply to any electronic record, including electronic signatures, established or maintained to meet a proposed requirement in this rule, if finalized as proposed. This would give manufacturers the maximum flexibility to use whatever recordkeeping system they find most appropriate. We request comment on the proposed requirements for the types of records that must be made and kept and the length of time that the records must be kept.

The proposal also would state that the records must be made available to us for examination or copying during an inspection upon request; this is consistent with our other recordkeeping regulations (see, *e.g.,* 21 CFR 111.605 and 111.610). The records would need to be reasonably accessible to FDA during an inspection at each manufacturing facility (even if not stored onsite) to determine whether the food has been manufactured and labeled in compliance with § 101.91. Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible. We anticipate that manufacturers may have questions about the confidentiality of the information inspected by us under this proposal. We would protect confidential information from disclosure, consistent with applicable statutes and regulations, including 5 U.S.C. 552(b)(4), 18 U.S.C. 1905, and 21 CFR part 20.

D. What are the requirements for distilled products? (Proposed § 101.91(c)(5))

If good manufacturing practices are followed, the process of distillation itself removes all protein. Scientifically valid methods to measure the protein content should find no detectable protein present and thus no gluten in distilled ingredients or distilled foods. The detection of any protein indicates poor manufacturing practices or controls and could point to the potential presence of gluten in the distilled ingredient or product. Likewise, the absence of protein or protein fragments in the distilled product should mean that the product's gluten level is below 20 ppm.

Consequently, proposed § 101.91(c)(5) would provide that, when a food or ingredient bearing the ''gluten-free'' claim is distilled, we will evaluate compliance by verifying the absence of protein in the food or ingredient using a scientifically valid method that can reliably detect the presence or absence of protein or protein fragments in the food. When choosing a method that will verify the absence of protein, among the factors that need to be considered is the sensitivity of the test method for this purpose, such as a limit of detection as close to zero as possible.

The detection of any protein or protein fragments in the food or ingredient may indicate poor manufacturing controls and indicate the presence of gluten in the distilled ingredient or product. We invite comment, especially including data, concerning the effectiveness of good manufacturing practices on distillation. We also invite comment, especially including data, concerning the effectiveness of other processes that can be used to remove gluten from food ingredients or food products. We also invite comment on measures food manufacturers of distilled products or products containing distilled ingredients can take to ensure that the distilled product or distilled ingredients do not contain protein or protein fragments.

E. What are the conforming changes? (Proposed § 101.91(b)(1) and (2))

The proposed rule would make two conforming changes to § 101.91(b)(1) and (2). In brief, § 101.91(b)(1) states that a food that bears the claim ''gluten-free'' in its labeling and fails to meet § 101.91(a)(3) (the definition for the term ''gluten-free'') will be deemed misbranded. Section 101.91(b)(2) creates a similar requirement if the food bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' and fails to meet § 101.91(a)(3). Because proposed § 101.91(c)(2) through (4) would establish requirements by which we would determine whether fermented foods, hydrolyzed foods, or foods containing a fermented or hydrolyzed ingredient are ''gluten-free'' within § 101.91, the proposed rule would amend § 101.91(b)(1) and (2) to add, ''if applicable, paragraphs (c)(2) through (4) of this section'' to the requirements that must be met if the food is not to be deemed misbranded.

F. Effective and Compliance Dates

We are proposing that the compliance date for any final rule resulting from this rulemaking be 1 year from the date of its publication. We recognize that we usually establish a uniform compliance date for food labeling changes that occur between specific dates. For example, January 1, 2016, is the next uniform compliance date for food labeling changes for food labeling regulations issued between January 1, 2013, and December 31, 2014 (77 FR 70885, November 28, 2012). In this case, however, we believe there is sufficient justification for establishing the compliance date of 1 year after the date of publication of a final rule, rather than use the next uniform compliance date for other food labeling changes that we periodically establish for such changes.

We believe that 12 months from the date of publication of the final rule for gluten-free labeling of fermented or hydrolyzed foods is sufficient time for manufacturers of fermented or hydrolyzed foods to review their products to ensure that these foods comply with that final rule or to remove ''gluten-free'' or similar claims from the label if their foods do not comply. This period of 12 months is consistent with what we have used in the past for compliance with the requirements of voluntary food labeling claims. We believe that waiting until FDA's next uniform compliance date would create

an unnecessary delay in the enforcement of a final rule because fermented or hydrolyzed foods bearing the voluntary label claim ''gluten-free'' that do not comply with FDA's requirements for use of the term ''gluten-free'' could have an adverse public health impact on persons with celiac disease who may be consuming those foods.

Therefore, we propose to establish the compliance date to enforce the provisions of a final rule for the gluten-free labeling of fermented or hydrolyzed foods as 1 year after the date of publication of the final rule in the **Federal Register**. By that time, manufacturers of fermented or hydrolyzed foods labeled with the ''gluten-free'' claim would have to comply with the final rule. We also propose an effective date of 30 days after publication in the **Federal Register**.

III. What is our legal authority for this proposed rule?

Section 206 of FALCPA directs the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, to issue a proposed rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods. Section 403(a)(1) of the FD&C Act states that, ''A food shall be deemed to be misbranded if its labeling is false or misleading in any particular.'' In determining whether food labeling is misleading, section 201(n) of the FD&C Act explicitly provides for consideration of the extent to which the labeling fails to reveal facts ''material with respect to the consequences which may result from the use of the [food] to which the labeling * * * relates under * * * such conditions of use as are customary or usual.'' Section 701(a) of the FD&C Act vests the Secretary (and by delegation, FDA) with authority to issue regulations for the efficient enforcement of the FD&C Act. Consistent with section 206 of FALCPA and sections 403(a)(1), 201(n), and 701(a) of the FD&C Act, we are proposing requirements for the use of the term ''gluten-free'' for hydrolyzed and fermented foods.

The proposed rule would establish requirements concerning records necessary to ensure compliance with our ''gluten-free'' labeling regulation for fermented or hydrolyzed food or that which contains a fermented or hydrolyzed ingredient. For these foods, there is no scientifically valid analytical method available that can reliably detect and accurately quantify the equivalent of 20 ppm intact gluten in the food. In enacting FALCPA, Congress recognized the importance to individuals with celiac disease of avoiding gluten (section 202(6)(B) of FALCPA). Therefore, defining the requirements for using the term ''gluten-free'' in the labeling of fermented or hydrolyzed foods is needed to ensure that individuals with celiac disease are not misled and are provided with truthful and accurate information with respect to foods so labeled.

We are proposing requirements for manufacturers to make and keep records containing information that provides adequate assurance that their food complies with the definition of ''gluten-free,'' including information that they gather or produce about their ingredients and the details of their manufacturing practices. These proposed record requirements would help ensure that the use of the term ''gluten-free'' is accurate, truthful, and not misleading based on information known to the manufacturer that FDA would not otherwise be able to access and to facilitate efficient and effective action to enforce the requirements when necessary. Our authority to establish records requirements has been upheld under other provisions of the FD&C Act where we have found such records to be necessary (*National Confectioners Assoc.* v. *Califano,* 569 F.2d 690, 693–94 (D.C. Cir. 1978)). The records we propose to require are only for foods for which an adequate analytical method is not available. The records would allow us to verify that the ''gluten-free'' claim on foods that are hydrolyzed or fermented or contain hydrolyzed or fermented ingredients is truthful and complies with the requirements of the definition. Thus, the proposed records requirements would help in the efficient enforcement of the FD&C Act.

The authority granted to us under sections 701(a), 403(a)(1), and 201(n) of the FD&C Act not only includes authority to establish records requirements, but also includes access to such records. Without such authority, we would not know whether the use of the term ''gluten-free'' on the label or in the labeling of these foods is truthful and not misleading under sections 403(a)(1) and 201(n) of the FD&C Act. The introduction or delivery for introduction into interstate commerce of a misbranded food is a prohibited act under section 301(a) of the FD&C Act (21 U.S.C. 331(a)). Thus, to determine whether the food is misbranded and the manufacturer has committed a prohibited act, we must have access to the manufacturer's records that we are requiring be made and kept under sections 403(a)(1), 201(n), and 701(a) of the FD&C Act. Failure to make and keep records and provide the records to FDA, as described in proposed § 101.91(c)(4), would result in the food being misbranded under sections 403(a)(1) and 201(n) of the FD&C Act.

IV. What is the analysis of impacts—Preliminary Regulatory Impact Analysis

A. Overview

FDA has examined the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all 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, and other advantages; distributive impacts; and equity). FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule (Ref. 16). FDA believes that the proposed rule will not be an economically significant regulatory action as defined by Executive Order 12866. FDA requests comments on the PRIA.

The summary analysis of benefits and costs included in this document is drawn from the detailed PRIA (Ref. 16), which is available to the public in the docket for this proposed rule at *http://www.regulations.gov* (enter Docket No. FDA–2014–N–1021), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

B. Regulatory Flexibility Act

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because many small businesses may need to implement a number of new testing and recordkeeping activities, FDA acknowledges that the proposed rule, if finalized, will have a significant economic impact on a substantial number of small entities.

C. Small Business Regulatory Enforcement Fairness Act of 1996

The Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual

effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, if finalized, is not a major rule for the purpose of congressional review.

D. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $144 million, using the most current (2014) Implicit Price Deflator for the Gross Domestic Product. FDA expects that the proposed rule, if finalized, will not result in a 1-year expenditure that would exceed this amount.

E. Public Access to the Analyses

The analyses that FDA has performed in order to examine the impacts of this proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) are available to the public in the docket for this proposed rule (Ref. 16) at *http://www.regulations.gov* (enter Docket No. FDA–2014–N–1021).

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in this section of the document with an estimate of the annual recordkeeping burden. Included in the burden estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We invite comments on the following topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Recordkeeping Requirements for Gluten-Free Labeling of Fermented or Hydrolyzed Foods.

Description of Respondents: Manufacturers of foods that are fermented, hydrolyzed, or contain fermented or hydrolyzed ingredients and bear the claim ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten.''

Description: If the rule is finalized as proposed, we would require manufacturers of food products covered by the rule to make and keep records providing adequate assurance that: (1) The food is gluten-free before fermentation or hydrolysis; (2) the manufacturer has evaluated the potential for cross-contact with gluten during the manufacturing process; and (3) if necessary, measures are in place to prevent the introduction of gluten into the food during the manufacturing process.

Manufacturers using an ingredient that is a hydrolyzed or fermented food only would be required to make and keep these records for the hydrolyzed or fermented ingredient. We estimate that the manufacturers would satisfy the recordkeeping requirements of this proposed rule, if finalized, by maintaining records of their tests or other appropriate verification procedures, their evaluation of the potential for gluten cross contact, and their standard operating procedures (SOPs) for preventing gluten cross-contact. It is also possible that manufacturers would instead comply with this proposed rule by obtaining and maintaining records of Certificates of Analysis, test results, or other appropriate verification procedures from their suppliers.

Written SOPs and records of testing and other activities are essential for FDA to be able to determine compliance with § 101.91 (the gluten-free regulation) for these products. Records would need to be reasonably accessible at each manufacturing facility and could be examined periodically by FDA inspectors during an inspection to determine whether the food has been manufactured and labeled in compliance with § 101.91 Records that can be immediately retrieved from another location by electronic means are considered reasonably accessible.

We estimate the burden of this collection of information as follows: We base our estimates of the average burden per recordkeeping on our experience with good manufacturing practices used to control the identity and composition of food and to limit contaminants and prevent adulteration. The hour estimates for the recordkeeping burdens presented here are averages. We anticipate that the records kept would vary based on the type of ingredients used. Some manufacturers, such as those producing fermented dairy products, would likely maintain fewer records overall. Other manufacturers, such as those producing foods with fermented or hydrolyzed grains, legumes, or seeds, would likely maintain more extensive records.

Our estimates of the numbers of manufacturers/recordkeepers reported in column 2 of tables 1 and 2 are based on the number of food products that would be covered by the proposed rule. We searched the FoodEssentials database (Ref. 3) for foods that are hydrolyzed, fermented, or contain fermented or hydrolyzed ingredients and bear the claim ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten,'' and found about 2,500 products that would be affected by the proposed rule. We estimate that this database has at least half of all products that would be covered by the proposed rule, so that there would be, at most, 5,000 products affected by the proposed rule.

We do not have any data about how many products are produced in each facility, so we assume that each product and its production line would be tested separately and would require a separate evaluation and SOP. Thus, we estimate the number of food production facilities and, accordingly, the number of manufacturers/recordkeepers to be 5,000. If multiple products are produced in the same facility and can share testing, evaluation, and SOPs, then the recordkeeping burden would be less than these estimates.

We do not know how many of these products are already being manufactured using gluten-free ingredients and/or with a process designed to prevent gluten introduction. A survey of food industry practices (Ref. 17) shows that about 45 percent of all food production facilities have a written allergen control plan, and about 39 percent require certificates of analysis for ingredients. Given that producers of

foods labeled ''gluten-free'' are marketing to customers who care more about gluten cross-contact, we estimate that about 75 percent of the 5,000 foods with a ''gluten-free'' labeling claim already have a written plan for preventing the introduction of gluten into the food product that includes the testing of ingredients and also procedures for evaluating and preventing gluten cross-contact. Therefore, we estimate that 1,250 facilities would incur new SOP development and ingredient testing burdens and all 5,000 facilities would incur certain new recordkeeping burdens.

Recordkeeping Burden Related to Standard Operating Procedures

We estimate that 1,250 facilities do not have a written SOP for preventing the introduction of gluten into the food product. For these facilities, developing an SOP would be a first year burden of the proposed rule. We estimate that it would take a facility an average of 7 hours to develop an SOP for gluten control. Thus, we estimate that in the first year of compliance with the proposed rule if finalized, 1,250 facilities would develop an SOP for a burden of 8,750 hours (1,250 × 7 = 8,750), as reported in table 1, row 1.

Updating the facility's SOP for gluten control would be a recurring burden of the proposed rule for the 1,250 facilities that do not currently have an SOP. We estimate that it would take a facility about 0.7 hours (42 minutes) annually to update its SOP for gluten control, for a burden of 875 hours (1,250 × 0.7 = 875), as reported in table 2, row 1.

We estimate that maintaining records of their updated SOPs would be a recurring burden of the proposed rule for all 5,000 facilities. We estimate that it would take each facility 1 hour annually to maintain records of its updated SOPs for gluten control, for a burden of 5,000 hours (5,000 × 1 = 5,000), as reported in table 2, row 2.

Recordkeeping Burden Related to Testing

In order to demonstrate that the food is gluten-free before fermentation or hydrolysis, we expect that most manufacturers would test their incoming ingredients or obtain Certificates of Analysis from their ingredient suppliers. A manufacturer may test their ingredients for gluten by sending ingredient samples to a testing company or by using test kits to test ingredient samples on site at their facility. Test kits would first undergo method validation for the testing situation in which they are to be used (Ref. 18). We assume that a manufacturer that begins a program of testing the gluten content of an ingredient will start by sending several samples to a lab and obtaining method extension for a test kit for the ingredient. Obtaining a validation for a test kit is a first-year burden only.

After the first year of testing, we assume the manufacturers would then use test kits to test the ingredient on a regular basis, and may also send one or two samples a year to an outside lab for testing. These are recurring testing burdens. We estimate that an average of two ingredients per product would be tested in this manner. Most foods affected by this proposed rule are those that contain a single hydrolyzed or fermented ingredient, so any testing would have been done by the ingredient supplier before that supplier performed hydrolysis or fermentation. Other products contain several ingredients that would be tested before fermentation or hydrolysis.

In the first year of compliance, we estimate that the 1,250 manufacturers not currently testing their ingredients and production facilities for gluten and would incur additional testing burdens as a result of the proposed rule. For these manufacturers, obtaining a method extension for a test kit would be a first year burden of the proposed rule. We estimate that 1,250 manufacturers would conduct seven tests for method extension, for each of two ingredients, for a total of 14 samples. We estimate that it would take a manufacturer 5 minutes to collect each sample, for a total of 1,453 hours (1,250 × 14 × (5 ÷ 60) = 1,453) as reported in table 1, row 2. We estimate that this proposed rule would result in manufacturers conducting 17,500 laboratory tests in the first year (1,250 × 14 = 17,500). These tests have an average cost of $84.33, which means that the estimated capital costs related to this first year paperwork burden is about $1.5 million (17,500 × $84.33 = $1,475,833) as reported in table 1, row 2.

We estimate that, as a first year burden of the proposed rule if finalized, all 5,000 manufacturers would begin retaining records of the method extension tests. We estimate that it would take a manufacturer 30 minutes per record, for a total of 35,000 hours (5,000 × 14 × 0.5 = 35,000), as reported in table 1, row 3.

We estimate that testing ingredients on a regular basis would be a recurring burden of the proposed rule, if finalized, for the 1,250 manufacturers not currently testing their ingredients and production facilities for gluten. We estimate that 1,250 manufacturers will use 21 test kits annually on average per ingredient, for a total of 42 kits, and that each test will require 5 minutes to collect a sample and 30 minutes to process and file the test results. We estimate that the burden of collecting samples for these tests would be 4,358 hours (1,250 × 21 × (5 ÷ 60) = 4,358), as reported in table 2, row 3. We estimate that this proposed rule, if finalized, would result in manufacturers using 52,500 test kits each year (1,250 × 42 = 52,500). These test kits have an average cost of $11, which means that the estimated capital costs related to this recurring paperwork burden is about $0.6 million (52,500 × $11 = $577,500), as reported in table 2, row 3. We estimate the burden to process and maintain records of the test results would be 105,000 hours (5,000 × 42 × 0.5 = 105,000), as reported in table 2, row 4.

We estimate that a recurring burden of the proposed rule, if finalized, for all 5,000 manufacturers would be to send one or two samples a year to an outside lab for testing. We estimate that 5,000 manufacturers will conduct one outside test annually on average per ingredient, for a total of 2 tests, and that each test will require 5 minutes to collect a sample and 30 minutes to process and file the test results. We estimate that the burden of collecting samples for these tests would be 208 hours (1,250 × 2 × (5 ÷ 60) = 208), as reported in table 2, row 5. We estimate that this proposed rule would result in manufacturers conducting 2,500 laboratory tests in the first year (1,250 × 2 = 2,500). These tests have an average cost of $84.33, which means that the estimated capital costs related to this recurring paperwork burden is about $0.2 million (2,500 × $84.33 = $210,833), as reported in table 3, row 5. We estimate the burden to process and maintain records of the test results would be 5,000 hours (5,000 × 2 × 0.5 = 5,000), as reported in table 2, row 6.

TABLE 1—ESTIMATED FIRST YEAR RECORDKEEPING BURDEN

Activity/Proposed 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Capital costs (USD Millions)
Developing an SOP for gluten control; proposed 101.91(c)(2) and (3).	1,250	1	1,250	7	8,750	0
Collecting samples for testing; proposed 101.91(c)(2) and (3).	1,250	14	17,500	0.083 (5 minutes)	1,453	$1.5
Maintaining records of method extension tests; proposed 101.91(c)(2) and (3).	5,000	14	70,000	0.5 (30 minutes)	35,000	0
Total					45,203	$1.5

There are no operating or maintenance cost associated with this collection information.

TABLE 2—ESTIMATED RECURRING RECORDKEEPING BURDEN

Activity/Proposed 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Capital costs (USD Millions)
Updating SOP for gluten control; proposed 101.91(c)(2) and (3).	1,250	1	1,250	0.7 (42 minutes)	875	0
Maintaining records of the updated SOP for gluten control; proposed 101.91(c)(2) and (3).	5,000	1	5,000	1	5,000	0
Collecting samples for test kit testing; proposed 101.91(c)(2) and (3).	1,250	42	52,500	0.083 (5 minutes)	4,358	$0.6
Maintaining records of test kit test results; proposed 101.91(c)(2) and (3).	5,000	42	210,000	0.5 (30 minutes)	105,000	0
Collecting samples for testing by an outside lab; proposed 101.91(c)(2) and (3).	1,250	2	2,500	0.083 (5 minutes)	208	$0.2
Maintaining records of testing by an outside lab; proposed 101.91(c)(2) and (3).	5,000	2	10,000	0.5 (30 minutes)	5,000	0
Total					120,441	$0.8

[1] There are no operating or maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by January 19, 2016, to the Office of Information and Regulatory Affairs, OMB.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Recordkeeping Requirements for Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods.'' These requirements will not be effective until we obtain OMB approval. We will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VI. What is the environmental impact of this rule?

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. What are the federalism impacts of this rule?

We have analyzed the proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of Executive Order 13132 requires Agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Here, as in the final rule published in the August 5, 2013, issue of the **Federal Register** (78 FR 47154 at 47175), we have determined that certain narrow exercises of State authority would conflict with the exercise of Federal authority under the FD&C Act.

In section 206 of FALCPA, Congress directed us to issue a proposed rule to define and permit use of the term ''gluten-free'' on the labeling of foods, in consultation with appropriate experts and stakeholders, to be followed by a proposed rule for the use of such term in labeling. In the preamble to the proposed rule regarding the ''gluten-free'' labeling of foods (72 FR 2795 at 2813 through 2814), we indicated that we had consulted with numerous experts and stakeholders in the proposed rule's development and in the final rule we determined that certain narrow exercises of State authority would conflict with the exercise of Federal authority under the FD&C Act. Different and inconsistent amounts of gluten in foods with ''gluten-free'' labeling result in the inability of those

individuals with celiac disease who adhere to a gluten-free diet to avoid exposure to gluten at levels that may result in adverse health effects. ''Gluten-free'' labeling, for purposes of this discussion, also includes the use of the terms ''no gluten,'' ''free of gluten,'' and without gluten,'' as indicated in § 101.91(b)(2). There is a need for national uniformity in the meaning of the term ''gluten-free,'' which includes the manner in which the definition is enforced, so that most individuals with celiac disease can make informed purchasing decisions that will enable them to adhere to a diet they can tolerate without causing adverse health effects and can select from a variety of available gluten-free foods.

This proposed rule would establish additional requirements for manufacturers of hydrolyzed and fermented foods or foods that contain hydrolyzed and fermented ingredients wishing to use the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' on their products, thus these requirements are a component of how we permit the use of the ''gluten-free'' claim. If States were able to establish different requirements regarding what manufacturers of hydrolyzed and fermented foods would need to demonstrate in order to use the term ''gluten-free,'' then individuals with celiac disease would not be able to rely on a consistent meaning for that term and thereby use the term to identify appropriate dietary selections. As a result, individuals with celiac disease may unnecessarily limit their food choices, or conversely, select foods with levels of gluten that are not tolerated and that may cause adverse health effects. Food manufacturers, if confronted by a State or various State requirements that adopted different requirements for hydrolyzed and fermented foods than this proposed rule, might decide to remove the ''gluten-free'' label, and such a result would make it more difficult for individuals with celiac disease to identify foods that they can tolerate and achieve a dietary intake from a variety of foods to meet an individual's nutrient needs. Moreover, consistent requirements regarding the way compliance with the final rule is determined, including the records that would need to be maintained in order for a hydrolyzed or fermented food manufacturer to use the ''gluten-free'' claim and the use of a scientifically valid method to detect the absence of protein to determine compliance for distilled products, enables us to more efficiently enforce the use of the ''gluten-free'' claim across all hydrolyzed and fermented foods to ensure labels bearing a ''gluten-free'' claim are truthful and not misleading.

Therefore, the objective of this proposed rule is standardizing use of the term ''gluten-free'' in the labeling of hydrolyzed and fermented foods so that foods with this claim in labeling, and foods with a claim of ''no,'' ''free of,'' and ''without'' gluten, which connote a similar meaning to that of ''gluten free,'' are used in a consistent way and will therefore prevent consumer confusion and assist individuals with celiac disease to make purchasing decisions.

Section 4(c) of Executive Order 13132 instructs us to restrict any Federal preemption of State law to the ''minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated.'' The proposed rule meets the preceding requirement because it would preempt State law narrowly, only to the extent required to achieve uniform national labeling with respect to the requirements related to the use of the term ''gluten-free,'' as well as the terms ''no gluten,'' ''free of gluten,'' or ''without gluten'' on hydrolyzed and fermented foods. As we explain later in this section, we are proposing to preempt State or local requirements only to the extent that they are different from the requirements in this section related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' for hydrolyzed and fermented foods. In addition, we cannot foresee every potential State requirement and preemption that may arise if a State requirement is found to obstruct the federal purpose articulated in this proposed rule. This proposed rule, like the final rule, is not intended to preempt other State or local labeling requirements with respect to other statements or warnings about gluten. For example, a State would still not be preempted from requiring a statement about the health effects of gluten consumption from hydrolyzed and fermented foods on persons with celiac disease or information about how the food was processed.

Section 4(d) of Executive Order 13132 states that when an Agency foresees the possibility of a conflict between State law and federally protected interests within the Agency's area of regulatory responsibility, the Agency ''shall consult, to the extent practicable, with appropriate State and local officials in an effort to avoid such a conflict.'' Section 4(e) of Executive Order 13132 provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA's Division of Federal and State Relations will invite the States' participation in this rulemaking by providing notice via fax and email transmission to State health commissioners, State agriculture commissioners, and State food program directors as well as FDA field personnel of the publication of the proposed rule.

In 2009, the President issued a memorandum entitled ''Preemption'' (74 FR 24693, May 22, 2009). The memorandum, among other things, instructs Agencies to ''not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation'' and ''not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132''. Because of the May 22, 2009, memorandum we explain in detail the principles underlying our conclusion that this proposed rule may result in preemption of State and local laws under a narrow set of circumstances and describe how the final rule's codified provision regarding preemption, which is now § 101.91(d), would apply to hydrolyzed and fermented foods.

Under the Supremacy Clause of the Constitution (U.S. Constitution; Art. VI, clause 2), State laws that interfere with or are contrary to Federal law are invalid. (See *Gibbons* v. *Ogden,* 22 U.S. (9 Wheat.) 1, 211 (1824).) Federal preemption can be express (stated by Congress in the statute) or implied. Implied preemption can occur in several ways. For example, Federal preemption may be found where Federal law conflicts with State law. Such conflict may be demonstrated either when ''compliance with both federal and state [law] is a physical impossibility'' (*Florida Lime and Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132, 142–143 (1963)), or when State law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress'' (*Crosby* v. *Nat'l Foreign Trade Council,* 530 U.S. 363, 372–74 (2000) (citing *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941))). State law is also preempted if it interferes with the methods by which a Federal law is designed to reach its goals. (See *Int'l Paper Co.* v. *Ouellette,* 479 U.S. 481, 494 (1987); *Michigan Canners & Freezers Ass'n* v. *Agricultural*

Marketing & Bargaining Bd., 467 U.S. 461, 477–478 (1984).)

Additionally, '' 'a federal agency acting within the scope of its congressionally delegated authority may preempt state regulation' and hence render unenforceable state or local laws that are otherwise not inconsistent with federal law'' (*City of New York* v. *FCC,* 486 U.S. 57, 63–64 (1988) (quoting *Louisiana Public Service Comm'n* v. *FCC,* 476 U.S. 355, 369 (1986)). ''Federal regulations have no less preemptive effect than federal statutes'' (*Fidelity Federal Savings and Loan Ass'n* v. *de la Cuesta,* 458 U.S. 141, 153 (1982)).

When an Agency's intent to preempt is clearly and unambiguously stated, a court's inquiry will be whether the preemptive action is within the scope of that Agency's delegated authority (*Capital Cities Cable, Inc.* v. *Crisp,* 467 U.S. 691, 700 (1984); *Fidelity Federal Savings,* 458 U.S. at 154). If the Agency's choice to preempt ''represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute [the regulation will stand] unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned'' (*United States* v. *Shimer,* 367 U.S. 374, 383 (1961)). In *Hillsborough County,* the Supreme Court stated that FDA possessed the authority to issue regulations preempting local laws that compromise the supply of plasma and could do so (*Hillsborough County, Fla.* v. *Automated Medical Laboratories, Inc.,* 471 U.S. 707, 721 (1985)). We believe we have similar authority to preempt State and local laws and regulations to the limited extent that they permit use of ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' for hydrolyzed and fermented foods differently from our proposed rule because different State or local requirements would be contrary to the Congressional directive for us to define and permit use of the term ''gluten-free.''

State or local laws or regulations that permit use of ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' differently from our proposed rule could frustrate the ability of most consumers to identify gluten-free foods and avoid adverse health effects and deter manufacturers from applying a ''gluten-free'' label to their foods. With the proposed rule, consumers throughout the United States can understand what is required to use the term ''gluten-free'' on a hydrolyzed or fermented packaged food. The proposed rule will also allow us to enforce more efficiently the definition on product labels of hydrolyzed and fermented foods, and manufacturers will be able to comply with a single set of requirements, which may lead to greater use of this voluntary labeling.

Therefore, we intend to preempt State or local requirements only to the extent that they are different from the proposed requirements related to the use of the terms ''gluten-free,'' ''no gluten,'' ''free of gluten,'' or ''without gluten'' on fermented or hydrolyzed foods, including the requirement to make and keep certain records and the use of a scientifically valid method to detect the absence of protein for distilled foods. There is no proposed change to § 101.91(d) regarding preemption, but these new proposed requirements in § 101.91(c) would become part of the requirements covered by § 101.91(d).

VIII. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

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8. Codex Alimentarius Commission, ''Codex Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten (Codex Standard 118–1979),'' Rome, Italy, pp. 1–3, 2008; available at *http://www.codexalimentarius.org/download/standards/291/CXS_118e_2015.pdf.*

9. Garber, E. A. E., Memorandum to the Administrative Record, ''ELISA Methods Used to Detect Gluten in Foods,'' August 25, 2015.

10. Garber, E. A. E., Memorandum to the Administrative Record, ''Use of Proline Endopeptidases to Make Gluten Containing Products Safe for Consumption by Individuals With Celiac Disease,'' August 25, 2015.

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15. United States Department of Agriculture, ''Federal Grain Inspection Service,'' dated September 1997 and revised April 2004, available at *http://www.gipsa.usda.gov/Publications/fgis/broch/fgisbrochure.pdf.*

16. FDA, ''Preliminary Regulatory Impact Analysis of Gluten-Free Labeling of Fermented or Hydrolyzed Foods,'' Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, July 2014, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.*

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List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is proposed to be amended as follows:

PART 101—FOOD LABELING

■ 1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

■ 2. In § 101.91, revise paragraphs (b)(1), (b)(2), and (c) to read as follows:

§ 101.91 Gluten-free labeling of food.

* * * * *

(b) *Requirements.* (1) A food that bears the claim ''gluten-free'' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section and, if applicable, paragraphs (c)(2) through (4) of this section will be deemed misbranded.

(2) A food that bears the claim ''no gluten,'' ''free of gluten,'' or ''without gluten'' in its labeling and fails to meet the requirements of paragraph (a)(3) of this section and, if applicable, paragraphs (c)(2) through (4) of this section will be deemed misbranded.

* * * * *

(c) *Compliance.* (1) When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products.

(2) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records regarding the fermented or hydrolyzed food demonstrating adequate assurance that:

(i) The food is ''gluten-free'' in compliance with paragraph (a)(3) of this section before fermentation or hydrolysis;

(ii) The manufacturer has adequately evaluated their processing for any potential for gluten cross-contact; and

(iii) Where a potential for gluten cross-contact has been identified, the manufacturer has implemented measures to prevent the introduction of gluten into the food during the manufacturing process.

(3) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food contains one or more ingredients that are fermented or hydrolyzed, the manufacturer of such foods bearing the claim must make and keep records demonstrating adequate assurance that that the fermented or hydrolyzed ingredients are ''gluten-free'' as described in paragraph (c)(2) of this section.

(4) Records necessary to verify compliance with paragraphs (c)(2) and (3) of this section must be retained for at least 2 years after introduction or delivery for introduction of the food into interstate commerce and may be kept as original records, as true copies, or as electronic records. Manufacturers must provide those records to us for examination and copying during an inspection upon request.

(5) When a scientifically valid method pursuant to paragraph (c)(1) of this section is not available because the food is distilled, FDA will evaluate compliance with paragraph (b) of this section by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the food.

* * * * *

Dated: November 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29292 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2510

RIN 1210–AB71

Savings Arrangements Established by States for Non-Governmental Employees

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Proposed rule.

SUMMARY: This document contains a proposed regulation under the Employee Retirement Income Security Act of 1974 (ERISA) setting forth a safe harbor describing circumstances in which a payroll deduction savings program, including one with automatic enrollment, would not give rise to an employee pension benefit plan under ERISA. A program described in this proposal would be established and maintained by a state government, and state law would require certain private-sector employers to make the program available to their employees. Several states are considering or have adopted measures to increase access to payroll deduction savings for individuals employed or residing in their jurisdictions. By making clear that state payroll deduction savings programs with automatic enrollment that conform to the safe harbor in this proposal do not establish ERISA plans, the objective of the safe harbor is to reduce the risk of such state programs being preempted if they were ever challenged. If adopted, this rule would affect individuals and employers subject to such laws.

DATES: Written comments should be received by the Department of Labor on or before January 19, 2016.

ADDRESSES: You may submit comments, identified by RIN 1210–AB71, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: e-ORI@dol.gov.* Include RIN 1210–AB71 in the subject line of the message.
- *Mail:* Office of Regulations and Interpretations, Employee Benefits Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: State Savings Arrangements Safe Harbor.

Instructions: All submissions must include the agency name and Regulatory Identification Number (RIN) for this rulemaking. Persons submitting comments electronically are encouraged to submit only by one electronic method and not to submit paper copies. Comments will be available to the public, without charge, online at *www.regulations.gov* and *www.dol.gov/ebsa* and at the Public Disclosure Room, Employee Benefits Security Administration, U.S. Department of Labor, Suite N–1513, 200 Constitution Avenue NW., Washington, DC 20210. WARNING: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. Comments are public records and are posted on the Internet as received, and can be retrieved by most internet search engines.

FOR FURTHER INFORMATION CONTACT: Janet Song, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500; or Jim Craig, Office of the Solicitor, Plan Benefits Security Division, (202) 693–5600. These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

A. Background

Approximately 68 million US employees do not have access to a retirement savings plan through their employers.[1] For older Americans,

[1] Copeland, Craig, Employment-Based Retirement Plan Participation: Geographic Differences and Trends, 2013, Employee Benefit Research Institute,

inadequate retirement savings can mean sacrificing or skimping on food, housing, health care, transportation, and other necessities. Inadequate retirement savings place greater stress on state and federal social welfare programs as guaranteed sources of income and economic security for older Americans. Accordingly, states have a substantial governmental interest in taking steps to address the problem and protect the economic security of their residents.[2] Concerned over the low rate of saving among American workers, some state governments have already sought to expand access to savings programs for their residents and other individuals employed in their jurisdictions by creating their own programs and requiring employer participation.[3]

1. State Payroll Deduction Savings Initiatives

One approach some states have taken is to establish state payroll deduction savings initiatives. Such programs encourage employees to establish tax-favored individual retirement plans (IRAs) funded by payroll deductions. Oregon, Illinois, and California, for example, have adopted laws along these lines.[4] These initiatives generally require specified employers that do not offer workplace savings arrangements to deduct amounts from their employees' paychecks in order that those amounts may be remitted to state-administered IRAs for the employees. Typically, with automatic enrollment, the states would require that the employer deduct specified amounts on behalf of the employee, unless the employee affirmatively elects not to participate. As a rule, employees can stop the payroll deductions at any time. The programs, as currently designed, do not require, provide for or permit employers to make matching or other contributions of their own into the employees' accounts. In addition, the state initiatives typically require that employers act as a conduit for information regarding the program, including disclosure of employees' rights and various program features, often based on state-prepared materials.

2. ERISA's Regulation of Employee Benefit Plans

ERISA defines the terms ''employee pension benefit plan'' and ''pension plan'' broadly to mean, in relevant part:

- Any plan, fund, or program which was heretofore or is hereafter established or maintained by an employer or by an employee organization, or by both, to the extent that by its express terms or as a result of surrounding circumstances such plan, fund, or program—
  - provides retirement income to employees, or
  - results in a deferral of income by employees for periods extending to the termination of covered employment or beyond, regardless of the method of calculating the contributions made to the plan, the method of calculating the benefits under the plan or the method of distributing benefits from the plan.

29 U.S.C. 1002(2)(A). The provisions of Title I of ERISA, ''shall apply to any employee benefit plan if it is established or maintained . . . by any employer engaged in commerce or in any industry or activity affecting commerce.''[5] 29 U.S.C. 1003(a).

Despite the express intent of the drafters of those state statutes not to have such a result, some have expressed concern that payroll deduction programs, such as those enacted in Oregon, California and Illinois, may cause employers to establish ERISA-covered plans inadvertently. The Department and the courts have interpreted the term ''established or maintained'' as requiring minimal involvement by the employer or employee organization to trigger the protections of ERISA coverage. For example, an employer may establish a benefit plan by purchasing insurance products for individual employees.[6] Moreover, retirement savings programs involving IRAs also fall within the broad definition of pension plan when those programs are established or maintained by an employer or employee organization.[7]

Pension plans covered by ERISA are subject to various statutory and regulatory requirements to protect the interests of the plan participants. These include reporting and disclosure rules and stringent conduct standards derived from trust law for plan fiduciaries. In addition, ERISA expressly prohibits certain transactions involving plans unless a statutory or administrative exemption applies.

Moreover, in order to assure nationwide uniformity of treatment, ERISA places the regulation of private-sector employee benefit plans (including employment-based pension plans) under federal jurisdiction. Section 514(a) of ERISA, 29 U.S.C. 1144(a), provides that the Act ''shall supersede any and all State laws insofar as they . . . relate to any employee benefit plan'' covered by the statute. The U.S. Supreme Court has long held that ''[a] law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan.'' *Shaw* v. *Delta Air Lines, Inc.,* 463 U.S. 85, 96–97 (1983) (footnote omitted). In various decisions, the Court has concluded that ERISA preempts state laws that: (1) mandate employee benefit structures or their administration; (2) provide alternative enforcement mechanisms; or (3) bind employers or plan fiduciaries to particular choices or preclude uniform administrative practice, thereby functioning as a regulation of an ERISA plan itself.[8]

IRAs generally are not established or maintained by employers or employee organizations, and ERISA coverage is contingent on an employer (or employee organization) establishing or maintaining the arrangement. 29 U.S.C. 1002(1)–(2). The Internal Revenue Code is the principal federal law that governs

Issue Brief No. 405 (October 2014) (available at *www.ebri.org*).

[2] *See* Christian E. Weller, Ph.D., Nari Rhee, Ph.D., and Carolyn Arcand, Financial Security Scorecard: A State-by-State Analysis of Economic Pressures Facing Future Retirees, National Institute on Retirement Security (March 2014) (*www.nirsonline.org/index.php?option=com_content&task=view&id=830&Itemid=48*).

[3] *See, for example,* Report of the Governor's Task Force to Ensure Retirement Security for All Marylanders, Kathleen Kennedy Townsend, Chair, 1,000,000 of Our Neighbors at Risk: Improving Retirement Security for Marylanders (2015). The Georgetown University Center for Retirement Initiatives (CRI) of the McCourt School of Public Policy has compiled a ''50 state survey'' providing information on state legislation that would establish state-sponsored retirement savings plans at *http://cri.georgetown.edu/states/*. The stated mission of the CRI is ''[to] strengthen the retirement security of American families by developing and promoting the bipartisan adoption of innovative state policies, legislation and administrative models, such as pooled and professionally managed funds, which will expand the availability and effectiveness of retirement solutions.''

[4] Illinois Secure Choice Savings Program Act, 2014 Ill. Legis. Serv. P.A. 98–1150 (S.B. 2758) (West); California Secure Choice Retirement Savings Act, 2012 Cal. Legis. Serv. Ch. 734 (S.B. 1234) (West); Oregon 2015 Session Laws, Ch. 557 (H.B. 2960) (June 2015).

[5] ERISA includes several express exemptions in section 4(b) from coverage under Title I, for example, for pension plans established or maintained by governmental entities or churches for their employees, certain foreign plans, unfunded excess benefit plans, and plans maintained solely to comply with applicable state laws regarding workers compensation, unemployment, or disability. 29 U.S.C. 1003(b).

[6] *Donovan* v. *Dillingham,* 688 F.2d 1367 (11th Cir. 1982); *Harding* v. *Provident Life and Accident Ins. Co.,* 809 F. Supp. 2d 403, 415–419 (W.D. Pa. 2011); DOL Adv. Op. 94–22A (July 1, 1994).

[7] ERISA section 404(c)(2) (simple retirement accounts); 29 CFR 2510.3–2(d) (safe harbor for certain payroll deduction individual retirement accounts); 29 CFR 2509–99–1 (interpretive bulletin on payroll deduction IRAs); *Cline* v. *The Industrial Maintenance Engineering & Contracting Co.,* 200 F.3d 1223, 1230–31 (9th Cir. 2000).

[8] *New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.,* 514 U.S. 645, 658 (1995); *Ingersoll-Rand Co.* v. *McClendon,* 498 U.S. 133, 142 (1990); *Egelhoff* v. *Egelhoff,* 532 U.S. 141, 148 (2001); *Fort Halifax Packing Co.* v. *Coyne,* 482 U.S. 1, 14 (1987).

such IRAs. The Code includes prohibited transaction provisions (very similar to those in ERISA), which are primarily enforced through imposition of excise taxes against IRA fiduciaries by the Internal Revenue Service. 26 U.S.C. 4975.

In other contexts, the Department has provided guidance to help employers determine whether their involvement in voluntary payroll deduction arrangements for sending employee retirement savings contributions to IRAs would amount to establishing or maintaining ERISA-covered plans. For example, in 1975, the Department promulgated a safe harbor regulation to clarify the circumstances under which IRAs funded by payroll deductions would not be treated as ERISA plans. 29 CFR 2510.3–2(d); 40 FR 34,526 (Aug. 15, 1975). This safe harbor is part of a more general regulation that ''clarifies the limits of the defined terms 'employee pension benefit plan' and 'pension plan' for purposes of title I of the Act . . . by identifying specific plans, funds and programs which do not constitute employee pension benefit plans for those purposes.'' 29 CFR 2510.3–2(a). Other similar safe harbors were published in the same **Federal Register** notice.[9]

The 1975 regulation provides that ERISA does not cover a payroll deduction IRA arrangement so long as four conditions are met: the employer makes no contributions, employee participation is ''completely voluntary,'' the employer does not endorse the program and acts as a mere facilitator of a relationship between the IRA vendor and employees, and the employer receives no consideration except for its own expenses.[10] In essence, if the employer merely allows a vendor to provide employees with information about an IRA product and then facilitates payroll deduction for employees who voluntarily initiate action to sign up for the vendor's IRA, the arrangement is not an ERISA pension plan.

In 1999, the Department published additional guidance on this safe harbor in the form of Interpretive Bulletin 99–1. 29 CFR 2509.99–1. This guidance explains that employers may, consistent with the third condition in the regulation, furnish materials from IRA vendors to the employees, answer employee inquiries about the program, and encourage retirement savings through IRAs generally, as long as the employer makes clear to employees its neutrality concerning the program and that its involvement is limited to collecting the deducted amounts and remitting them promptly to the IRA sponsor, just as it remits other payroll deductions to taxing authorities and other third parties. 29 CFR 2510.99–1(c).[11]

The Department's publication of the 1975 payroll deduction IRA safe harbor was prompted by comments on an earlier proposal indicating ''considerable uncertainty concerning Title I coverage of individual retirement programs . . . .'' 40 FR 34528. When it promulgated the safe harbor regulation, the Department did not consider payroll deduction savings arrangements for private-sector employees with terms required by state laws. Instead, the payroll deduction IRA safe harbor and the group insurance safe harbor published that day focused on employers acting in coordination with IRA and other vendors, without state involvement. Under those circumstances, it was important for both safe harbors to contain conditions to limit employer involvement, both to avoid establishing or maintaining an employee benefit plan and to prevent undue employer influence in arrangements that would not be subject to ERISA's protective provisions. When a program meets the conditions of the safe harbor, employer involvement in the arrangement is minimal and employees' control of their participation in the program is nearly complete. In such circumstances, it is fair to say that each employee, rather than the employer, individually establishes and maintains the program.

One of the 1975 payroll deduction IRA safe harbor's conditions is that an employee's participation must be ''completely voluntary.'' The Department intended this term to mean considerably more than that employees are free to opt out of participation in the program. Instead, the employee's enrollment must be self-initiated. In various contexts, courts have held that opt-out arrangements are not consistent with a requirement for a ''completely voluntary'' arrangement.[12] This condition is important because where the employer is acting on his or her own volition to provide the benefit program, the employer's actions—*e.g.,* requiring an automatic enrollment arrangement—would constitute its ''establishment'' of a plan within the meaning of ERISA's text, and trigger ERISA's protections for the employees whose money is deposited into an IRA. As a result, state payroll deduction savings initiatives with automatic enrollment do not meet the 1975 safe harbor's ''completely voluntary'' requirement.

[9] 29 CFR 2510.3–1(j), Certain group or group-type insurance arrangements; 29 CFR 2510.3–2(f), Tax sheltered annuities. 40 FR 34530 (Aug. 15, 1975).

[10] The payroll deduction IRA safe harbor regulation, 29 CFR 2510.3–2(d), Individual Retirement Accounts.

[11] The Department has also issued advisory opinions discussing the application of the safe harbor regulation to particular facts. *See, e.g.,* Advisory Opinion 82–67A (Dec. 21, 1982), 1982 WL 21250; DOL Adv. Op. 84–25A (June 18, 1984), 1984 WL 23439.

[12] *See Doe* v. *Wood Co. Bd. Of Educ.,* 888 F.Supp.2d 771, 775–77 (S.D. W. Va. 2012) (Education Department regulations requiring ''completely voluntary'' choice of single-gender education not satisfied by opt-out provision); *Schear* v. *Food Scope America, Inc.,* 297 F.R.D. 114, 125 (S.D.N.Y. 2014) (''For a voluntary 'tip pooling' arrangement to exist, it must be 'undertaken by employees on a completely voluntary basis and may not be mandated or initiated by employers' and an employer can take 'no part in the organization or the conduct of [the] tip-pool.' '') (quoting N.Y. Dept. of Labor Opinion Letter RO–08–0049). *See also Carter* v. *Guardian Life Ins. Co.,* Civil No. 11–3–ART, 2011 WL 1884625, *1 (W.D. Ky. May 18, 2011) (''Courts have held that employees' participation is not 'completely voluntary' if their enrollment in the plan is 'automatic.' ''); *Thompson* v. *Unum Life Ins. Co.,* No. Civ.A. 3:03–CV–0277–B, 2005 WL 722717, *6 (N.D. Tex. Mar. 29, 2005) (analyzing group welfare plan safe harbor, ''Thompson's participation in the plan was automatic rather than voluntary''); *cf. The Meadows* v. *Employers Health Ins.,* 826 F. Supp. 1225, 1229 (D. Ariz. 1993) (enrollment not ''completely voluntary'' where health insurance contract required 75 percent of employees to participate); *Davis* v. *Liberty Mut. Ins. Co.,* Civ. A. No. 87–2851, 1987 WL 16837, *2 (D.D.C. Aug. 31, 1987) (health insurance enrollment not completely voluntary because employee would receive no alternative compensation for refusing coverage, therefore making refusal comparable to a cut in pay). *See generally* Advisory Council On Employee Welfare And Pension Benefit Plans, Current Challenges And Best Practices For ERISA Compliance For 403(b) Plan Sponsors (2011) (available at *www.dol.gov/ebsa/publications/2011ACreport1.html*) (''The Council also considered, but is not recommending, that DOL permit the inclusion of an automatic enrollment feature within the context of an ERISA safe harbor 403(b) plan. The majority of Council members concluded that automatic enrollment would require actions typically performed by a plan sponsor/fiduciary (*e.g.,* designation of a default investment alternative), and consequently, an automatic enrollment option in the plan may not be viewed as voluntary even in light of the participant's right to opt out of the automatic contributions.''). DOL Field Assistance Bulletin (FAB) 2004–1 stated that an employer could open a health savings account (HSA) and deposit employer funds into it without the employee's affirmative consent so long as, among other things, the arrangement was ''completely voluntary on the part of the employees'' and also that employees exercised control over the account with the power to withdraw or transfer the employer money. FAB 2004–1 was focused on the effect of employer contributions, so there was no specific discussion of what was meant by ''completely voluntary'' in the context of an HSA. Field Assistance Bulletin 2006–2 clarified that the completely voluntary requirement in FAB 2004–1 related to employee contributions to an HSA and confirms that completely voluntary employee contributions to the HSA must be self-initiated. The only ''opt out'' considered in FAB 2004–1 was the employees' power to move employer contributions out of the HSA. Neither FAB suggested that employee contributions to an HSA could be completely voluntary under an opt out arrangement.

However, when a state government sets the terms for and administers a payroll deduction savings arrangement, the situation is far different than when the employer sets the terms and administers the program—the 1975 safe harbor was not written with such state laws in mind. Therefore, the Department is promulgating this new safe harbor that does permit automatic enrollment in such state payroll deduction savings arrangements. Where states require employers to offer savings arrangements, undue employer influence or pressure to enroll is far less of a concern. Moreover, the state's active involvement and the limitations on the employers' role removes the employer from the equation such that the payroll deduction arrangements are not established or maintained by an employer or employee organization within the meaning of ERISA section 3(2). Accordingly, the safe harbor proposed today permits automatic enrollment with an opt-out provision in the context of state required and administered programs that meet the terms of the proposal. The safe harbor should remove uncertainty about Title I coverage of such state payroll deduction savings arrangements by promulgating a ''voluntary'' standard that permits automatic enrollment arrangements with employee opt-out features. By removing this uncertainty, the objective of the proposed safe harbor is to diminish the chances that, if the issue were ultimately litigated, the courts would conclude that state payroll deduction savings arrangements are preempted by ERISA.

3. Purpose and Scope of Proposed Regulation

Section 505 of ERISA gives the Secretary of Labor broad authority to prescribe such regulations as he finds necessary and appropriate to carry out the provisions of Title I of the Act. The Department believes that regulatory guidance in this area is necessary to ensure that governmental bodies, employers, and others in the regulated community have guidelines concerning whether state efforts to encourage savings implicate Title I of ERISA by requiring the establishment or maintenance of ERISA-covered employee pension benefit plans.

The 1975 payroll deduction IRA safe harbor sets forth standards for judging whether employer conduct crosses the line between permitted ministerial activities with respect to non-plan IRAs and activities that involve the establishment or maintenance of an ERISA-covered plan. State payroll deduction savings initiatives are similar to arrangements covered under the 1975 safe harbor if the employer's involvement is limited to withholding and forwarding payroll deductions and performing other related ministerial duties and the state has sole authority to determine the terms and administration of the state savings arrangement. The 1975 safe harbor, however, does not envision state involvement in the IRA programs nor does it envision use of automatic enrollment and related provisions.

The proposed regulation thus would provide a new and additional ''safe harbor'' for state savings arrangements that conform to the proposed regulation's provisions. The proposed regulation departs from the 1975 safe harbor for payroll deduction IRA programs by adopting a standard that enrollment be ''voluntary'' rather than ''completely voluntary.'' The new safe harbor's voluntary standard will allow employees' participation in state required programs to be initiated by automatic enrollment with an opt-out provision. The Department is also proposing to add other provisions to assure that employer involvement remains minimal.

The proposed regulation, however, as a ''safe harbor,'' does not purport to define every possible program that could fall outside of Title I of ERISA because it was not ''established or maintained'' by an employer. The Department also is not expressing any view regarding the application of provisions of the Internal Revenue Code (Code).

B. Description of the Proposed Regulation

The proposed regulation § 2510.3–2(h) provides that for purposes of Title I of ERISA, the terms ''employee pension benefit plan'' and ''pension plan'' do not include an individual retirement plan (as defined in 26 U.S.C. 7701(a)(37)) established and maintained pursuant to a state payroll deduction savings program if the program satisfies all of the conditions set forth in paragraphs (h)(1)(i) through (xii) of the proposed regulation. In the Department's view, compliance with these conditions will assure that the employer's involvement in the state program is limited to the ministerial acts necessary to implement the payroll deduction program as required by state law. In addition, the proposed conditions would give employees sufficient freedom not to enroll or to discontinue their enrollment, as well as meaningful control over their IRAs.

The term ''individual retirement plan'' means an individual retirement account described in section 408(a) and an individual retirement annuity described in section 408(b) of the Code.[13] Thus, by limiting the safe harbor to programs that use such individual retirement plans (which would include both traditional and Roth IRAs), the proposal incorporates the applicable protections under the Code, including the prohibited transaction provisions.

The safe harbor conditions under the proposed regulations require that the program be established by a state government pursuant to state law. As discussed above, if an employer's activities are limited to those ministerial functions required by the state law, the arrangement is not established or maintained by the employer. The term ''State'' in the proposed regulation has the same meaning as in Title I of ERISA generally. As in section 3(10) of ERISA, a ''State'' includes any ''State of the United States, the District of Columbia,'' and certain territories.[14] 29 U.S.C. 1002(10). The state must also administer the program either directly or through a governmental agency or other instrumentality. The safe harbor also contemplates that a state or the governmental agency or instrumentality could contract with commercial service providers, such as investment managers and recordkeepers, to operate and administer its program.

The proposal does not address whether the employees that participate in the program must be employed within the state that establishes the program, or alternatively whether the covered employees must be residents of the state or employed by employers doing business within the state. The extent to which a state can regulate employers is already established under existing legal principles. The proposal simply requires that the program be established by a state pursuant to state law. The Department solicits comments on whether the safe harbor should be limited to require some connection between the employers and employees covered by the program and the state that establishes the program, and if so, what kind of connection.

[13] Whether a state program meets the statutory requirements under the Code is a question within the jurisdiction of the Internal Revenue Service.

[14] The term ''State'' in the proposed regulation has the same meaning as in section 3(10) of ERISA. This would not include Indian tribes, tribal subdivisions, or agencies or instrumentalities of either in coverage under the regulation. To date, the Department is unaware of any tribal initiatives similar to the state initiatives described elsewhere in this preamble. Comments are welcome on whether, on what basis, and under what circumstances, payroll deduction programs required by Indian tribes might be covered under the safe harbor.

The proposed regulation requires that participation in the program be voluntary for employees. As discussed above, this requirement is different from the current payroll deduction IRA safe harbor in 29 CFR 2510.3–2(d), which requires that participation be ''completely voluntary.'' The proposed regulation expressly permits opt-out programs and, accordingly, does not require that participation be ''completely voluntary.'' By using only the term ''voluntary,'' the Department intends to make clear that the proposed regulation, unlike the existing safe harbor, would allow the state to require employers to automatically enroll employees, unless they affirmatively elect not to participate in the program.[15]

The proposed regulation also includes conditions to assure that control of the payroll deduction program and the savings accounts lies with the state and the employees, and not the employer. These include requirements that (1) the program does not require that an employee or beneficiary retain any portion of contributions or earnings in his or her IRA and does not otherwise impose any restrictions on withdrawals or impose any cost or penalty on transfers or rollovers permitted under the Internal Revenue Code; (2) all rights of the employee, former employee, or beneficiary under the program are enforceable only by the employee, former employee, or beneficiary, an authorized representative of such person, or by the state (or the designated agency or instrumentality); and (3) the state adopts measures to ensure that employees are notified of their rights under the program and creates a mechanism for enforcement of those rights. In addition, the proposal requires the state to assume responsibility for the security of payroll deductions and employee savings. These conditions assure that the employees will have meaningful control over their retirement savings, that the state will enforce the employer's payroll deduction obligations and oversee the security of retirement savings, and that the employer will have no role in enforcing employee rights under the program.

Limited employer involvement in the program is the key to a determination that a state savings program is not an employee pension benefit program. Thus, the employer's facilitation must be required by state law—if it is voluntary, the safe harbor does not apply. Further, the proposal does not permit the employer to contribute to the program.[16] All contributions under the program must be made voluntarily by the employees. When employers make contributions to fund benefits of the type enumerated in Section 3(2) of ERISA, they effectively sponsor an ERISA-covered plan. Similarly, the employer may not have discretionary authority, control, or responsibility under the program and may not receive any direct or indirect compensation in the form of cash or otherwise in connection with the program, other than the reimbursement of the actual costs of the program to the employer. Finally, the proposal specifies that employer involvement must be limited to all or some of the following: (1) Collecting employee contributions through payroll deductions and remitting them to the program; (2) providing notice to the employees and maintaining records regarding the employer's collection and remittance of payments under the program; (3) providing information to the state necessary to facilitate the operation of the program; and (4) distributing program information to employees from the state and permitting the state to publicize the program to employees.

A program could fit within the safe harbor and include terms that require employers to certify facts within the employer's knowledge as employer, such as employee census information (*e.g.,* status of a full time employee, employee addresses, attendance records, compensation levels, etc.). The employer could also conduct reviews to ensure it was complying with program eligibility requirements and limitations established by the state. The Department requests comments on whether the final regulation should provide more clarity and specificity on the types of functions that could be permitted consistent with the requirements of the safe harbor.[17]

A state program that meets all of the foregoing conditions will not fail to qualify for the safe harbor merely because the program is directed toward employees who are not already eligible for some other workplace savings arrangement. Nor will it fail merely because it requires automatic enrollment subject to employees having a right to opt out. Similarly, if the state program offers employees a choice of multiple IRA sponsors to which employees may make payroll deduction contributions, the state program can create a default option, *i.e.,* designate the IRA provider to which the employer must remit the payroll withholding contributions in the absence of an affirmative election by the employee.

ERISA's expansive plan definition is critical to its protective purposes. When employers establish or maintain ERISA-covered plans, the plan's participants are protected by trust-law obligations of fiduciary conduct, reporting requirements, and a regulatory regime designed to ensure the security of promised benefits. In the circumstances specified by the proposed regulation, however, the employer does not ''establish or maintain'' the plan. Instead, the program is created and administered by the state for the benefit of those employees who voluntarily participate with minimal employer involvement. State administration of the voluntary program does not give rise to ERISA coverage, and presumably ensures that the program will be administered in accordance with the interests of the state's citizens.[18]

As noted above, ERISA generally preempts state laws that relate to employee benefit plans. The U.S. Supreme Court has long held that ''[a] law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan.'' *Shaw* v. *Delta Air Lines, Inc.,* 463 U.S. 85, 96–97 (1983) (footnote omitted); *see, e.g., New York State Conference of Blue Cross & Blue Shield Plans* v. *Travelers Ins. Co.,* 514 U.S. 645, 656 (1995). This proposed regulation would provide that certain state savings

[15] If a program requires automatic enrollment, adequate notice of their right to opt out must be furnished to employees in order for the program to meet the safe harbor's voluntariness condition. The proposal does not define the manner and content of ''adequate notice'' for this purpose. The Department expects that states and their vendors would look to analogous notice requirements contained in federal laws pertaining to automatic enrollment provisions. *See, e.g.,* 26 U.S.C. 401(k)(13)(E) and 414(w); 29 U.S.C. 1144(e)(3); and 29 CFR 2550.404c–5(d). The Department solicits comments on this issue.

[16] This provision, of course, would not prohibit an employer from allowing employees to review program materials on company time or to use an employer's computer to make elections under the program.

[17] In previous guidance issued by the Department under other safe harbors involving private parties, the Department concluded that employers could take certain corrective actions to stay within the safe harbor and that such actions, in and of themselves, did not lead to the establishment of an employee benefit plan. *See* DOL Information Letter to Siegel Benefit Consultants (Feb. 27, 1996) and Field Assistance Bulletin 2007–02 on the safe harbor for tax sheltered annuity programs under 29 CFR 2510.3–2(f).

[18] To the extent that the state program allows employees not subject to the automatic enrollment requirement to voluntarily choose to participate, the employee's voluntarily participation would not result in the employer establishing an ERISA-covered plan or the state program including an ERISA-covered plan if the employer and the state program satisfy the conditions in the Department's existing safe harbor for payroll deduction IRAs at 29 CFR 2510.3–2(d). Of course, as described above, automatic enrollment of employees is not permitted under the existing payroll deduction IRA safe harbor.

programs would not create employee benefit plans. However, the fact that state programs do not create ERISA covered plans does not necessarily mean that, if the issue were litigated, the state laws would not be preempted by ERISA. The courts' determinations would depend on the precise details of the statute at issue, including whether that state's program successfully met the requirements of the safe harbor.

Moreover, states should be advised that a program may be preempted by other Federal laws apart from ERISA. A state law that alters, amends, modifies, invalidates, impairs or supersedes a Federal law would risk being preempted by the Federal law so affected. Such preemption issues are beyond the scope of this proposed rule, however, which addresses only the question of whether particular programs involve the establishment of one or more ERISA covered employee benefit plans.

Finally, some states are considering approaches that differ from state payroll deduction savings initiatives. In 2012, Massachusetts, for example, enacted a law providing for a state-sponsored plan for non-profit employers with 20 or fewer employees.[19] Washington enacted a law to establish a small business retirement market place to assist small employers by making available a number of approved savings plans, some of which may be covered by ERISA, even though the marketplace arrangement itself is not.[20] This proposal does not address such state initiatives.

C. Effective Date

The Department proposes to make this regulation effective 60 days after the date of publication of the final rule in the **Federal Register**.

D. Regulatory Impact Analysis

1. Executive Order 12866 Statement

Under Executive Order 12866, the Office of Management and Budget (OMB) must determine whether a regulatory action is ''significant'' and therefore subject to the requirements of the Executive Order and subject to review by the OMB. Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as an ''economically significant'' action); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

OMB has tentatively determined that this regulatory action is not economically significant within the meaning of section 3(f)(1) of the Executive Order. However, it has been determined that the action is significant within the meaning of section 3(f)(4) of the Executive Order and the Department accordingly provides the following assessment of its potential benefits and costs.

a. Direct Benefits

As stated earlier in this preamble, some state governments have passed laws designed to expand workers' access to workplace savings programs. Some states are looking at ways to encourage employers to provide coverage under state-administered 401(k)-type plans, while others have adopted or are considering approaches that combine several retirement alternatives including IRAs, ERISA-covered plans and the Department of the Treasury's new starter savings program, *my*RA.

One of the challenges states face in expanding retirement savings opportunities for private sector employees is uncertainty about ERISA preemption of such efforts. ERISA generally would preempt a state law that required employers to establish and maintain ERISA-covered employee benefit pension plans. The Department therefore believes that states and other stakeholders would benefit from clear guidelines to determine whether state saving initiatives would effectively require employers to create ERISA-covered plans. The proposed rule would provide a new ''safe harbor'' from coverage under Title I of ERISA for state savings arrangements that conform to certain requirements. State initiatives within the safe harbor would not result in the establishment of employee benefit plans under ERISA. The Department expects that the proposed rule would reduce legal costs, including litigation costs, by (1) removing uncertainty about whether such state savings arrangements are covered by title I of ERISA, and (2) creating efficiencies by eliminating the need for multiple states to incur the same costs to determine their non-plan status.

The Department notes that the proposal would not prevent states from identifying and pursuing alternative policies, outside the safe harbor, that also would not require employers to establish or maintain ERISA-covered plans. Thus, while the proposal would reduce uncertainty about state activity within the safe harbor, it would not impair state activity outside it.

b. Direct Costs

The proposed rule does not require any new action by employers or the states. It merely clarifies that certain state initiatives that encourage workplace savings would not result in the creation of employee benefit plans covered by Title I of ERISA.

States may incur legal costs to analyze the rule and determine whether their laws fall within the proposed rule's safe harbor. However, the Department expects that these costs will be less than the savings that will be generated. Moreover, states will avoid incurring the greater costs that might be incurred to determine their programs' non-plan status without benefit of this proposed rule.

States that design their payroll deduction programs to conform to the safe harbor may incur costs to develop notices to be provided to participants and beneficiaries covered by the program and enter into contracts with investment managers and other service providers to operationalize and administer the programs. The Department's review of existing state payroll deduction legislation indicates that these requirements are customarily part of most state programs, and the initiatives generally could not operate without such requirements. Therefore, to the extent that state programs would exist even in the absence of this rule, only the relatively minor costs of revisions for conformity to the safe harbor are attributable to the rule, because other cost-generating activities are necessary and essential to operate and administer the programs. On the other hand, if state programs are adopted more widely in the rule's presence than in its absence, there would be more general state operational and administrative costs that are attributable to the rule. The Department does not have sufficient data to estimate the number of systems that would need to be updated; therefore, the Department invites comments and any relevant data that would allow it to make a more thorough assessment.

[19] Mass. Gen. Laws ch. 29, sec. 64E (2014)

[20] 2015 Wash. Sess. Laws chap. 296 (SB 5826).

c. Uncertainty

The Department is confident that the proposed regulation, by clarifying that certain state programs do not require employers to establish ERISA-covered plans, will benefit states and many other stakeholders otherwise beset by greater uncertainty. However, the Department is unsure as to the magnitude of these benefits. The magnitude of the proposed regulation's benefits, costs and transfer impacts will depend on the states' independent decisions on whether and how best to take advantage of the safe harbor, and on the cost that otherwise would have attached to uncertainty about the legal status of the states' actions. The Department cannot predict what actions states will take, stakeholders' propensity to challenge such actions' legal status, either absent or pursuant to the proposed regulation, or courts' resultant decisions, and therefore the Department invites data submission or other comment that would allow for more thorough assessment of these issues.

d. Impact of State Initiatives

There are a number of cases in which this rulemaking could increase the prevalence of state workplace savings initiatives, thus bringing the effects of these initiatives within the scope of this regulatory impact analysis. For instance, if this issue were ultimately resolved in the courts, the courts could make a different preemption decision in the rule's presence than in its absence. Furthermore, even if a potential court decision would be the same with or without the rulemaking, the potential reduction in states' uncertainty-related costs could induce more states to pursue these workplace savings initiatives. An additional possibility is that the rule would not change the prevalence of state retirement savings programs, but would accelerate the implementation of programs that would exist anyway. With any of these possibilities, there would be benefits, costs and transfer impacts that are indirectly attributable to this rule, via the increased or accelerated creation of state-level workplace savings programs.

Employers may incur costs to update their payroll systems to transmit payroll deductions to the state or its agent and develop recordkeeping systems to document their collection and remittance of payments under the program. As with states' operational and administrative costs (discussed in section D.1.b, above), some portion of these employer costs would be attributable to the rule if more state workplace savings programs are implemented in the rule's presence than in its absence. Because employers' role in the programs must be minimal in order to satisfy the safe harbor, they will incur little cost beyond the costs associated with updating payroll systems. However, the costs that are incurred could fall most heavily on small and start-up companies, which tend to be least likely to offer pensions. Most state payroll deduction programs do exempt the smallest companies, which could significantly mitigate such costs. The Department does not have sufficient data to estimate the number of payroll systems that would have to be updated. Therefore, the Department invites the public to provide comments and relevant data that would allow it to make a more thorough assessment.

The Department believes that well-designed state-level initiatives have the potential to effectively reduce gaps in retirement security. Relevant variables such as pension coverage,[21] labor market conditions,[22] population demographics,[23] and elderly poverty,[24] vary widely across the states, suggesting a potential opportunity for progress at the state level. For example, payroll deduction savings statutes in California and Illinois could extend savings opportunities for 7.8 million workers in California and 1.7 million workers in Illinois who currently do not have access to employment-based savings arrangements.[25] The Department offers the following policy discussion for consideration, and invites public input on the issues raised, on the potential for state initiatives to foster retirement security, and on the potential for this proposal or other Departmental action to facilitate effective state activity.

Effective state initiatives will advance retirement security. Some workers currently may save less than would be optimal because of behavioral biases (such as myopia or inertia) or labor market frictions that prevent them from accessing plans at work. Effective state initiatives would help such workers save more. Such workers will have traded some consumption today for more in retirement, potentially reaping some net gain in overall lifetime well-being. Their additional saving may also reduce fiscal pressure on publicly financed retirement programs and other public assistance programs, such as the Supplemental Nutritional Assistance Program, that support low-income Americans, including older Americans.

The Department believes that well-designed state initiatives can achieve their intended, positive effects of fostering retirement security. However, the initiatives might have some unintended consequences as well. Those workers least equipped to make good retirement savings decisions arguably stand to benefit most from state initiatives, but also arguably are most at risk of suffering adverse unintended effects. Workers who would not benefit from increased retirement savings could opt out, but some might fail to do so. Such workers might increase their savings too much, unduly sacrificing current economic needs. Consequently they might be more likely to cash out early and suffer tax losses, and/or to take on more expensive debt. Similarly, state initiatives directed at workers who do not currently participate in workplace savings arrangements may be imperfectly targeted to address gaps in retirement security. For example, a college student might be better advised to take less in student loans rather than open an IRA, and a young family might do well to save more first for their children's education and later for their own retirement.

Employers that wish to provide retirement benefits are likely to find that ERISA-covered programs, such as 401(k) plans, have advantages for them and their employees over participation in state programs. Potential advantages include: Greater tax preferences, greater flexibility in plan selection and design, opportunity for employers to contribute, ERISA protections, and larger positive recruitment and retention effects. Therefore it seems unlikely that state initiatives will ''crowd-out'' many ERISA-covered plans. However, if they do, some workers might lose ERISA-protected benefits that would have been more generous and more secure than state-based (or IRA) benefits, unless states adopt consumer protections similar to those Congress provided under ERISA. Some workers who would otherwise have saved more might reduce their savings to the low, default levels associated with some state programs. States can address this last concern by incorporating into their programs ''auto-escalation'' features that increase default contribution rates over time and/or as pay increases.

[21] *See for example* Craig Copeland, ''Employment-Based Retirement Plan Participation: Geographic Differences and Trends, 2013,'' Employee Benefit Research Institute, Issue Brief No. 405 (October 2014) (available at *www.ebri.org*).

[22] *See for example* US Bureau of Labor Statistics, ''Regional and State Employment and Unemployment—JUNE 2015,'' USDL–15–1430, July 21, 2015.

[23] *See for example* Lindsay M. Howden and Julie A. Meyer, ''Age and Sex Composition: 2010,'' US Bureau of the Census, 2010 Census Briefs C2010BR–03, May 2011.

[24] Constantijn W. A. Panis & Michael Brien, August 28, 2015, ''Target Populations of State-Level Automatic IRA Initiatives.''

[25] *Id.*

2. Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department of Labor conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

The Department has determined this proposed rule is not subject to the requirements of the PRA, because it does not contain a *collection of information* as defined in 44 U.S.C. 3502(3). The rule does not require any action by or impose any requirements on employers or the states. It merely clarifies that certain state payroll deduction programs that encourage retirement savings would not result in the creation of employee benefit plans covered by Title I of ERISA.

Moreover, the PRA definition of *burden* excludes time, effort, and financial resources necessary to comply with a collection of information that would be incurred by respondents in the normal course of their activities. *See* 5 CFR 1320.3(b)(2). The definition of *burden* also excludes burdens imposed by a state, local, or tribal government independent of a Federal requirement. *See* 5 CFR 1320.3(b)(3). The Department's review of existing state payroll deduction programs indicates that they customarily have notification and recordkeeping requirements and that the initiatives could not operate without such requirements, especially programs that include automatic enrollment. Therefore, the proposed rule imposes no burden, because states customarily include notice and recordkeeping requirements that are an essential and routine part of administering state payroll deduction programs. In addition, employers are responding to state, not Federal, requirements when providing notices to individuals covered under state payroll deduction programs and maintaining records regarding the employers' collection and remittance of payments under the program.

Although the Department has determined that the proposed rule does not contain a collection of information, when rules contain information collections the Department invites comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In addition to having an opportunity to file comments with the Department, comments may also be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Attention: Desk Officer for the Employee Benefits Security Administration. OMB requests that comments be received within 30 days of publication of the proposed rule to ensure their consideration.

3. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations and governmental jurisdictions.

Because the proposed rule imposes no requirements or costs on employers, the Department believes that it would not have a significant economic impact on a substantial number of small entities. Accordingly, pursuant to section 605(b) of the RFA, the Assistant Secretary of the Employee Benefits Security Administration hereby certifies that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

4. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*), as well as Executive Order 12875, this rule does not include any federal mandate that may result in expenditures by state, local, or tribal governments, or the private sector, which may impose an annual burden of $100 million.

5. Congressional Review Act

The proposed rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and, if finalized, would be transmitted to Congress and the Comptroller General for review.

6. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism. It also requires adherence to specific criteria by federal agencies in formulating and implementing policies that have ''substantial direct effects'' on the states, the relationship between the national government and states, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the final regulation.

In the Department's view, the proposed regulations, by clarifying that certain workplace savings arrangements under consideration or adopted by certain states will not result in the establishment or maintenance by employers or employee organizations of employee benefit plans under ERISA, would provide more latitude and certainty to state governments and employers regarding the treatment of such arrangements under ERISA. The Department will affirmatively engage in outreach with officials of states, and with employers and other stakeholders, regarding the proposed rule and seek their input on the proposed rule and any federalism implications that they believe may be presented by it.

List of Subjects in 29 CFR Part 2510

Accounting, Employee benefit plans, Employee Retirement Income Security Act, Pensions, Reporting, Coverage.

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR 2510 as set forth below:

PART 2510—DEFINITIONS OF TERMS USED IN SUBCHAPTERS C, D, E, F, AND G OF THIS CHAPTER

■ 1. The authority citation for part 2510 is revised to read as follows:

Authority: 29 U.S.C. 1002(2), 1002(21), 1002(37), 1002(38), 1002(40), 1031, and 1135; Secretary of Labor's Order No. 1–2011, 77 FR 1088 (Jan. 9, 2012); Sec. 2510.3–101 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713 (Oct. 17, 1978), E.O. 12108, 44 FR 1065 (Jan. 3, 1979) and 29 U.S.C. 1135 note. Sec. 2510.3–38 is also issued under sec. 1, Pub. L. 105–72, 111 Stat. 1457 (1997).

■ 2. Section 2510.3–2 is amended by adding paragraph (h) to read as follows:

§ 2510.3–2 Employee pension benefit plans.

* * * * *

(h) *Certain State Savings Programs.* (1) For the purpose of Title I of the Act and this chapter, the terms ''employee pension benefit plan'' and ''pension plan'' shall not include an individual retirement plan (as defined in 26 U.S.C. 7701(a)(37)) established and maintained pursuant to a State payroll deduction savings program, provided that:

(i) The program is established by a State pursuant to State law;

(ii) The program is administered by the State establishing the program, or by a governmental agency or instrumentality of the State, which is responsible for investing the employee savings or for selecting investment alternatives for employees to choose;

(iii) The State assumes responsibility for the security of payroll deductions and employee savings;

(iv) The State adopts measures to ensure that employees are notified of their rights under the program, and creates a mechanism for enforcement of those rights;

(v) Participation in the program is voluntary for employees;

(vi) The program does not require that an employee or beneficiary retain any portion of contributions or earnings in his or her IRA and does not otherwise impose any restrictions on withdrawals or impose any cost or penalty on transfers or rollovers permitted under the Internal Revenue Code;

(vii) All rights of the employee, former employee, or beneficiary under the program are enforceable only by the employee, former employee, or beneficiary, an authorized representative of such a person, or by the State (or the designated governmental agency or instrumentality described in paragraph (h)(1)(ii) of this section);

(viii) The involvement of the employer is limited to the following:

(A) Collecting employee contributions through payroll deductions and remitting them to the program;

(B) Providing notice to the employees and maintaining records regarding the employer's collection and remittance of payments under the program;

(C) Providing information to the State (or the designated governmental agency or instrumentality described in paragraph (h)(1)(ii) of this section) necessary to facilitate the operation of the program; and

(D) Distributing program information to employees from the State (or the designated governmental agency or instrumentality described in paragraph (h)(1)(ii) of this section) and permitting the State or such entity to publicize the program to employees;

(ix) The employer contributes no funds to the program and provides no bonus or other monetary incentive to employees to participate in the program;

(x) The employer's participation in the program is required by State law;

(xi) The employer has no discretionary authority, control, or responsibility under the program; and

(xii) The employer receives no direct or indirect consideration in the form of cash or otherwise, other than the reimbursement of the actual costs of the program to the employer of the activities referred to in paragraph (h)(1)(viii) of this section.

(2) A State savings program will not fail to satisfy the provisions of paragraph (h)(1) of this section merely because the program—

(i) Is directed toward those employees who are not already eligible for some other workplace savings arrangement;

(ii) Utilizes one or more service or investment providers to operate and administer the program, provided that the State (or the designated governmental agency or instrumentality described in paragraph (h)(1)(ii) of this section) retains full responsibility for the operation and administration of the program; or

(iii) Treats employees as having automatically elected payroll deductions in an amount or percentage of compensation, including any automatic increases in such amount or percentage, specified under State law until the employee specifically elects not to have such deductions made (or specifically elects to have the deductions made in a different amount or percentage of compensation allowed by the program), provided that the employee is given adequate notice of the right to make such elections; provided, further, that a program may also satisfy this paragraph (h) without requiring or otherwise providing for the automatic elections described in this paragraph (h)(2)(iii).

(3) For purposes of this section, the term State shall have the same meaning as defined in section 3(10) of ERISA.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2015–29426 Filed 11–16–15; 4:15 pm]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2560

RIN 1210–AB39

Claims Procedure for Plans Providing Disability Benefits

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed amendments to claims procedure regulations for plans providing disability benefits under the Employee Retirement Income Security Act of 1974 (ERISA). The amendments would revise and strengthen the current rules primarily by adopting certain of the new procedural protections and safeguards made applicable to group health plans by the Affordable Care Act. If adopted as final, the proposed regulation would affect plan administrators and participants and beneficiaries of plans providing disability benefits, and others who assist in the provision of these benefits, such as third-party benefits administrators and other service providers that provide benefits to participants and beneficiaries of these plans.

DATES: Written comments should be received by the Department of Labor on or before January 19, 2016.

ADDRESSES: You may submit written comments, identified by RIN 1210–AB39, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: e-ORI@dol.gov.* Include RIN 1210–AB39 in the subject line of the message.
- *Mail:* Office of Regulations and Interpretations, Employee Benefits

Security Administration, Room N–5655, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, Attention: Claims Procedure Regulation Amendment for Plans Providing Disability Benefits.

Instructions: All submissions received must include the agency name and Regulatory Identifier Number (RIN) for this rulemaking. All comments will be available to the public, without charge, online at *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and at the Public Disclosure Room, Employee Benefits Security Administration, Suite N–1513, 200 Constitution Avenue NW, Washington, DC 20210.

Warning: Do not include any personally identifiable or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records.

FOR FURTHER INFORMATION CONTACT: Frances P. Steen, Office of Regulations and Interpretations, Employee Benefits Security Administration, (202) 693–8500. This is not a toll free number.

SUPPLEMENTARY INFORMATION:

A. Executive Summary

In accordance with Executive Order 13563, this section of the preamble contains an executive summary of the proposed rulemaking in order to promote public understanding and to ensure an open exchange of information and perspectives. Sections B through E of this preamble, below, contain a more detailed description of the regulatory provisions and need for the rulemaking, as well as its costs and benefits.

1. Purpose of Regulatory Action

The purpose of this action is to improve the current procedural protections for workers who become disabled and make claims for disability benefits from an employee benefit plan. ERISA requires that plans provide claimants with written notice of benefit denials and an opportunity for a full and fair review of the denial by an appropriate plan fiduciary. The current regulations governing the processing of claims and appeals were published 15 years ago. Because of the volume and constancy of litigation in this area, and in light of advancements in claims processing technology, the Department recognizes a need to revisit, reexamine, and revise the current regulations in order to ensure that disability benefit claimants receive a fair review of denied claims as provided by law. To this end, the Department has determined to start by proposing to uplift the current standards applicable to the processing of claims and appeals for disability benefits so that they better align with the requirements regarding internal claims and appeals for group health plans under the regulations implementing the requirements of the Affordable Care Act.[1] Inasmuch as disability and lost earnings can be sources of severe hardship for many individuals, the Department thinks that disability benefit claimants deserve protections equally as stringent as those that Congress and the President have put into place for health care claimants under the Affordable Care Act.

2. Summary of Major Provisions

The major provisions in the proposal largely adopt the procedural protections for health care claimants in the Affordable Care Act, including provisions that seek to ensure that: (1) Claims and appeals are adjudicated in manner designed to ensure independence and impartiality of the persons involved in making the decision; (2) benefit denial notices contain a full discussion of why the plan denied the claim and the standards behind the decision; (3) claimants have access to their entire claim file and are allowed to present evidence and testimony during the review process; (4) claimants are notified of and have an opportunity to respond to any new evidence reasonably in advance of an appeal decision; (5) final denials at the appeals stage are not based on new or additional rationales unless claimants first are given notice and a fair opportunity to respond; (6) if plans do not adhere to all claims processing rules, the claimant is deemed to have exhausted the administrative remedies available under the plan, unless the violation was the result of a minor error and other specified conditions are met; (7) certain rescissions of coverage are treated as adverse benefit determinations, thereby triggering the plan's appeals procedures; and (8) notices are written in a culturally and linguistically appropriate manner.

3. Costs and Benefits

The Department expects that these proposed regulations would improve the procedural protections for workers who become disabled and make claims for disability benefits from employee benefit plans. This would cause some participants to receive benefits they might otherwise have been incorrectly denied absent the fuller protections provided by the proposed regulations. In other circumstances, expenditures by plans may be reduced as a fuller and fairer system of disability claims and appeals processing helps facilitate participant acceptance of cost management efforts. Greater certainty and consistency in the handling of disability benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated may lead to efficiency gains in the system, both in terms of the allocation of spending at a macro-economic level as well as operational efficiencies among individual plans.

The Department expects the proposed regulations would impose modest costs on disability benefit plans, because many plans already are familiar with the rules that would apply to disability benefit claims due to their current application to group health plans. As discussed in detail in the cost section below, the Department quantified the costs associated with two provisions of the proposed regulations: the requirement to provide additional information to claimants in the appeals process ($1.9 million annually) and the requirement to provide information in a culturally and linguistically appropriate manner ($1.1 million annually).

B. Background

1. Section 503 of ERISA and the Section 503 Regulations

Section 503 of ERISA requires every employee benefit plan, in accordance with regulations of the Department, to ''provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant'' and to ''afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.''

In 1977, the Department published a regulation pursuant to section 503, at 29 CFR 2560.503–1, establishing minimum requirements for benefit claims procedures for employee benefit plans covered by title I of ERISA (hereinafter ''Section 503 Regulation'').[2] The Department revised and updated the

[1] The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, was enacted on March 30, 2010. (These statutes are collectively known as the ''Affordable Care Act.'')

[2] 42 FR 27426 (May 27, 1977).

Section 503 Regulation in 2000 by improving and strengthening the minimum requirements for employee benefit plan claims procedures under section 503 of ERISA.[3] As revised in 2000, the Section 503 Regulation provided new time frames and enhanced requirements for notices and disclosure with respect to decisions at both the initial claims decision stage and on review. Although the Section 503 Regulation applies to all covered employee benefit plans, including pension plans, group health plans, and plans that provide disability benefits, the more stringent procedural protections apply to group health plans and to claims with respect to disability benefits.[4]

2. The Affordable Care Act Additions to the Section 503 Regulations

Section 715(a)(1) of ERISA, added by the Affordable Care Act, provides that certain provisions of the Public Health Service Act (PHS Act) apply to group health plans and health insurance issuers in connection with providing health insurance coverage as if the provisions were included ERISA . Such provisions include section 2719 of the PHS Act which addresses among other items internal claims and appeals and processes for group health plans and health insurance issuers. Section 2719 of the PHS Act provides that group health plans must have in effect an internal claims and appeals process and that such plans must initially incorporate the claims and appeals processes set forth in the Section 503 Regulation and update such processes in accordance with standards established by the Secretary of Labor.

On July 23, 2010, the Departments of Health and Human Services, Labor, and the Treasury (collectively the Departments) issued interim final regulations implementing PHS Act section 2719 and issued amendments to the IFR on June 24, 2011 (hereinafter ''the 2719 IFR'').[5] The 2719 IFR updated the Section 503 Regulation to ensure that non-grandfathered group health plans implement an effective internal claims and appeal process, in compliance with the Affordable Care Act.[6]

Elsewhere in today's version of the **Federal Register**, the Departments published final regulations implementing section PHS Act section 2719 (regarding internal claims and appeals and external review processes) and PHS Act 2712 (regarding restrictions on rescissions) (collectively ''the 2719 Final Rule''). The 2719 Final Rule implements the requirements regarding internal claims and appeals and external review processes for group health plans and health insurance coverage in the group and individual markets under the Affordable Care Act.

The 2719 Final Rule adopts and clarifies the new requirements in the 2719 IFR that apply to internal claims and appeals processes for non-grandfathered group health plans.

3. Substantial Litigation

Even though fewer private-sector employees participate in disability plans than in other types of plans,[7] disability cases dominate the ERISA litigation landscape today.[8] An aging American workforce may likely be a contributing factor to the significant volume of disability cases. Aging workers initiate more disability claims, as the prevalence of disability increases with age.[9] And as a result, insurers and plans looking to contain disability benefit costs are often motivated to aggressively dispute disability claims. This aggressive posture coupled with the inherently factual nature of disability claims highlight for the Department the need to review and strengthen the procedural rules governing the adjudication of disability benefit claims.

4. ERISA Advisory Council Recommendations

In 2012, the ERISA Advisory Council undertook a study on issues relating to managing disability in an environment of individual responsibility. The Advisory Council issued a report containing, in relevant part, recommendations for review of the Section 503 Regulation to determine updates and modifications for disability benefit claims, drawing upon analogous processes described in the 2719 IFR where appropriate, to address (1) what is an adequate opportunity to develop the record; and (2) content for denials of such claims.[10]

Based on the foregoing, the Department believes that in order to afford claimants of disability benefits a reasonable opportunity to pursue a full and fair review, as required by ERISA section 503, modifications to the Section 503 Regulation, that align with the updated standards required by the Affordable Care Act and extended to non-grandfathered group health plans in paragraph (b) of the 2719 Final Rule at 29 CFR 2590.715–2719, are necessary.

C. Overview of Proposed Regulation

1. Independence and Impartiality—Avoiding Conflicts of Interest

In order to ensure a full and fair review of claims and appeals, the Section 503 Regulation already contains certain standards of independence for persons making claims decisions, and the proposal would build on these standards by providing new criteria for avoiding conflicts of interest. In alignment with criteria in the 2719 Final Rule, paragraph (b)(7) of the proposal explicitly provides that plans providing disability benefits would have to ''ensure that all disability benefit claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision.'' The proposal also would require that decisions regarding hiring, compensation, termination, promotion, or similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of disability benefits. For example, a plan would not be permitted to provide bonuses based on the number of denials made by a claims adjudicator. Similarly, a plan would not be permitted to contract with a medical expert based on the expert's reputation

[3] 65 FR 70246 (Nov. 21, 2000), amended at 66 FR 35887 (July 9, 2001).

[4] A benefit is a disability benefit, subject to the special rules for disability claims under the Section 503 Regulation, if the plan conditions its availability to the claimant upon a showing of disability. It does not matter how the benefit is characterized by the plan or whether the plan as a whole is a pension plan or a welfare plan. If the claims adjudicator must make a determination of disability in order to decide a claim, the claim must be treated as a disability claim for purposes of the Section 503 Regulation. *See* FAQs About The Benefit Claims Procedure Regulation, A–9 (*http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html*).

[5] *See* 75 FR 37188 (June 28, 2010), 75 FR 43330 (July 23, 2010) and 76 FR 37208 (June 24, 2011).

[6] The requirements of the Affordable Care Act and the 2719 IFR do not apply to grandfathered health plans under section 1251 of the Affordable Care Act. The Department in conjunction with the Department of Health and Human Services and the Department of the Treasury published interim final regulations implementing section 1251 of the Affordable Care Act. *See* 75 FR 34538 (June 17, 2010) and 75 FR 70114 (Nov. 17, 2010). Elsewhere in today's version of the **Federal Register**, the Departments published final regulations implementing section 1251 of the Affordable Care Act.

[7] BLS National Compensation Survey, March 2014, at *http://www.bls.gov/ncs/ebs/benefits/2014/ebbl0055.pdf.*

[8] *See* Sean M. Anderson, *ERISA Benefits Litigation: An Empirical Picture,* 28 ABA J. Lab. & Emp. L. 1 (2012).

[9] *See* Francine M. Tishman, Sara Van Looy, & Susanne M. Bruyere, *Employer Strategies for Responding to an Aging Workforce,* NTAR Leadership Center (2012).

[10] The report may be accessed at *http://www.dol.gov/ebsa/publications/2012ACreport2.html.*

for outcomes in contested cases, rather than based on the expert's professional qualifications. These added criteria address practices and behavior which, in the context of disability benefits, the Department finds difficult to reconcile with the ''full and fair review'' guarantee in section 503 of ERISA and which are questionable under ERISA's basic fiduciary standards.

2. Improvements to Basic Disclosure Requirements

The proposal would amend the current disclosure requirements in three significant respects. First, adverse benefit determinations on disability benefit claims would have to contain a discussion of the decision, including the basis for disagreeing with any disability determination by the Social Security Administration (SSA), by a treating physician, or other third party disability payor, to the extent that the plan did not follow those determinations presented by the claimant. This provision would address the confusion often experienced by claimants when there is little or no explanation provided for their plan's determination and/or their plan's determination is contrary to their doctor's opinion or their SSA award of disability benefits.[11]

Second, adverse benefit determinations would have to contain the internal rules, guidelines, protocols, standards or other similar criteria of the plan that were used in denying the claim (or a statement that these do not exist). Third, a notice of adverse benefit determination at the claim stage would have to contain a statement that the claimant is entitled to receive, upon request, relevant documents. Under the current Section 503 Regulation, such statement is required only in notices of an adverse benefit determination denied on appeal.

These provisions would serve the purpose of ensuring that claimants fully understand why their disability benefit claim was denied so they are able to meaningfully evaluate the merits of pursuing an appeal.[12] As described below, paragraph (p) of the proposal incorporates the provision from the 2719 Final Rule that requires notices to be written in a culturally and linguistically appropriate manner.

3. Right To Review and Respond to New Information Before Final Decision

The proposal would add criteria to ensure a full and fair review of denied disability claims by explicitly providing that claimants have a right to review and respond to new evidence or rationales developed by the plan during the pendency of the appeal, as opposed merely to having a right to such information on request only after the claim has already been denied on appeal, as some courts have held under the Section 503 Regulation. Specifically, the proposal provides that prior to a plan's decision on appeal, a disability benefit claimant must be provided, free of charge, with any new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan in connection with the claim, as well as any new or additional rationale for a denial, and a reasonable opportunity for the claimant to respond to such new or additional evidence or rationale. *See* paragraph (h)(4)(i)–(iii) of the proposal. Although these important protections are direct imports from the 2719 Final Rule, they would correct procedural problems evidenced in the litigation even predating the ACA.[13] It is the view of the Department that claimants are deprived of a full and fair review, as required by section 503 of ERISA, when they are prevented from responding at the administrative stage level to evidence and rationales.[14] Accordingly, adding these provisions to the Section 503 Regulation would explicitly address this problem and redress the procedural wrongs evidenced in the litigation under the current regulation.

As an example of how these new provisions would work, assume the plan denies a claim at the initial stage based on a medical report generated by the plan administrator. Also assume the claimant appeals the adverse benefit determination and, during the 45-day period the plan has to make its decision on appeal, the plan administrator causes a new medical report to be generated by a medical specialist who was not involved with developing the first medical report. The proposal would require the plan to automatically furnish to the claimant any new evidence in the second report. The plan would have to furnish the new evidence to the claimant before the expiration of the 45-day period. The evidence would have to be furnished as soon as possible and sufficiently in advance of the applicable deadline (including an extension if available) in order to give the claimant a reasonable opportunity to respond to the new evidence. The plan would be required to consider any response from the claimant. If the claimant's response happened to cause the plan to generate a third medical report containing new evidence, the plan would have to automatically furnish to the claimant any new evidence in the third report. The new evidence would have to be furnished as soon as possible and sufficiently in advance of the applicable deadline to allow the claimant a reasonable opportunity to respond to the new evidence in the third report.

The right of disability benefit claimants to review new evidence or new rationales is a less meaningful right standing by itself than if accompanied by a right to respond to the new information. Consequently, the proposal would also grant the claimant a right to respond to the new information by explicitly providing claimants the right to present evidence and written testimony as part of the claims and appeals process. *See* paragraph (h)(4)(i) of the proposal.[15]

[11] *See, e.g., McDonough* v. *Aetna Life Ins. Co.,* 783 F.3d 374, 382 (1st Cir. 2015) (holding that ''Aetna's failure to articulate the contours of the own occupation standard, apply that standard in a meaningful way, and reason from that standard to an appropriate conclusion regarding the appellant's putative disability renders its benefits-termination decision arbitrary and capricious.''). *See also Montour* v. *Hartford Life and Accident Ins. Co.,* 588 F.3d 623, 637 (9th Cir. 2009) (''Hartford's failure to explain why it reached a different conclusion than the SSA is yet another factor to consider in reviewing the administrator's decision for abuse of discretion, particularly where, as here, a plan administrator operating with a conflict of interest requires a claimant to apply and then benefits financially from the SSA's disability finding.'').

[12] *See, e.g., Bard* v. *Boston Shipping Ass'n.,* 471 F.3d 229, 240 (1st Cir. 2006) (''in relying on the McLaughlin arbitration to reject Bard's claim, the Board relied on a rule, guideline, protocol, or other similar criterion[,] [y]et Bard was not notified of even a condensed version of this rule, nor does it appear that he was timely notified that the McLaughlin arbitrator's opinion existed at all.'') (internal quotation and citation omitted); *Salomaa* v. *Honda Long Term Disability Plan,* 642 F.3d 666, 679 (9th Cir. 2011) (''The review was not 'fair,' as the statute requires, because the plan did not give Salomaa and his attorney and physicians access to the two medical reports of its own physicians upon which it relied, among other reasons. In addition, the plan administrator denied the claim largely on account of absence of objective medical evidence, yet failed to tell Salomaa what medical evidence it wanted.'').

[13] *See, e.g., Metzger* v. *Unum Life Ins. Co. of America,* 476 F.3d 1161, 1165–67 (10th Cir. 2007) (holding that ''subsection (h)(2)(iii) does not require a plan administrator to provide a claimant with access to the medical opinion reports of appeal-level reviewers prior to a final decision on appeal.''). *Accord Glazer* v. *Reliance Standard Life Ins. Co.,* 524 F.3d 1241 (11th Cir. 2008); *Midgett* v. *Washington Group Int'l Long Term Disability Plan,* 561 F.3d 887 (8th Cir. 2009).

[14] Brief of the Secretary of Labor, Hilda L. Solis, as Amicus Curiae in Support of Plaintiff-Appellant's Petition for Rehearing, *Midgett* v. *Washington Group Int'l Long Term Disability Plan,* 561 F.3d 887 (8th Cir. 2009) (No. 08–2523).

[15] Consistent with paragraph (h)(2)(ii) of the Section 503 Regulation (granting claimants the right to ''submit written comments, documents, records, and other information relating to the claim for benefits''), paragraph (h)(4)(i) of the proposal contemplates written evidence and testimony and

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These new rights (*i.e.,* review and response rights) are being proposed as an overlay to the detailed timing rules already in the Section 503 Regulation. In particular, the Section 503 Regulation already contains timing rules for disability claims that allow plan administrators extensions ''for special circumstances'' at the appeals stage, with a related tolling provision if the reason for an extension is ''due to a claimant's failure to submit information necessary to decide a claim.'' *See* 29 CFR 2560.503–1(i)(3)(i) and (i)(4). Comments are requested on whether, and to what extent, modifications to the existing timing rules are needed to ensure that disability benefit claimants and plans will have ample time to engage in the back-and-forth dialog that is contemplated by the new review and response rights.

For instance, is a special tolling rule like the one adopted today for group health plans under the 2719 Final Rule also needed for disability benefit appeals? The 2719 Final Rule, in relevant part, provides ''if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan or issuer must notify the claimant of the benefit determination as soon as a plan or issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.'' *See* 29 CFR 2590.715–2719(b)(2)(ii)(C)(2). The proposal does not adopt this tolling provision from the 2719 Final Rule because, as noted above, the existing Section 503 Regulation already permits plans providing disability benefits to take extensions at the appeals stage. This special tolling provision under the 2719 Final Rule was needed for group health plans because the Section 503 Regulation generally does not permit them to take extensions at the appeals stage.

4. Deemed Exhaustion of Claims and Appeals Processes

The proposal would strengthen the deemed exhaustion provision in the Section 503 Regulation in three important respects. First, the more stringent standards in the 2719 Final Rule would replace existing standards for disability benefit claims in cases where the plan fails to adhere to all the requirements of the Section 503 Regulation. Thus, in this respect, the proposal would adopt the 2719 Final Rule's approach, including an exception in paragraph (l)(2)(ii) for errors that are minor and meet certain other specified conditions. Second, in those situations when the minor errors exception does not apply, the proposal clarifies that the reviewing tribunal should not give special deference to the plan's decision, but rather should review the dispute de novo. Third, protection would be given to claimants whose attempts to pursue remedies in court under section 502(a) of ERISA based on deemed exhaustion are rejected by a reviewing tribunal.[16]

The minor errors exception would operate as follows. The proposal would provide that any violation of the procedural rules in the Section 503 Regulation would permit a claimant to seek immediate court action, unless the violation was: (i) de minimis; (ii) non-prejudicial; (iii) attributable to good cause or matters beyond the plan's control; (iv) in the context of an ongoing good-faith exchange of information; and (v) not reflective of a pattern or practice of non-compliance. In addition, the claimant would be entitled upon request, to an explanation of the plan's basis for asserting that it meets this standard, so that claimant could make an informed judgment about whether to seek immediate review.

Too often claimants find themselves without any forum to resolve their disputes if they prematurely pursued their claims in court before exhausting the plan's administrative remedies. To prevent this from happening to disability benefit claimants even more frequently due to the interplay between the strict compliance standard and the minor errors exception, the proposal contains a special safeguard for claimants who erroneously concluded their plan's violation of the Section 503 Regulation entitled them to take their claim directly to court. The safeguard provides that if a court rejects the claimant's request for immediate review on the basis that the plan met the standards for the minor errors exception, the claim would be considered as re-filed on appeal upon the plan's receipt of the decision of the court. In addition, within a reasonable time after the receipt of the decision, the plan would be required to provide the claimant with notice of the resubmission. At this point, the claimant would have the right to pursue the claim in accordance with the plan's provisions governing appeals, including the right to present evidence and testimony.

The proposed standards set forth the Department's view of the consequences that ensue when a plan fails to provide procedures for disability benefit claims that meet the requirements of section 503 of ERISA as set forth in regulations. They reflect the Department's view that if the plan fails to provide processes that meet the regulatory minimum standards, and does not otherwise qualify for the minor errors exception, the disability benefit claimant should be free to pursue the remedies available under section 502(a) of ERISA on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim. The Department's intentions in including this provision in the proposal are to clarify that the procedural minimums of the Section 503 Regulation are essential to procedural fairness and that a decision made in the absence of the mandated procedural protections should not be entitled to any judicial deference. In this regard, the proposal provides that if a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary. Consequently, rather than giving special deference to the plan, the reviewing court should review the dispute de novo.

5. Coverage Rescissions—Adverse Benefit Determinations

The proposal would add a new provision to address coverage rescissions not already covered under the Section 503 Regulation. For this purpose, a rescission generally is a cancellation or discontinuance of disability coverage that has retroactive effect. The Section 503 Regulation already covers a rescission if the rescission is the basis, in whole or in part, of an adverse benefit determination. For instance, if a plan were to deny a claim based on a conclusion that the claimant is ineligible for benefits due to a rescission of coverage, the claimant would have a right to appeal the adverse benefit determination under the plan's

therefore, in the Department's view, does not entitle the claimant to an oral hearing.

[16] The deemed exhaustion provision in the proposal, if adopted in a final regulation, would supersede any and all prior Departmental guidance with respect to disability benefit claims to the extent such guidance is contrary to the final regulation, including but not limited to FAQ F–2 in Frequently Asked Questions About The Benefit Claims Procedure Regulation (*http://www.dol.gov/ebsa/faqs/faq_claims_proc_reg.html*).

procedures for reviewing denied claims. Other rescissions (those made in the absence of a claim, such as resulting from an internal audit), however, may not be covered by the Section 503 Regulation and, consequently, would not trigger the procedural protections of section 503 of ERISA. Although many rescissions may be proper under the terms of the plan, some rescissions may be improper or erroneous. In the latter case, participants and beneficiaries may face dangerous and unwanted lapses in disability coverage without their knowledge, and without knowing how to challenge the rescission.

Accordingly, the proposed rule would amend the definition of an adverse benefit determination to include, for plans providing disability benefits, a rescission of disability benefit coverage that has a retroactive effect, whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time. Thus, for example, a rescission of disability benefit coverage would be an adverse benefit determination even if the affected participant or beneficiary was not receiving disability benefits at the time of the rescission. The specific amendment would expand the scope of the current definition by expressly providing that an ''adverse benefit determination'' includes a rescission of disability coverage with respect to a participant or beneficiary, and define the term ''rescission'' to mean ''a cancellation or discontinuance of coverage that has retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.'' This new definition is modeled on the definition of rescission in the 2719 Final Rule, but would not be limited to rescissions based upon fraud or intentional misrepresentation of material fact.[17] Consequently, if a plan provides for a rescission of coverage for disability benefits if an individual makes a misrepresentation of material fact, even if the misrepresentation was not intentional or made knowingly, the rescission would be an adverse benefit determination under this proposal. This proposed change would not prohibit rescissions; rather, it would require plans to treat certain rescissions as adverse benefit determinations, thereby triggering the applicable procedural rights under the Section 503 Regulation.

6. Culturally & Linguistically Appropriate Notices

The proposal contains safeguards for individuals who are not fluent in English. The safeguards would require that adverse benefit determinations with respect to disability benefits be provided in a culturally and linguistically appropriate manner in certain situations. The safeguards include standards that illustrate what would be considered ''culturally and linguistically appropriate'' in these situations. The safeguards and standards are incorporated directly from the 2719 Final Rule and reflect public comment on that rule. The relevant standards are contained in paragraph (p) of the proposal.

Under the proposed safeguards, if a claimant's address is in a county where 10 percent or more of the population residing in that county, as determined based on American Community Survey (ACS) data published by the United States Census Bureau, are literate only in the same non-English language, notices of adverse benefit determinations to the claimant would have to include a prominent one-sentence statement in the relevant non-English language about the availability of language services.[18] In addition, the plan would be required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request. Oral language services includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals in any applicable non-English language.

Two hundred and fifty-five (255) U.S. counties (78 of which are in Puerto Rico) meet the 10 percent threshold at the time of this proposal. The overwhelming majority of these are Spanish; however, Chinese, Tagalog, and Navajo are present in a few counties, affecting five states (specifically, Alaska, Arizona, California, New Mexico, and Utah). A full list of the affected U.S. counties is available on the Department's Web site and updated annually.[19]

D. Miscellaneous

1. Technical Correction

The Department has determined that a minor technical fix to the Section 503 Regulation is required with respect to disability claims. The Department proposes to clarify that the extended time frames for deciding disability claims, provided by the quarterly meeting rule found in the current regulation at 29 CFR 2560.503–1(i)(1)(ii), are applicable only to multiemployer plans. Accordingly, the proposal would amend paragraph (i)(3) to correctly refer to the appropriate subparagraph in (i)(1) of the Section 503 Regulation.

2. Request for Comments—Statute of Limitations

ERISA does not specify the period after a final adverse benefit determination within which a civil action must be filed under section 502(a)(1)(B) of ERISA. Instead, the federal courts have generally looked to analogous state laws to determine an appropriate limitations period. Analogous state law limitations periods vary, but they generally start with the same event, the plan's final benefit determination. Plan documents and insurance contracts sometimes have limitations periods which may override analogous state laws. These contractual limitations periods are not uniform and the events that trigger their running vary. In addition, claimants may not have read the relevant plan documents or the documents may be difficult for claimants to understand. The Supreme Court recently upheld the use of contractual limitations periods so long as they are reasonable.[20]

A separate issue, not before the Supreme Court in *Heimeshoff* v. *Hartford Life & Accident Ins. Co.,* is whether plans should provide participants with notice with respect to contractual limitations periods in adverse benefit determinations on review. The courts of appeals are currently in disagreement on whether plans should provide such notice under the Section 503 Regulation.[21] Inasmuch

[17] The Affordable Care Act prohibits group health plans from rescinding coverage with respect to an individual once the individual is covered, except in the case of fraud or intentional misrepresentation of material fact. Consequently, the definition of adverse benefit determination in the 2719 Final Rule effectively is limited to these situations. *See* 75 FR 37188 and 75 FR 43330.

[18] The Department provides sample sentences in Model Notices at *www.dol.gov/ebsa/healthreform/regulations/internalclaimsandappeals.html.*

[19] *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data.pdf.*

[20] *Heimeshoff* v. *Hartford Life & Accident Ins. Co.,* 134 S.Ct. 604, 611 (2013).

[21] *Compare Moyer* v. *Metropolitan Life Ins. Co.,* 762 F.3d 503, 505 (6th Cir. 2014) (''The claimant's right to bring a civil action is expressly included as a part of those procedures for which applicable time limits must be provided'' in the notice of adverse benefit determination on review) *with Wilson* v. *Standard Ins. Co.,* 613 F. App'x 841, 844 n.3 (11th Cir. 2015) (per curiam) (''We are not persuaded by the Sixth Circuit's conclusion that a claims administrator's interpretation of the ambiguous § 2560.503–1(g)(1)(iv) not to require notice in the

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as plans are responsible for implementing contractual limitations provisions, plans may be in a better position than claimants to understand and to explain what those provisions mean.[22] In addition, it could prove costly to a participant to hire a lawyer to provide an interpretation that should be readily available to the plan at little or no cost. Accordingly, the Department solicits comments on whether the final regulation should require plans to provide claimants with a clear and prominent statement of any applicable contractual limitations period and its expiration date for the claim at issue in the final notice of adverse benefit determination on appeal and with an updated notice of that expiration date if tolling or some other event causes that date to change.

E. Effective Date

The Department proposes to make this regulation effective 60 days after the date of publication of the final rule in the **Federal Register**.

F. Economic Impact and Paperwork Burden

1. Background and Need for Regulatory Action

As discussed in Section B of this preamble, the proposed amendments would revise and strengthen the current rules regarding claims and appeals applicable to ERISA-covered plans providing disability benefits primarily by adopting several of the new procedural protections and safeguards made applicable to ERISA-covered group health plans by the Affordable Care Act. Before the enactment of the Affordable Care Act, group health plan sponsors and sponsors of ERISA-covered plans providing disability benefits were required to implement claims and appeal processes that complied with the Section 503 Regulation. The enactment of the ACA and the issuance of the implementing interim final regulations resulted in disability benefit claimants receiving fewer procedural protections than group health plan participants even though litigation regarding disability benefit claims is prevalent today.

The Department believes this action is necessary to ensure that disability claimants receive the more stringent procedural protections that Congress and the President established for group health care claimants under the Affordable Care Act. This will result in some participants receiving benefits they might otherwise have been incorrectly denied in the absence of the fuller protections provided by the proposed regulation. This will help alleviate the financial and emotional hardship suffered by many individuals when they lose earnings due to their becoming disabled. The proposed rule also should help limit the volume and constancy of disability benefits litigation.

The Department has crafted these proposed regulations to secure the protections of those submitting disability benefit claims. In accordance with OMB Circular A–4, the Department has quantified the costs where possible and provided a qualitative discussion of the benefits that are associated with these proposed regulations.

2. Executive Order 12866 and 13563—Department of Labor

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

Under Executive Order 12866 (58 FR 51735), ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. It has been determined that this rule is significant within the meaning of section 3(f) (4) of the Executive Order. Therefore, OMB has reviewed these proposed rules pursuant to the Executive Order. The Department provides an assessment of the potential costs and benefits of proposed rule below, as summarized in Table 1, below.

claim denial letter of the contractual time limit for judicial review necessarily amounts to a failure to comply with § 1133 that renders the contractual limitations provision unenforceable.'').

[22] *Cf. Moyer,* 762 F.3d at 507 (''The exclusion of the judicial review time limits from the adverse benefit determination letter was inconsistent with ensuring a fair opportunity for review and rendered the letter not in substantial compliance.'')

TABLE 1—ACCOUNTING TABLE

Category	Estimate	Year dollar	Discount rate	Period covered
Benefits—Qualitative	The Department expects that these proposed regulations would improve the procedural protections for workers who become disabled and make claims for disability benefits from employee benefit plans. This would cause some participants to receive benefits they might otherwise have been incorrectly denied absent the fuller protections provided by the proposed regulations. In other circumstances, expenditures by plans may be reduced as a fuller and fairer system of disability claims and appeals processing helps facilitate participant acceptance of cost management efforts. Greater certainty and consistency in the handling of disability benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated may lead to efficiency gains in the system, both in terms of the allocation of spending at a macro-economic level as well as operational efficiencies among individual plans.			
Costs				
Annualized	$3,019,000	2015	7%	2016–2025
Monetized	$3,019,000	2015	3%	2016–2025
Qualitative	These requirements would impose modest costs on plan, because many plans already are familiar with the rules that would apply to disability benefit claims due to their current application to group health plans. As discussed in detail in the cost section below, the Department quantified the costs associated with two provisions of the proposed regulations: the requirement to provide additional information to claimants in the appeals process and the requirement to provide information in a culturally and linguistically appropriate manner.			

3. Estimated Number of Affected Entities

The Department does not have complete data on the number of plans providing disability benefits or the total number of participants covered by such plans. All ERISA-covered welfare benefit plans with more than 100 participants are required to file a Form 5500. Only some ERISA-covered welfare benefit plans with less than 100 participants are required to file for various reasons, but this number is very small. Based on current trends in the establishment of pension and health plans, there are many more small plans than large plans, but the majority of participants are covered by the large plans.

Data from the 2013 Form 5500 indicates that there are 34,300 plans covering 52.2 million participants reporting a code indicating they provide temporary disability benefits, and 26,400 plans covering 46.9 million participants reporting a code indicating they provide long-term disability benefits. To put these numbers in perspective, using the CPS and the MEPS–IC, the Department estimates that there are 140,000 large group health plans and 2.2 million small group health plans.

4. Benefits

In developing these proposed regulations, the Department closely considered their potential economic effects, including both benefits and costs. The Department does not have sufficient data to quantify the benefits associated with these proposed regulations due to data limitations and a lack of effective measures. Therefore, the Department provides a qualitative discussion of the benefits below.

These proposed regulations would implement a more uniform and rigorous system of disability claims and appeals processing that conforms to the rules applicable to group health plans. In general, the Department expects that these proposed regulations would improve the procedural protections for workers who become disabled and make claims for disability benefits from employee benefit plans. This will cause some participants to receive benefits that, absent the fuller protections of the regulation, they might otherwise have been incorrectly denied. In other circumstances, expenditures by plans may be reduced as a fuller and fairer system of claims and appeals processing helps facilitate participant acceptance of cost management efforts. Greater certainty and consistency in the handling of disability benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated may lead to efficiency gains in the system, both in terms of the allocation of spending at a macro-economic level as well as operational efficiencies among individual plans. This certainty and consistency can also be expected to benefit, to varying degrees, all parties within the system and to lead to broader social welfare gains, particularly for participants.

The Department expects that these proposed regulations also will improve the efficiency of plans providing disability benefits by enhancing their transparency and fostering participants' confidence in their fairness. The enhanced disclosure and notice requirements of these proposed regulations would benefit participants and beneficiaries better understand the reasons underlying adverse benefit determinations and their appeal rights.

For example, the proposed regulations would require adverse benefit determinations to contain a discussion of the decision, including the basis for disagreeing with any disability determination by the Social Security Administration (SSA), a treating physician, or other third party disability determinations, to the extent that the plan did not follow those determinations presented by the

claimant. This provision would address the confusion often experienced by claimants when there is little or no explanation provided for their plan's determination and/or their plan's determination is contrary to their doctor's opinion or their SSA award of disability benefits.

Under the proposal, adverse benefit determinations would have to contain the internal rules, guidelines, protocols, standards or other similar criteria of the plan that were used in denying the claim (or a statement that these do not exist), and a notice of adverse benefit determination at the claim stage would have to contain a statement that the claimant is entitled to receive, upon request, relevant documents. These provisions would benefit claimants by ensuring that they fully understand why their claim was denied so they are able to meaningfully evaluate the merits of pursuing an appeal.

The proposal also would require adverse benefit determinations for certain participants and beneficiaries that are not fluent in English to be provided in a culturally and linguistically appropriate manner in certain situations. Specifically, if a claimant's address is in a county where 10 percent or more of the population residing in that county, as determined based on American Community Survey (ACS) data published by the United States Census Bureau, are literate only in the same non-English language, notices of adverse benefit determinations to the claimant would have to include a prominent one-sentence statement in the relevant non-English language about the availability of language services. This provision would ensure that certain disability claimants that are not fluent in English understand the notices received from the plan regarding their disability claims and their right to appeal denied claims. The proposal also would provide claimants with the right to review and respond to new evidence or rationales developed by the plan during the pendency of the appeal, as opposed merely to having a right to such information on request only after the claim has already been denied on appeal, as some courts have held under the current regulation. Specifically, the proposal provides that prior to a plan's decision on appeal, a disability benefit claimant must be provided, free of charge, with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan in connection with the claim, as well as any new or additional rationale for a denial, and a reasonable opportunity for the claimant to respond to such new or additional evidence or rationale. These important protections would benefit participants and beneficiaries by correcting procedural wrongs evidenced in the litigation even predating the ACA.

The voluntary nature of the employment-based benefit system in conjunction with the open and dynamic character of labor markets make explicit as well as implicit negotiations on compensation a key determinant of the prevalence of employee benefits coverage. The prevalence of benefits is therefore largely dependent on the efficacy of this exchange. If workers perceive that there is the potential for inappropriate denial of benefits or handling of appeals, they will discount the value of such benefits to adjust for this risk. This discount drives a wedge in compensation negotiation, limiting its efficiency. With workers unwilling to bear the full cost of the benefit, fewer benefits will be provided. To the extent that workers perceive that these proposed regulations, supported by enforcement authority, reduces the risk of inappropriate denials of disability benefits, the differential between the employers' costs and workers' willingness to accept wage offsets is minimized.

These proposed regulations would reduce the likelihood of inappropriate benefit denials by requiring all disability claims and appeals to be adjudicated by persons that are independent and impartial. Specifically, the proposal would prohibit hiring, compensation, termination, promotion, or other similar decisions with respect to any individual (such as a claims adjudicator or medical expert) to be made based upon the likelihood that the individual will support the plan's benefits denial. This would enhance participants' perception that their disability plan's claims and appeals processes are operated in a fair manner.

The proposal would add criteria to ensure a full and fair review of denied claims by making it explicitly clear that claimants have a right to review and respond to new evidence or rationales developed by the plan during the pendency of the appeal rather than only after the claim has already been denied on appeal, as some courts have held under the current regulation. Specifically, the proposal would require a disability benefit claimant to be provided, free of charge, with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan in connection with the claim, as well as any new or additional rationale for a denial, and a reasonable opportunity for the claimant to respond to such new or additional evidence or rationale before issuing an adverse benefit determination on review.

Providing a more formally sanctioned framework for adjudicating disability claims and appeals facilitates the adoption of cost containment programs by employers who, in the absence of a regulation providing some guidance, may have opted to pay questionable claims rather than risk alienating participants or being deemed to have breached their fiduciary duty.

In summary, the proposed rules provide more uniform standards for handling disability benefit claims and appeals that are comparable to the rules applicable to group health plans. These rules would reduce the incidence of inappropriate denials, averting serious financial hardship and emotional distress for participants and beneficiaries that are impacted by a disability. They also would enhance participants' confidence in the fairness of their plans' claims and appeals processes. Finally, by improving the transparency and flow of information between plans and claimants, the proposed regulations would enhance the efficiency of labor and insurance markets. The Department therefore concludes that the economic benefits of these proposed regulations will justify their costs.

5. Costs and Transfers

The Department has quantified the primary costs associated with these proposed regulations' requirements to (1) provide the claimant free of charge with any new or additional evidence considered, and (2) to providing notices of adverse benefit determinations in a culturally and linguistically appropriate manger. These requirements and their associated costs are discussed below.

Provision of new or additional evidence or rationale: As stated earlier in this preamble, before a plan providing disability benefits can issue a notice of adverse benefit determination on review on a disability benefit claim, these proposed regulations would require such plans to provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan as soon as possible and sufficiently in advance of the date the notice of adverse benefit determination on review is required to be provided and any new or additional rationale sufficiently in advance of the due date of the response to an adverse benefit determination on review. This requirement increases the administrative burden on plans to

prepare and deliver the enhanced information to claimants. The Department is not aware of data suggesting how often plans rely on new or additional evidence or rationale during the appeals process or the volume of materials that are received.

For purposes of this regulatory impact analysis, the Department assumes, as an upper bound, that all appealed claims will involve a reliance on additional evidence or rationale. The Department assumes that this requirement will impose an annual aggregate cost of $1.9 million. The Department estimated this cost by assuming that compliance will require medical office staff, or other similar staff in other service setting with a labor rate of $30, five minutes [23] to collect and distribute the additional evidence considered, relied upon, or generated by (or at the direction of) the plan during the appeals process. The Department estimates that on average, material, printing and postage costs will total $2.50 per mailing. The Department further assumes that 75 percent of all mailings will be distributed electronically with no associated material, printing or postage costs.[24]

The Department lacks data on the number of disability claims that are filed or denied. Therefore, the Department estimates the number of short- and long-term disability claims based on the percentage of private sector employees (119 million) [25] that participate in short- and long-term disability programs (approximately 39 and 33 percent respectively).[26] The Department estimates the number of claims per covered life for long-term disability benefits based on the percentage of covered individuals that file claims under the Social Security Disability Insurance Program (two percent of covered individuals). The Department does not have sufficient data to estimate the percentage of covered individuals that file short-term disability claims. Therefore, for purposes of this analysis, the Department estimates of six percent of covered lives file such claims, because it believes that short-term disability claims rates are higher than long-term disability claim rates.

The Department estimates the number of denied claims that would be covered by the rule in the following manner: For long-term disability, the percent of claims denied is estimated using the percent of denied claims for the Social Security Disability Insurance Program (75 percent). For short-term disability, the estimate of denied claims (three percent) is from the 2012 National Compensation Survey: Employee Benefits in Private Industry in the United States. The estimates are provided in the table below.

TABLE 2—FAIR AND FULL REVIEW BURDEN

[in thousands]

	Short-Term		Long-Term		Total		
	Electronic	Paper	Electronic	Paper	Electronic	Paper	All
Denied Claims and lost Appeals with Additional Information	63	21	463	154	526	175	701
Mailing cost per event	$0.00	$0.99	$0.00	$0.99	$0.00	$0.99	
Total Mailing Cost	$0.00	$21	$0.00	$153	$0.00	$173	$173
Preparation Cost per event	$2.50	$2.50	$2.50	$2.50	$2.50	$2.50	$2.50
Total Preparation cost	$157	$52	$1,156	$385	$1,313	$438	$1,751
Total	$157	$73	$1,156	$538	$1,313	$611	$1,925

Providing Notices in a Culturally and Linguistically Appropriate Manner: The proposed regulations would require notices of adverse benefit determinations with respect to disability benefits to be provided in a culturally and linguistically appropriate manner in certain situations. This requirement is satisfied if plans provide oral language services including answering questions and providing assistance with filing claims and appeals in any applicable non-English language. These proposed regulations also require each notice sent by a plan to which the requirement applies to include a one-sentence statement in the relevant non-English that translation services are available. Plans also must provide, upon request, a notice in any applicable non-English language.

The Department expects that the largest cost associated with the requirement for culturally and linguistically appropriate notices will be for plans to provide notices in the applicable non-English language upon request. Based on the 2013 ACS data, the Department estimates that there are

[23] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/archives/ocwage_04012014.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/archives/ecec_09102014.pdf*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/archives/eci_10312014.pdf*).

[24] This estimate is based on the methodology used to analyze the cost burden for the Section 503 Regulation (OMB Control Number 1210–0053).

[25] BLS Employment, Hours, and Earnings from the Current Employment Statistics survey (National) Table B–1.

[26] ''Beyond the Numbers: Disability Insurance Plans Trends in Employee Access and Employer Cost,'' February 2015 Vol. 4 No. 4. *http://www.bls.gov/opub/btn/volume-4/disability-insurance-plans.htm.*

about 11.4 million individuals living in covered counties that are literate in a non-English Language.[27] To estimate the number of the 11.4 million individuals that might make a request, the Department estimates the number of workers in each state with access to short-term and long-term disability insurance (total population in county* state labor force participation rate* state employment rate).[28] [29] The number of employed workers then was multiplied by an estimate of the share of workers participating in disability benefits, 39 percent for short-term and 33 percent for long term disability.[30]

In discussions with the regulated community, the Department found that experience in California, which has a State law requirement for providing translation services, indicates that requests for translations of written documents averages 0.098 requests per 1,000 members for health claims. While the California law is not identical to these proposed regulations, and the demographics for California do not match other counties, for purposes of this analysis, the Department uses this percentage to estimate of the number of translation service requests that plans could expect to receive. As there are fewer disability claims than health claims, the Department believes that this estimate significantly overstates the cost. Industry experts also told the Department that while the cost of translation services varies, $500 per document is a reasonable approximation of translation cost.

Based on the foregoing, the Department estimates that the cost to provide translation services will be approximately $1.1 million annually (23,206,000 lives * 0.098/1000 * $500).

6. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities. Unless an agency determines that a proposal is not likely to have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis (IRFA) of the proposed rule. The Department's IRFA of the proposed rule is provided below.

Need for and Objectives of the Rule: As discussed in section B of this preamble, the proposed amendments would revise and strengthen the current rules regarding claims and appeals applicable to ERISA-covered plans providing disability benefits primarily by adopting several of the new procedural protections and safeguards made applicable to ERISA-covered group health plans by the Affordable Care Act. Before the enactment of the Affordable Care Act, group health plan sponsors and sponsors of ERISA-covered plans providing disability benefits were required to implement internal claims and appeal processes that complied with the Section 503 Regulation. The enactment of the Affordable Care Act and the issuance of the implementing interim final regulations resulted in disability plan claimants receiving fewer procedural protections than group health plan participants even though litigation regarding disability benefit claims is prevalent today.

The Department believes this action is necessary to ensure that disability claimants receive the same protections that Congress and the President established for group health care claimants under the Affordable Care Act. This will result in some participants receiving benefits they might otherwise have been incorrectly denied in the absence of the fuller protections provided by the proposed regulation. This will help alleviate the financial and emotional hardship suffered by many individuals when they lose earnings due to their becoming disabled. The proposed rule also should help limit the volume and constancy of disability benefits litigation.

Affected Small Entities: The Department does not have complete data on the number of plans providing disability benefits or the total number of participants covered by such plans. All ERISA-covered welfare benefit plans with more than 100 participants are required to file a Form 5500. Only some ERISA-covered welfare benefit plans with less than 100 participants are required to file for various reasons, but this number is very small. Based on current trends in the establishment of pension and health plans, there are many more small plans than large plans, but the majority of participants are covered by the large plans.

Data from the 2013 Form 5500 indicates that there are 34,300 plans covering 52.2 million participants reporting a code indicating they provide temporary disability benefits, and 26,400 plans covering 46.9 million participants reporting a code indicating they provide long-term disability benefits. To put these numbers in perspective, using the CPS and the MEPS–IC, the Department estimates that there are 140,000 large group health plans and 2.2 million small group health plans.

Impact of the Rule: The Department has quantified the primary costs associated with these proposed regulations' requirements to (1) provide the claimant free of charge with any new or additional evidence considered, and (2) to providing notices of adverse benefit determinations in a culturally and linguistically appropriate manger. These requirements and their associated costs are discussed in the Costs and Transfers section above.

Provision of new or additional evidence or rationale: As stated earlier in this preamble, before a plan can issue a notice of adverse benefit determination on review, these proposed regulations would require plans to provide disability benefit claimants, free of charge, with any new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan as soon as possible and sufficiently in advance of the date the notice of adverse benefit determination on review is required to be provided and any new or additional rationale sufficiently in advance of the due date of the response to an adverse benefit determination on review.

The Department is not aware of data suggesting how often plans rely on new or additional evidence or rationale during the appeals process or the volume of materials that are received. The Department estimated the cost per claim by assuming that compliance will require medical office staff, or other similar staff in other service setting with a labor rate of $30, five minutes[31] to

[27] *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2009-13-CLAS-County-Data.pdf. http://www.dol.gov/ebsa/pdf/coveragebulletin2014.pdf* Table 1C.

[28] Labor force Participation rate: *http://www.bls.gov/lau/staadata.txt* Unemployment rate: *http://www.bls.gov/lau/lastrk14.htm.*

[29] Please note that using state estimates of labor participation rates and unemployment rates could lead to an over estimate as those reporting in the ACS survey that they speak English less than ''very well'' are less likely to be employed.

[30] ''Beyond the Numbers: Disability Insurance Plans Trends in Employee Access and Employer Cost,'' February 2015 Vol. 4 No. 4. *http://www.bls.gov/opub/btn/volume-4/disability-insurance-plans.htm.*

[31] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/archives/ocwage_04012014.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June

collect and distribute the additional evidence considered, relied upon, or generated by (or at the direction of) the plan during the appeals process. The Department estimates that on average, material, printing and postage costs will total $2.50 per mailing. The Department further assumes that 75 percent of all mailings will be distributed electronically with no associated material, printing or postage costs.

Providing Notices in a Culturally and Linguistically Appropriate Manner: The proposed regulations would require that notices of adverse benefit determinations with respect to disability benefits be provided in a culturally and linguistically appropriate manner in certain situations. This requirement is satisfied if plans provide oral language services including answering questions and providing assistance with filing claims and appeals in any applicable non-English language. These proposed regulations also require such notices of adverse benefit determinations sent by a plan to which the requirement applies to include a one-sentence statement in the relevant non-English language about the availability of language services. Plans also must provide, upon request, such notices of adverse benefit determinations in the applicable non-English language.

The Department expects that the largest cost associated with the requirement for culturally and linguistically appropriate notices will be for plans to provide notices in the applicable non-English language upon request. Industry experts also told the Department that while the cost of translation services varies, $500 per document is a reasonable approximation of translation cost.

In discussions with the regulated community, the Department found that experience in California, which has a State law requirement for providing translation services, indicates that requests for translations of written documents averages 0.098 requests per 1,000 members for health claims. While the California law is not identical to these proposed regulations, and the demographics for California do not match other counties, for purposes of this analysis, the Department used this percentage to estimate of the number of translation service requests plans could expect to receive. Based on the low number of requests per claim, the Department expects that translation costs would be included as part of a package of services offered to a plan, and that the costs of actual requests will be spread across multiple plans.

Duplication, Overlap, and Conflict with Other Rules and Regulations: The Department does not believe that the proposed actions would conflict with any relevant regulations, federal or other.

Based on the foregoing, the Department hereby certifies that these final regulations will not have a significant economic impact on a substantial number of small entities.

7. Paperwork Reduction Act

As part of its continuing effort to reduce paperwork and respondent burden, the Department conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This helps to ensure that the public understands the Department's collection instructions, respondents can provide the requested data in the desired format, reporting burden (time and financial resources) in minimized, collection instructions are clearly understood, and the Department can properly assess the impact of collection requirements on respondents.

As discussed above, these proposed regulations would require plans providing disability benefits to meet additional requirements when complying with the Department's claims procedure regulation. Some of these requirements would require disclosures covered by the PRA. These requirements include disclosing information to ensure a full and fair review of a claim or appeal, and the content of notices of benefit determinations.

Currently, the Department is soliciting 60 days of public comments concerning these disclosures. The Department has submitted a copy of these proposed regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Department and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395–7285 or by email to *oira_submission@omb.eop.gov.* A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers. Email: *ebsa.opr@dol.gov.* ICRs submitted to OMB also are available at reginfo.gov (*http://www.reginfo.gov/public/do/* PRAMain).

ERISA-covered group health plans already are required to comply with the requirements of the Section 503 Regulation. The Section 503 Regulation requires, among other things, plans to provide a claimant who is denied a claim with a written or electronic notice that contains the specific reasons for denial, a reference to the relevant plan provisions on which the denial is based, a description of any additional information necessary to perfect the claim, and a description of steps to be taken if the participant or beneficiary wishes to appeal the denial. The regulation also requires that any adverse decision upon review be in writing (including electronic means) and include specific reasons for the decision, as well as references to relevant plan provisions.

With the implementation of the ACA claims regulations, participants of disability plans receive fewer procedural protections than participants in group health plan participants, while they experience similar if not significantly more issues with the claims review process. These proposed regulations would reduce the inconsistent procedural rules applied to health and disability benefit plan claims and provide similar procedural

2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/archives/ecec_09102014.pdf*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/archives/eci_10312014.pdf*).

protections to both groups of plan participants.

The burdens associated with this proposed regulatory requirements are summarized below.

Type of Review: Revised collection.

Agencies: Employee Benefits Security Administration, Department of Labor.

Title: ERISA Claims Procedures.

OMB Number: 1210–0053.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 5,961,000.

Total Responses: 311,867,000.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 515,000.

Estimated Total Annual Burden Cost: $654,579,000.

8. Congressional Review Act

These proposed regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and, if finalized, would be transmitted to Congress and the Comptroller General for review. The proposed rule is not a ''major rule'' as that term is defined in 5 U.S.C. 804, because it is not likely to result in an annual effect on the economy of $100 million or more.

9. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statements assessing the effects of any Federal Mandate in a proposed or final agency rule that may result in annual expenditures of $100 million (as adjusted for inflation) in any one year by State, local and tribal governments, in the aggregate, or the private sector. Such a mandate is deemed to be a ''significant regulatory action.'' These proposed regulations are not a ''significant regulatory action.'' Therefore the Department concludes that these proposed regulations would not impose an unfunded mandate on State, local and tribal governments, in the aggregate, or the private sector.

10. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the final regulation.

In the Departments of Labor's view, these proposed regulations have federalism implications because they would have direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government to the extent states have enacted laws affecting disability plan claims and appeals that contain similar requirements to the proposal. The Department believes these effects are limited, because although section 514 of ERISA supersedes State laws to the extent they relate to any covered employee benefit plan, it preserves State laws that regulate insurance, banking, or securities. In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Department welcomes input from affected States, including the National Association of Insurance Commissioners and State insurance officials, regarding this assessment.

List of Subjects in 29 CFR Part 2560

Claims, Employee benefit plans, Pensions.

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 2560 as set forth below:

PART 2560—RULES AND REGULATIONS FOR ADMINISTRATION AND ENFORCEMENT

■ 1. The authority citation for part 2560 is revised to read as follows:

Authority: 29 U.S.C. 1132, 1135, and Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012). Section 2560.503–1 also issued under 29 U.S.C. 1133. Section 2560.502c–7 also issued under 29 U.S.C. 1132(c) (7). Section 2560.502c–4 also issued under 29 U.S.C. 1132(c)(4). Section 2560.502c–8 also issued under 29 U.S.C. 1132(c)(8).

■ 2. Section 2560.503–1 is amended by:

■ a. Adding paragraph (b)(7).

■ b. Revising paragraph (g)(1)(v) introductory text.

■ c. Adding paragraphs (g)(1)(vii) and (viii).

■ d. Revising paragraphs (h)(4), (i)(3)(i), and (j)(5) introductory text.

■ e. Adding paragraphs (j)(6) and (7).

■ f. Revising paragraphs (l) and (m)(4).

■ g. Adding paragraphs (m)(9) and (p).

The revisions and additions read as follows:

§ 2560.503–1 Claims procedure.

* * * * *

(b) * * *

(7) In the case of a plan providing disability benefits, the plan must ensure that all claims and appeals for disability benefits are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

* * * * *

(g)* * * (1) * * *

(v) In the case of an adverse benefit determination by a group health plan—

* * * * *

(vii) In the case of an adverse benefit determination with respect to disability benefits—

(A) A discussion of the decision, including, to the extent that the plan did not follow or agree with the views presented by the claimant to the plan of health care professionals treating a claimant or the decisions presented by the claimant to the plan of other payers of benefits who granted a claimant's similar claims (including disability benefit determinations by the Social Security Administration), the basis for disagreeing with their views or decisions;

(B) Either the specific internal rules, guidelines, protocols, standards or other similar criteria of the plan relied upon in making the adverse determination or, alternatively, a statement that such rules, guidelines, protocols, standards or other similar criteria of the plan do not exist; and

(C) A statement that the claimant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the claimant's claim for benefits. Whether a document, record, or other information is relevant to a claim for benefits shall be determined by reference to paragraph (m)(8) of this section.

(viii) In the case of an adverse benefit determination with respect to disability benefits, the notification shall be provided in a culturally and linguistically appropriate manner (as described in paragraph (p) of this section).

* * * * *

(h) * * *

(4) *Plans providing disability benefits.* The claims procedures of a plan providing disability benefits will not, with respect to claims for such benefits, be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless, in addition to complying with the requirements of paragraphs (h)(2)(ii) through (iv) and (h)(3)(i) through (v) of this section, the claims procedures—

(i) Allow a claimant to review the claim file and to present evidence and testimony as part of the disability benefit claims and appeals process;

(ii) Provide that, before the plan can issue an adverse benefit determination on review on a disability benefit claim, the plan administrator shall provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan (or at the direction of the plan) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided under paragraph (i) of this section to give the claimant a reasonable opportunity to respond prior to that date; and

(iii) Provide that, before the plan can issue an adverse benefit determination on review on a disability benefit claim based on a new or additional rationale, the plan administrator shall provide the claimant, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided under paragraph (i) of this section to give the claimant a reasonable opportunity to respond prior to that date.

* * * * *

(i) * * *

(3) *Disability claims.* (i) Except as provided in paragraph (i)(3)(ii) of this section, claims involving disability benefits (whether the plan provides for one or two appeals) shall be governed by paragraph (i)(1)(i) of this section, except that a period of 45 days shall apply instead of 60 days for purposes of that paragraph.

* * * * *

(j) * * *

(5) In the case of a group health plan—

* * *

(6) In the case of an adverse benefit decision with respect to disability benefits—

(i) A discussion of the decision, including, to the extent that the plan did not follow or agree with the views presented by the claimant to the plan of health care professionals treating a claimant or the decisions presented by the claimant to the plan of other payers of benefits who granted a claimant's similar claims (including disability benefit determinations by the Social Security Administration), the basis for disagreeing with their views or decisions; and

(ii) Either the specific internal rules, guidelines, protocols, standards or other similar criteria of the plan relied upon in making the adverse determination or, alternatively, a statement that such rules, guidelines, protocols, standards or other similar criteria of the plan do not exist.

(7) In the case of an adverse benefit determination on review with respect to a claim for disability benefits, the notification shall be provided in a culturally and linguistically appropriate manner (as described in paragraph (p) of this section).

* * * * *

(l) *Failure to establish and follow reasonable claims procedures.* (1) *In general.* Except as provided in paragraph (l)(2) of this section, in the case of the failure of a plan to establish or follow claims procedures consistent with the requirements of this section, a claimant shall be deemed to have exhausted the administrative remedies available under the plan and shall be entitled to pursue any available remedies under section 502(a) of the Act on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim.

(2) *Plans providing disability benefits.* (i) In the case of a claim for disability benefits, if the plan fails to strictly adhere to all the requirements of this section with respect to a claim, the claimant is deemed to have exhausted the administrative remedies available under the plan, except as provided in paragraph (l)(2)(ii) of this section. Accordingly, the claimant is entitled to pursue any available remedies under section 502(a) of ERISA on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(ii) Notwithstanding paragraph (l)(2)(i) of this section, the administrative remedies available under a plan with respect to claims for disability benefits will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan demonstrates that the violation was for good cause or due to matters beyond the control of the plan and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan. The claimant may request a written explanation of the violation from the plan, and the plan must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the administrative remedies available under the plan to be deemed exhausted. If a court rejects the claimant's request for immediate review under paragraph (l)(2)(i) of this section on the basis that the plan met the standards for the exception under this paragraph (l)(2)(ii), the claim shall be considered as re-filed on appeal upon the plan's receipt of the decision of the court. Within a reasonable time after the receipt of the decision, the plan shall provide the claimant with notice of the resubmission.

* * * * *

(m) * * *

(4) The term ''adverse benefit determination'' means:

(i) Any of the following: a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant's or beneficiary's eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate; and

(ii) In the case of a plan providing disability benefits, the term ''adverse benefit determination'' also means any rescission of disability coverage with respect to a participant or beneficiary (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time). For

this purpose, the term ''rescission'' means a cancellation or discontinuance of coverage that has retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

* * * * *

(9) The term ''claim file'' means the file or other compilation of relevant information, as described in paragraph (m)(8) of this section, to be considered in the full and fair review of a disability benefit claim.

* * * * *

(p) *Standards for culturally and linguistically appropriate notices.* A plan is considered to provide relevant notices in a ''culturally and linguistically appropriate manner'' if the plan meets all the requirements of paragraph (p)(1) of this section with respect to the applicable non-English languages described in paragraph (p)(2) of this section.

(1) *Requirements.* (i) The plan must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals in any applicable non-English language;

(ii) The plan must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan.

(2) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

Signed at Washington, DC, this 6th day of November, 2015.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2015–29295 Filed 11–13–15; 4:15 pm]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 7 and 75

[Docket No. MSHA–2013–0033]

RIN 1219–AB79

Refuge Alternatives for Underground Coal Mines

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for Information; extension of comment period.

SUMMARY: In response to requests from interested parties, the Mine Safety and Health Administration (MSHA) is extending the comment period on the Request for Information on Refuge Alternatives for Underground Coal Mines. This extension gives stakeholders additional time to provide input on the current state of refuges in use and recent research and new technology that may lead to the development of a new generation of refuges.

DATES: Comments must be received or postmarked by midnight Eastern Standard Time on January 15, 2016.

ADDRESSES: Submit comments and informational materials, identified by RIN 1219–AB79 or Docket No. MSHA–2013–0033, by one of the following methods:

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-Mail: zzMSHA-comments@dol.gov.* Include RIN 1219–AB79 or Docket No. MSHA–2014–0033 in the subject line of the message.
- *Mail:* MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452.
- *Fax:* 202–693–9441.
- *Hand Delivery or Courier:* MSHA, 201 12th Street South, Suite 4E401, Arlington, Virginia, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal holidays. Sign in at the receptionist's desk on the 4th floor.

Instructions: All submissions must include RIN 1219–AB79 or Docket No. MSHA–2013–0033. Do not include personal information that you do not want publicly disclosed; MSHA will post all comments without change to *http://www.regulations.gov* and *http://www.msha.gov/currentcomments.asp*, including any personal information provided.

Docket: For access to the docket to read comments received, go to *http://www.regulations.gov* or *http://www.msha.gov/currentcomments.asp.* To read background documents, go to *http://www.regulations.gov.* Review the docket in person at MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202–5452, between 9:00 a.m. and 5:00 p.m. Monday through Friday, except Federal Holidays. Sign in at the receptionist's desk on the 4th floor.

E-Mail Notification: To subscribe to receive an email notification when MSHA publishes rules in the **Federal Register**, and program information, instructions, and policy, go to *http://www.msha.gov/subscriptions/subscribe.aspx.*

FOR FURTHER INFORMATION CONTACT: Sheila A. McConnell, Acting Director, Office of Standards, Regulations, and Variances, MSHA, at *mcconnell.sheila.a@dol.gov* (email); 202–693–9440 (voice); or 202–693–9441 (facsimile).

SUPPLEMENTARY INFORMATION: On October 19, 2015, MSHA held a public meeting to gather information on issues and options relevant to coal miners' escape and refuge. The meeting was announced in the **Federal Register** on September 18, 2015 (80 FR 56416). Coal mine operators, coal miners, equipment manufacturers, academia, and the public were invited to provide information on the current state of refuge alternatives in underground coal mines, particularly on the challenges related to the use of built-in-place refuges and enhancing voice communication when using escape breathing devices. In response to stakeholders, MSHA is providing additional time for interested parties to comment. MSHA is extending the comment period from November 16, 2015, to January 15, 2016.

Joseph A. Main,

Assistant Secretary of Labor for Mine Safety and Health.

[FR Doc. 2015–29433 Filed 11–16–15; 11:15 am]

BILLING CODE 4510–43–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 171

[EPA–HQ–OPP–2011–0183; FRL–9936–82]

RIN 2070–AJ20

Pesticides; Certification of Pesticide Applicators; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: EPA issued a proposed rule in the **Federal Register** of August 24, 2015, concerning certification of applicators of restricted use pesticides. This document extends the comment period for 30 days, from November 23, 2015 to December 23, 2015. The comment period is being extended to provide additional time for commenters to prepare their responses.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0183, must be received on or before December 23, 2015.

ADDRESSES: Follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of August 24, 2015 (80 FR 51356) (FRL–9931–83).

FOR FURTHER INFORMATION CONTACT: Michelle Arling, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (703) 308–5891; email address: *arling.michelle@epa.gov*.

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** document of August 24, 2015. In that document, comments were required to be submitted by November 23, 2015. EPA is hereby extending the comment period to December 23, 2015.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of August 24, 2015. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

List of Subjects in 40 CFR Part 171

Environmental protection, Administrative practice and procedure, Certified applicator, Commercial applicator, Indian Country, Indian Tribes, Noncertified applicator, Pesticides and pests, Private applicator, Reporting and recordkeeping requirements, Restricted use pesticides.

Dated: November 10, 2015.

James Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2015–29370 Filed 11–17–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CG Docket Nos. 10–51 and 03–123; FCC 15–143]

Structure and Practices of the Video Relay Service Program; Telecommunications Relay Services and Speech-to-Speech Services for Individuals With Hearing and Speech Disabilities

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes to amend its rules to modify its current four-year compensation rate plan for Video Relay Service (VRS), adopted in 2013, by adopting a limited-duration compensation rate freeze applicable to VRS providers with 500,000 or fewer monthly minutes, and solicits comment on whether to adopt a number of service quality measures that could enhance the functional equivalence of VRS.

DATES: Comments on the section entitled VRS Compensation Rates (paragraphs 1–9) are due on or before December 9, 2015, and reply comments are due on or before December 24, 2015. Comments on the section entitled VRS Improvements (paragraphs 10–25) are due on or before January 4, 2016, and reply comments are due on or before February 1, 2016.

ADDRESSES: You may submit comments, identified by CG Docket Nos. 10–51 and 03–123, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's Electronic Comment Filing System (ECFS), through the Commission's Web site *http://fjallfoss.fcc.gov/ecfs2/*. Filers should follow the instructions provided on the Commission's Web site for submitting comments. For ECFS filers, in completing the transmittal screen, filers should include their full name, U.S. Postal service mailing address, and CG Docket Nos. 10–51 and 03–123.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Eliot Greenwald, Consumer and Governmental Affairs Bureau, Disability Rights Office, at 202–418–2235 or email *Eliot.Greenwald@fcc.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW., Room TW–A325, Washington, DC 20554. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.
- Commercial Mail sent by overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street SW., Washington, DC 20554.

This is a summary of the Commission's document FCC 15–143, *Structure and Practices of the Video Relay Service Program and Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* Further Notice of Proposed Rulemaking, adopted on October 21, 2015, and released on November 3, 2015, in CG Docket Nos. 10–51 and 03–123. The full text of document FCC 15–143 will be available for public inspection and copying via ECFS, and during regular business hours at the FCC Reference Information Center, Portals II, 445 12th Street SW., Room

CY–A257, Washington, DC 20554. Document FCC 15–143 can also be downloaded in Word or Portable Document Format (PDF) at: *https://www.fcc.gov/encyclopedia/disability-rights-office-headlines.* This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. 47 CFR 1.1200 *et seq.* Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with § 1.1206(b) of the Commission's rules. In proceedings governed by § 1.49(f) of the Commission's rules or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

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

Initial Paperwork Reduction Act of 1995 Analysis

Document FCC 15–143 seeks comment on proposed rule amendments that may result in modified information collection requirements. If the Commission adopts any modified information collection requirements, the Commission will publish another notice in the **Federal Register** inviting the public to comment on the requirements, as required by the Paperwork Reduction Act. Public Law 104–13, 109 Stat. 163; 44 U.S.C. 3501–3520. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, the Commission seeks comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees. Public Law 107–198, 116 Stat. 729; 44 U.S.C. 3506(c)(4).

Synopsis

1. *VRS Compensation Rates.* In 2013, the Commission adopted a report and order amending its telecommunications relay service (TRS) rules to improve the structure, efficiency, and quality of the VRS program, reduce the risk of waste, fraud, and abuse, and ensure that the program makes full use of advances in commercially-available technology. *Structure and Practices of the Video Relay Services Program, Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities,* CG Docket Nos. 10–51, 03–123, Report and Order and Further Notice of Proposed Rulemaking, published at 78 FR 40407, July 5, 2013, and 78 FR 40582, July 5, 2013 (*VRS Reform Order*), *aff'd in part and vacated in part sub nom. Sorenson Communications, Inc.* v. *FCC,* 765 F.3d 37 (D.C. Cir. 2014) (*Sorenson*). The *VRS Reform Order* established the rates at which VRS providers are compensated from the Interstate Telecommunications Relay Service Fund (TRS Fund) for a four-year period beginning July 1, 2013, and adopted structural reforms designed to establish a more level playing field for all VRS providers.

2. Under the current compensation methodology for VRS, providers submit the number of minutes of service they provide to the TRS Fund administrator on a monthly basis and are compensated for these minutes based on rates set annually by the Commission. The Commission currently uses a three-tier compensation rate structure that allows smaller providers to receive a higher average per-minute rate than larger providers. In the *VRS Reform Order,* the Commission found that, for many years, VRS compensation rates had exceeded providers' average allowable costs, causing overcompensation of VRS providers. To address this issue, the Commission proposed basing VRS compensation rates largely on competitively established pricing—*i.e.,* prices that would be set through a competitive bidding process, and which would be instituted after the completion of structural reforms to the VRS program in the FNPRM accompanying the *VRS Reform Order.* Pending the resolution of these matters, however, in the *VRS Reform Order,* the Commission adopted a four-year schedule for gradually adjusting VRS compensation rates downward towards cost based levels.

3. On March 30, 2015, the six currently certified VRS providers jointly filed a petition (Joint VRS Providers Proposal) in which they urged the Commission to freeze the currently applicable VRS compensation rates of $5.29, $4.82, and $4.25 per minute. They also indicated that they would support the following measures to improve the service quality of VRS: (1) A faster speed-of-answer standard, under which 80 percent of calls must be answered within 45 seconds, measured monthly; (2) a limited trial of ''skills-based routing'' in order to assess the cost and feasibility of offering that service feature; and (3) authorization for providers to use deaf sign language interpreters, to supplement hearing interpreters who are communications assistants (CAs), for the purpose of achieving functionally equivalent relay calls to or from certain categories of deaf users.

4. Generally, the Commission believes the four-year compensation rate plan continues to be justified. For the three smallest providers, however, the record does indicate that their average per-minute costs are higher than the applicable rates in effect as of July 1, 2015. According to recent filings by the smallest providers, while these companies generally have achieved significant reductions in their per-minute costs over the last two years, and while they have begun to increase market share to some extent, they have yet to approach the size or efficiency levels of their larger rivals.

5. The Commission continues to believe that, as stated in the *VRS Reform Order,* ''it is worth tolerating some degree of additional inefficiency in the short term, in order to maximize the opportunity for successful participation of multiple efficient providers in the future, in the more competition-friendly environment that the Commission expect to result from our structural reforms.'' The Commission proposes a

limited modification of the *VRS Reform Order,* to allow small providers a reasonable measure of temporary relief from rate reductions that, according to the TRS Fund administrator, are potentially jeopardizing their continuation of service. Specifically, the Commission proposes to freeze for a maximum of 16 months the rate of compensation paid to ''small'' VRS providers, defined as providers whose monthly compensable minutes do not exceed 500,000 minutes. The Tier I rate of $5.29 per minute that was in effect prior to June 30, 2015, would be frozen only for those providers whose monthly minutes fall entirely within Tier I. Larger providers would be subject to the Tier I rate established in the *VRS Reform Order,* as well as the established Tier II and III rates. The Commission invites comment on whether a different dividing line is appropriate for purposes of a rate freeze and also seeks comment generally on this proposal and its costs and benefits.

6. The Commission next seeks comment on how the proposed partial rate freeze should be implemented. The partial rate freeze proposed herein would extend, for qualifying providers and for a maximum of 16 months, beginning July 1, 2015, the Tier I rate of $5.29 per minute that was in effect prior to June 30, 2015. The Commission seeks comment on this approach, including the precise duration of the proposed rate freeze. The Commission seeks additional comment regarding these providers' actual expectations regarding their progress in closing the gap between rates and costs, what specific structural reform milestones are most critical to their ability to compete effectively, what criteria should be used in determining when such milestones were or will be achieved, and what specific dates for the end of a rate freeze result from that analysis. In addition, the Commission seeks comment on how rate adjustments should be resumed upon the termination of a rate freeze period, regardless of its duration. The Commission also seeks comment on whether it is the case that some small providers may not be likely in the foreseeable future to achieve ''minimum efficient scale'' but may nevertheless provide significant value to certain consumer groups. The Commission seeks comment on the extent to which some providers offer types of specialized features or services to specific segments of consumers, the nature of such specialized features or services, and the costs of providing them. The Commission also seeks comment on the extent to which larger companies are able to efficiently provide comparable features or services to the specific market segments served by smaller providers and whether they have an adequate incentive to do so notwithstanding the applicability of higher-tier compensation rates.

7. Generally, the Commission seeks comment on whether the Commission should apply different rates to well-defined categories of specialized service, and how such rate categories could appropriately be defined consistently with the objectives of section 225 of the Act and the need to prevent fraud, abuse, and waste of the TRS Fund. For example, what specific features or services are necessary to ensure the provision of functionally equivalent VRS to deaf-blind individuals, what would be the additional per-minute cost for a company to provide such a service ''in the most efficient manner,'' and how could such a service be defined and an applicable VRS compensation rate be structured to best meet the statutory objectives? Are there any other specialized features or services that are or could be provided to specific segments of VRS consumers and that are necessary for such consumers to receive functionally equivalent VRS? If so, what is the per-minute cost for a company to provide such features or services ''in the most efficient manner,'' and how could such services or features be defined and an applicable VRS compensation rate be structured to best meet the statutory objectives?

8. The Commission tentatively concludes that it would not advance the objectives of section 225 of the Act to freeze VRS compensation rates in all rate tiers, for all providers, at the Jan. 1–June 30, 2015 levels, as proposed by the VRS providers, or to freeze the Tier I rate for all providers. However, the Commission invites comment on the merits, including the costs and benefits, of these alternatives and others that may be suggested by commenting parties. The Commission also seeks comment on the appropriate duration and other parameters of such alternatives.

9. The Commission invites any party advocating a more broadly applicable rate freeze to provide a detailed, fact-based showing as to why such a rate freeze is necessary to prevent service degradation rather than to provide debt service far in excess of the amounts for which recovery from the TRS Fund is allowed by the Commission's rules and orders. The Commission also invites commenters to suggest how any proposed alternative rate freeze could be structured to ensure that TRS Fund monies are no longer used to subsidize excessive levels of debt.

10. *VRS Improvements.* The Commission is charged with ensuring that TRS is made available to the extent possible, and in the most efficient manner, and that it provides the ability for individuals with hearing or speech disabilities to engage in communication by telephone in a manner that is functionally equivalent to the ability of individuals who do not have such disabilities. (47 U.S.C. 225(a)(3), (b)(1).) The Commission seeks comment on whether to: (1) Impose a faster speed-of-answer standard; (2) adopt a limited trial of ''skills-based routing''; (3) authorize providers to use qualified deaf sign language interpreters, in addition to the hearing interpreters, as CAs; (4) authorize the use of at-home interpreters under certain conditions; and (5) permit the assignment of ten-digit numbers for telephones used by hearing individuals. In general, the Commission seeks comment on the costs and benefits of these proposals and alternatives discussed in document FCC 15–143 or submitted by the parties, and on whether and how such proposals and alternatives comport with section 225 of the Act and any other relevant legal authorities.

11. In the *VRS Reform Order,* the Commission amended the VRS speed-of-answer standard, requiring that (1) effective January 1, 2014, VRS providers must answer 85 percent of all VRS calls within 60 seconds, measured on a daily basis, and (2) effective July 1, 2014, VRS providers must answer 85 percent of all VRS calls within 30 seconds, measured on a daily basis. The U.S. Court of Appeals for the District of Columbia Circuit vacated the amended requirements, ruling that the Commission had failed to consider the cost impact of the strengthened requirements. In the Joint VRS Providers Proposal, the providers endorse strengthening the speed-of-answer rule to require that 80 percent of all VRS calls be answered within 45 seconds, measured on a monthly basis. On June 23, 2015, the Disability Advisory Committee (DAC) submitted to the Commission the same recommendation as was made in the Joint VRS Providers Proposal.

12. The Commission proposes to amend the speed-of-answer rule to require that 80 percent of all VRS calls be answered within 45 seconds, measured on a monthly basis, and invites parties to comment on the costs and benefits of this proposal. The Commission tentatively concludes that there are factors besides functional equivalence—including the availability

of sign language interpreters, the need to ensure adequate working conditions for CAs who handle VRS calls, and the need to ensure a high quality of interpreting—that merit consideration in setting the speed-of-answer standard.

13. The Commission proposes to continue to measure compliance with the speed-of-answer requirement for VRS on a monthly rather than a daily basis. The Commission seeks comment on this proposal and on whether, as the VRS providers assert, a daily measurement requirement, under which a provider must meet the requirement every day or lose compensation for that day, can be counterproductive because providers are subject to random variation in demand that cannot reasonably be anticipated. To what extent will such standard enable the Commission to meet its obligation to ensure functionally equivalent service? Will a daily measurement have value because it would encourage providers to maintain sufficient staffing to ensure a consistent level of service over time? Is it likely that competitive forces will prompt providers to exceed the level of service the Commission sets by this rulemaking?

14. The Commission seeks comment on its tentative conclusion that compliance with the proposed standard could be achieved without any provider incurring additional costs in excess of those incurred over the past year.

15. The Commission seeks comment on the providers' proposal that, in lieu of the ''all-or-nothing'' compensation withholding policy, under which a provider that misses the speed-of-answer requirement on a particular day or month loses all compensation from the TRS Fund for that period, the Commission adopt a ''sliding scale'' approach, whereby the consequence for missing the speed-of-answer requirement in a given period is limited to withholding that percentage of the provider's total VRS billing that corresponds to the percentage by which the provider fell short of the applicable standard during that period.

16. The Commission also seeks comment on (1) whether to adopt an incentive-based system in which providers who meet stricter speed of answer thresholds receive additional compensation, (2) whether the Commission should publish summaries of each provider's speed-of-answer performance data, so that consumers can compare the performance of various providers, and the amount of detail that would be useful for consumers to know, and (3) whether to adopt a self-executing exemption from the speed-of-answer standard for calls occurring as a result of specific extraordinary events beyond a provider's control and a streamlined waiver procedure to address other events that may justify a waiver of the speed-of-answer standard.

17. Finally, the Commission seeks comment on whether the existing speed-of-answer rule for VRS, which states that the speed of answer for VRS is measured beginning from the time a VRS call reaches facilities operated by the VRS CA service provider, adequately defines when the speed-of-answer ''clock'' starts. The Commission proposes to amend the speed-of-answer rule for VRS so that it expressly incorporates the same language applicable to other TRS calls, *i.e.,* that the call must be ''answered . . . by any method which results in the caller's call immediately being placed, not put in a queue or on hold.''

18. In the *VRS Reform Order,* the Commission considered comments advocating the authorization of ''skills-based routing,'' a practice whereby VRS callers could request that calls be routed to VRS CAs with particular skill sets—such as particular spoken-language abilities, interpreting, transliteration, and signing styles and skills, or knowledge of specific subject matters (*e.g.,* medicine, law, or technology). As suggested in the Joint VRS Providers Proposal, the Commission now seeks comment on whether to authorize ''skills-based routing'' on a trial basis.

19. The Commission seeks additional comment on the merits of skills-based routing generally. To what extent is skills-based routing necessary to achieve a telephone service that is functionally equivalent to the service provided to voice telephone users? Is skills-based routing consistent with the fundamental nature of TRS, which is currently subject to requirements that TRS calls must be answered in the order received, that providers must not unreasonably discriminate in the handling of calls, and that CAs must not refuse calls? If skills-based routing is authorized on a permanent basis, how should the types of calls appropriate for skills-based routing be defined? Would it be appropriate to provide compensation for the cost of such interpreters from the TRS Fund as a cost of providing service that meets minimum TRS standards? Generally, what additional costs would be incurred by providers for the provision of skills-based routing? What indirect impact might its provision have on the TRS Fund? For example, we seek comment on whether providers expect that they would need to pay higher wages to interpreters employed in the provision of skills-based routing. Should such additional labor costs be recoverable in VRS compensation rates, and if so, in what manner? To what extent could the provision of skills-based routing using higher-paid interpreters cause a migration of the most qualified interpreters to those positions, lowering the average quality of interpretation available on non-specialized calls?

20. If the Commission were to authorize a trial of skills-based routing, how should it be structured? Should skills-based routed calls during a trial period be exempt from all speed-of-answer compliance but subject to collection and reporting of speed-of-answer data, as the providers suggest? What types of skills-based routing (*e.g.,* medical, legal, other call categories) should be included in the trial? Should the Commission limit the percentage of calls that can be subject to skills-based routing? Should the Commission waive the ''sequential call rule'' for successive calls not requiring specialized interpretation, so that such calls can be routed to a generalist interpreter? Should the Commission impose a requirement that a caller requesting a specialist interpreter be given an estimate of the expected wait time and the option of waiting for a skills-based CA or proceeding with a regular interpreter?

21. If the Commission were to authorize a trial of skills-based routing, how long should that trial last? What types of data should be collected during the trial to assess the costs and benefits of skills-based routing? What standards should be applied in assessing whether the interpreters to whom calls are routed actually have the relevant specialized skills and whether specialized interpreting is actually provided on such calls? The Commission also seeks comment on its assumption that any provider's participation in a trial of skills-based routing should be voluntary and thus that any costs incurred by providers to participate in such a trial would not be billable to the TRS Fund as exogenous costs or otherwise.

22. The Commission seeks comment on whether to amend its rules to permit compensation for the use of deaf interpreters where needed to achieve functionally equivalent service on VRS calls for consumers of VRS where the provision of a hearing video interpreter in a VRS call is not sufficient for effective communications. The Commission seeks comment on the types and estimated percentage of VRS users who would benefit from the availability of deaf interpreters and on the costs of providing deaf interpreters. How many additional interpreter-hours

would be needed and at what hourly rate? In the event that the Commission decides to adopt a rule that supports the provision of deaf interpreters, how should the Commission define the necessary qualifications for a deaf interpreter? What recordkeeping and reporting requirements are appropriate? Should the Commission treat deaf interpreters as a form of skills-based routing, exempting calls requiring a deaf interpreter from the speed-of-answer calculations? The Commission also seeks comment on whether, before authorizing the use of deaf interpreters on a permanent basis, the Commission should first conduct a trial of this practice, similar to the trial of skills-based routing discussed previously.

23. To prevent fraud and abuse, the Commission previously adopted a rule prohibiting VRS interpreters from working from their homes. (47 CFR 64.604 (b)(4)(iii).) In the *VRS Reform Order,* the Commission sought comment on whether to permit VRS CAs to work from home during the overnight hours when the safety and security of CAs may be endangered from travelling to or from VRS call centers. The Commission now seeks comment on whether circumstances have changed sufficiently so that CAs should be permitted to work from home at any time, subject to appropriate safeguards. The Commission asks what specific safeguards are needed to ensure protection against fraud and abuse of the VRS program were such rule change to take place. The Commission further notes that home interpreting arrangements might fall short of achieving full compliance with the Commission's mandatory minimum standards for TRS, including standards protecting call privacy, requiring the handling of 911 calls, mandating service redundancy, and assuring certain call quality. The Commission asks commenters to address the costs and benefits of permitting CAs to work from home and how such costs and benefits would differ, based on whether CAs are permitted to work from home at any time or only during overnight hours.

24. The Commission proposes to allow VRS providers to assign ten-digit Internet-based TRS numbers to hearing individuals so that they are able to place and receive direct (point-to-point) video calls to and from other VRS users. In the *VRS Reform Order,* the Commission previously sought comment on whether to allow such use. The Commission seeks comment on whether the Commission has statutory authority to allow such use of VRS facilities. The Commission seeks comment on whether permitting eligible VRS users to communicate directly with hearing people who can use American Sign Language (ASL) will increase the functional equivalence of TRS by facilitating telephone communication between members of the deaf and hearing communities, conserve the resources of the TRS Fund, and allow more natural, efficient, and effective communication between the parties, and whether to require or merely authorize providers to register hearing individuals for this service.

25. The Commission seeks comment on its tentative conclusion that assigning hearing individuals their own numbers would cause no significant increase in the costs incurred by VRS providers and on who should bear such costs as will be incurred to provide this service. The Commission also proposes to adopt measures to prevent fraud, abuse, and waste in connection with ten-digit numbers assigned to hearing individuals, including requiring the default provider to transmit a hearing person's registration information, as well as the assigned ten-digit number, to the TRS User Registration Database (TRS–URD) and to notify both the TRS Numbering Directory and the TRS–URD that the registrant is a hearing person who is not entitled to place or receive VRS calls. The Commission seeks comment on what additional registration information, if any, beyond that collected for eligible VRS users, the Commission should require the default provider to collect and provide to the TRS–URD for hearing users.

Initial Regulatory Flexibility Act Analysis

26. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in document FCC 15–143. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments as indicated in the Dates section. The Commission will send a copy of document FCC 15–143, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). (*See* 5 U.S.C. 603(a).)

A. Need For, and Objectives of, the Proposed Rules

27. The Commission proposes to modify in part the four-year compensation rate plan for video relay service (VRS) adopted in 2013 and also seeks comment on whether to adopt a number of measures that could enhance the functional equivalence of VRS.

28. Although the Commission believes that the four-year schedule of VRS compensation rate reductions continues to be justified in order to gradually move compensation rates close to a level close to average allowable provider costs, the Commission proposes to modify the schedule as applied to the smallest VRS providers, *i.e.,* those providing 500,000 or fewer compensable minutes of use of VRS per month. Spreading rate reductions over a four-year period was largely intended to provide a reasonable opportunity for the smallest providers to reach minimum efficient scale while benefitting from the *VRS Reform Order* initiatives which were intended to address many of the issues that have made it difficult for small providers to operate efficiently.

29. The smallest providers have achieved significant reductions in their per-minute costs but have yet to approach the size or efficiency levels of their larger rivals. Further, some relevant *VRS Reform Order* initiatives, such as the open source video access platform, will soon be implemented, and the Commission believes all existing providers should have a fair opportunity to participate in this important reform. Finally, some small providers offer service features that may be helpful in advancing the goal of functionally equivalent service for certain subsets of VRS consumers, such as Spanish language speakers, deaf-blind consumers, and deaf-owned businesses.

30. Therefore, the Commission proposes to temporarily ''freeze'' the rate applicable to providers with monthly call volumes that do not exceed 500,000 compensable minutes per month, effective July 1, 2015, at the level of the Tier I rate ($5.29 per minute) in effect on June 30, 2015. The Commission proposes that this rate remain in effect for a maximum of 16 months and seeks comment on the specific duration of the rate freeze and the rate that should apply upon its expiration. The Commission also seeks comment on whether there are unique types of VRS that are inherently more expensive to provide and to which an alternative rate level should apply. Finally, the Commission invites comment on alternatives to its rate freeze proposal, such as freezing rates in all tiers, for all providers, or freezing rates for all providers for their first 500,000 minutes.

31. In addition to the proposed VRS compensation rate freeze, the FNPRM seeks comment on a number of rule

changes that may improve the functional equivalence of VRS. Specifically, the FNPRM seeks comment on whether to: (1) Impose a faster speed-of-answer standard, *e.g.,* requiring VRS providers to answer 80 percent of all VRS calls within 45 seconds, as measured on a monthly basis, in lieu of the current requirement to answer 80 percent of all VRS calls within 120 seconds, as measured on a monthly basis; (2) adopt a limited trial of ''skills-based routing,'' allowing VRS callers to request that calls be routed to VRS communications assistants (CAs) with particular skill sets, such as particular spoken-language abilities, interpreting, transliteration, and signing styles and skills, or knowledge of specific subject matters (*e.g.,* medicine, law, or technology); (3) authorize providers to use qualified deaf sign language interpreters, in addition to the hearing interpreters, as CAs for those consumers who need such additional assistance for effective communication; (4) authorize the use of at-home interpreters under certain conditions; and (5) permit the assignment of ten-digit numbers for video phones used by hearing individuals who know American Sign Language (ASL) to communicate directly with deaf consumers. The Commission seeks comment on the costs and benefits of each of these measures.

B. Legal Basis

32. The authority for this proposed rulemaking is contained in sections 4(i), 201(b), 225, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 201(b), 225, 303(r).

C. Description and Estimate of the Number of Small Entities Impacted

33. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the proposed rules and policies, if adopted. (5 U.S.C. 603(b)(3).) The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' (5 U.S.C. 601(6).) In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. (5 U.S.C. 601(3).) Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'') A ''small business concern'' is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA. (15 U.S.C. 632.)

34. *VRS Providers.* These services can be included within the broad economic category of All Other Telecommunications. Six providers currently receive compensation from the TRS Fund for providing VRS: ASL Services Holdings, LLC (ASL Services); CSDVRS, LLC (CSDVRS); Convo Communications, LLC (Convo); Hancock, Jahn, Lee and Puckett, LLC d/b/a ''Communications Axess Ability Group'' (CAAG); Purple Communications, Inc. (Purple); and Sorenson Communications, Inc. (Sorenson) (VRS and IP CTS).

35. *All Other Telecommunications.* ''All Other Telecommunications'' is defined as follows: ''This U.S. industry comprises establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Establishments providing Internet services or voice over Internet protocol (VoIP) services via client-supplied telecommunications connections are also included in this industry.'' (U.S. Census Bureau, North American Industry Classification System, Definition of NAICS Code 517919. *See http://www.census.gov/cgi-bin/sssd/naics/naicsrch.*)

36. The SBA has developed a small business size standard for All Other Telecommunications, which consists of all such firms with gross annual receipts of $32.5 million or less. (*See* 13 CFR 121.201, NAICS Code 517919.) All the authorized VRS providers can be included within the broad economic census category of All Other Telecommunications. Under this category and the associated small business size standard, approximately half of the VRS providers can be considered small.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

37. No additional compliance requirements would be imposed by the VRS compensation rate freeze proposed in document FCC 15–143. If the Commission were to adopt some or all of the service improvement measures on which comments are sought in document FCC 15–143, the adoption of such measures could result in additional reporting, recordkeeping, and other compliance requirements. Specifically, in seeking comments on whether to authorize a limited trial of ''skills-based routing,'' provide for the use of qualified deaf sign language interpreters to provide additional communications assistance for VRS users who need such additional assistance for effective communication, or permit the assignment of ten-digit numbers for video phones used by hearing individuals to communicate directly with deaf consumers, the Commission has also sought comment on whether additional reporting and recordkeeping requirements would be needed to document the use of such features in order to prevent fraud, abuse, and waste. There may also be associated recordkeeping, reporting, or compliance requirements if the Commission were to allow the use of at-home interpreters, but such compliance requirements would apply only if a provider chooses to permit its interpreters to work from home. If the Commission were to increase the required speed of answer for VRS calls, no additional reporting and recordkeeping requirements are contemplated, and the cost of compliance would increase only to the extent that the new standard exceeded providers' current performance.

E. Steps Taken To Minimize Significant Impact on Small Entities, and Significant Alternatives Considered

38. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities. (5 U.S.C. 603(b).)

39. The temporary compensation rate freeze proposed in document FCC 15–143 would not impose additional compliance burdens and would temporarily ease the impact of existing VRS regulations on small entities by temporarily increasing the VRS

compensation rate for small entities above the rate currently in effect. Similarly, if the Commission were to amend its rules to authorize at-home interpreting for VRS, the impact of existing VRS regulations on small entities could be reduced because providers would have additional flexibility to structure their VRS operations so as to minimize cost and maximize efficiency.

40. Regarding the possible additional record-keeping and reporting requirements that could be adopted if the Commission were to authorize skills-based routing, deaf interpreters, or assignment of ten-digit numbers to hearing individuals using video phones, the Commission is seeking comment on the alternative of allowing providers to choose whether to provide such features and incur the associated compliance requirements.

F. Federal Rules Which Duplicate, Overlap, or Conflict With, the Commission's Proposals

41. None.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015–29371 Filed 11–17–15; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 4, 9, 12, 19 and 52

[FAR Case 2015–022; Docket No. 2015–0022; Sequence No. 1]

RIN 9000–AN00

Federal Acquisition Regulation; Unique Identification of Entities Receiving Federal Awards

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to re-designate the terminology for unique identification of entities receiving Federal awards. The change to the FAR will remove the proprietary standard or number.

DATES: Interested parties should submit written comments to the Regulatory Secretariat at one of the addresses shown below on or before January 19, 2016 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments in response to FAR Case 2015–022 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''FAR Case 2015–022''. Select the link ''Comment Now'' that corresponds with FAR Case 2015–022. Follow the instructions provided at the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2015–022'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Ms. Flowers, 1800 F Street NW., 2nd Floor, Washington, DC 20405.

Instructions: Please submit comments only and cite FAR Case 2015–022, in all correspondence related to this case. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Edward Loeb, Procurement Analyst, at 202–501–0650, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAR Case 2015–022.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to re-designate the terminology for unique identification of entities receiving Federal awards. The change to the FAR will remove the proprietary standard or number. Unique identification of such entities is critical to ensure Federal dollars are awarded to responsible parties, awardees are paid in a timely manner, and awards are appropriately recorded and reported. This is currently accomplished through regulation (*i.e.,* the FAR) using the proprietary Data Universal Numbering System (DUNS®) number from Dun and Bradstreet. This rule proposes to eliminate references to the proprietary standard or number and to provide appropriate references to the Web site where information on the unique entity identifier used for Federal contractors will be located. In addition, the proposed rule establishes definitions of ''unique entity identifier'', and ''electronic funds transfer (EFT) indicator''.

In recent years, legislation has been enacted (*e.g.,* the Federal Funding Accountability and Transparency Act and the Digital Accountability and Transparency Act) that requires expanded identification of entities working with the Government and the development of standards, processes, and policies to better trace Federal dollars from appropriation to final outcomes or results. Creation and maintenance of data standards will facilitate collection and display of essential information. A data standard for identification of entities receiving Federal awards has been developed as part of the implementation for the Digital Accountability and Transparency Act and is available at *http://fedspendingtransparency.github.io/whitepapers/unique-id-business-name/.*

Going forward, the Federal Government will establish a transparent process for exploring potential alternatives to existing entity identifiers. Office of Management and Budget (OMB) and Treasury, in collaboration with the General Services Administration and the Award Committee for E-Government will establish a process for considering options, including soliciting information about viable alternatives from and reaching out about nonproprietary alternatives to all sectors, including private companies, nonprofits, and Federal government providers. This process will result in an analysis of alternatives for the unique identification of entities working with the Federal government while maintaining the statutory and regulatory integrity protections for the needs of the various awarding communities (loans, financial assistance, procurement, etc.) as well as transparency communities. The analysis of alternatives will include consideration of costs, implementation considerations, and protections for Federal taxpayers. The analysis of alternatives is anticipated to be completed in Fiscal Year (FY) 2017.

Although the Government is not currently in a position to move away from use of the DUNS number in the short term, elimination of regulatory references to a proprietary entity identifier will provide opportunities for future competition that can reduce costs to taxpayers. The current requirement limits competition by using a proprietary number and organization to

meet the identification need as well as the need for other business information associated with that number.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* However, an Initial Regulatory Flexibility Analysis (IRFA) has been prepared consistent with 5 U.S.C. 605. The IRFA is summarized as follows:

The rule is being proposed to remove a proprietary standard or number for the unique identification of entities receiving Federal awards. The current requirement limits competition by using a proprietary number and organization to meet the identification needs.

Unique identification of such entities is critical to ensure Federal dollars are awarded to responsible parties, awardees are paid in a timely manner, and awards are appropriately recorded and reported. This is currently accomplished through regulation in the FAR using the proprietary Data Universal Numbering System (DUNS®) number from Dun and Bradstreet. This rule proposes to eliminate references to the proprietary standard or number, and to provide appropriate references to the Web site where information on the unique entity identifier used for Federal contractors will be designated.

Although the Government does not intend to move away from use of the DUNS number in the short term, elimination of regulatory references to a proprietary entity identifier will provide opportunities for future competition that can reduce costs to taxpayers.

The proposed rule is internal to the Government and does not directly impose any requirements on the vendor community. However, the rule may affect certain entities if those entities have arranged certain of their business systems to utilize, accept, or otherwise recognize the existing unique identifier (DUNS Number) and should that unique identifier be changed at some point to another identifier. As of June 2015, there were 380,092 unique and active DUNS numbers designated in the System for Award Management and attributed to Government contracting.

There is no change to recordkeeping as a result of this rule.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no known significant alternative approaches to the rule that would meet the requirements.

The Regulatory Secretariat has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2015–022), in correspondence.

IV. Paperwork Reduction Act

The rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 2, 4, 9, 12, 19 and 52

Government procurement.

William Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 2, 4, 9, 12, 19 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 2, 4, 9, 12, 19 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 51 U.S.C. 20113.

PART 2—DEFINITIONS OF WORDS AND TERMS

■ 2. Amend section 2.101, in paragraph (b)(2) by—

■ a. Removing the definitions ''Data Universal Numbering System (DUNS) number'' and ''Data Universal Numbering System +4 (DUNS+4) number'';

■ b. Adding, in alphabetical order the definition ''Electronic Funds Transfer (EFT) indicator'';

■ c. Revising paragraph (1) of the definition ''Registered in the System for Award Management (SAM) database''; and

■ d. Adding, in alphabetical order, the definition, ''Unique entity identifier''.

The added and revised text reads as follows:

2.101 Definitions.

* * * * *

(b) * * *

(2) * * *

Electronic Funds Transfer (EFT) indicator means a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the commercial, non-profit, or Government entity to establish additional System for Award Management records for identifying alternative Electronic Funds Transfer (EFT) accounts (see subpart 32.11) for the same entity.

* * * * *

Registered in the System for Award Management (SAM) database * * *

(1) The Contractor has entered all mandatory information, including the unique entity identifier and the Electronic Funds Transfer indicator, (if applicable), the Commercial and Government Entity (CAGE) code, as well as data required by the Federal Funding Accountability and Transparency Act of 2006 (see subpart 4.14), into the SAM database;

* * * * *

Unique entity identifier means a number or other identifier used to identify a specific commercial, non-profit, or Government entity. See *www.sam.gov* for the designated entity for establishing unique entity identifiers.

* * * * *

PART 4—ADMINISTRATIVE MATTERS

■ 3. Amend section 4.601 by removing the definition ''Generic DUNS number'' and adding in alphabetical order a definition ''Generic entity identifier'' to read as follows:

4.601 Definitions.

* * * * *

Generic entity identifier means a number or other identifier assigned to a category of vendors and not specific to any individual or entity.

* * * * *

■ 4. Amend section 4.605 by revising paragraph (b), the heading of paragraph (c), and paragraphs (c)(1), and (c)(2) introductory text; and removing from paragraph (c)(2)(i)(C) ''DUNS number''

and adding ''unique entity identifier'' in its place.

The revised text reads as follows.

4.605 Procedures.

* * * * *

(b) *Unique entity identifier.* The contracting officer shall identify and report a unique entity identifier for the successful offeror on a contract action. The unique entity identifier shall correspond to the successful offeror's name and address as stated in the offer and resultant contract, and as registered in the System for Award Management database in accordance with the provision at 52.204–7, System for Award Management. The contracting officer shall ask the offeror to provide its unique entity identifier by using either the provision at 52.204–6, Unique Entity Identifier, the provision at 52.204–7, System for Award Management, or the provision at 52.212–1, Instructions to Offerors—Commercial Items. (For a discussion of the Commercial and Government Entity (CAGE) Code, which is a different identifier, see subpart 4.18.)

(c) *Generic entity identifier.* (1) The use of a generic entity identifier should be limited, and only used in the situations described in paragraph (c)(2) of this section. Use of a generic entity identifier does not supersede the requirements of either provisions 52.204–6, Unique Entity Identifier or 52.204–7, System for Award Management (if present in the solicitation) for the contractor to have a unique entity identifier assigned.

(2) Authorized generic entity identifiers, maintained by the Integrated Award Environment (IAE) program office (*http://www.gsa.gov/portal/content/105036*), may be used to report contracts in lieu of the contractor's actual unique entity identifier only for—

* * * * *

■ 5. Amend section 4.607 by—

■ a. Removing from paragraph (b) ''Data Universal Numbering System Number'' and adding ''Unique Entity Identifier'' in its place; and

■ b. Revising paragraph (c) to read as follows.

4.607 Solicitation provisions and contract clause.

* * * * *

(c) Insert the clause at 52.204–12, Unique Entity Identifier Maintenance, in solicitations and resulting contracts that contain the provision at 52.204–6, Unique Entity Identifier.

■ 6. Amend section 4.1103 by—

■ a. Removing from paragraph (a)(1) ''must register;'' and adding ''shall register;'' in its place;

■ b. Removing from paragraph (a)(2) introductory text ''DUNS number or, if applicable, the DUNS+4 number'' and adding ''unique entity identifier'' in its place; and

■ c. Revising paragraphs (a)(3) and (d) to read as follows:

4.1103 Procedures.

(a) * * *

(3) Need not verify registration before placing an order or call if the contract or agreement includes the provision at 52.204–7, System for Award Management, or the clause at 52.212–4, Contract Terms and Conditions-Commercial Items, or a similar agency clause, except when use of the Governmentwide commercial purchase card is contemplated as a method of payment. (See 32.1108(b)(2)).

* * * * *

(d) The contracting officer shall, on contractual documents transmitted to the payment office, provide the unique entity identifier and, if applicable, the Electronic Funds Transfer indicator, in accordance with agency procedures.

4.1402 [Amended]

■ 7. Amend section 4.1402 by removing from paragraph (b), last sentence, ''DUNS number'' and adding ''entity identifier'' in its place.

4.1705 [Amended]

■ 8. Amend section 4.1705 by removing from paragraphs (a) and (b) ''DUNS number'' and adding ''entity identifier'' in their places.

■ 9. Amend section 4.1800 by revising paragraph (b) to read as follows.

4.1800 Scope of subpart.

* * * * *

(b) For information on the unique entity identifier, which is a different identifier, see 4.605 and the provisions at 52.204–6, Unique Entity Identifier, and 52.204–7, System for Award Management.

■ 10. Amend section 4.1802 by:

■ a. Revising paragraph (a)(1); and

■ b. Removing from paragraph (b) ''DUNS Number'' and adding ''unique entity identifier'' in its place.

The revised text reads as follows:

4.1802 Policy.

(a) * * * (1) Offerors shall provide the contracting officer the CAGE code assigned to that offeror's location prior to the award of a contract action above the micro-purchase threshold, when there is a requirement to be registered in the System for Award Management (SAM) or a requirement to have a unique entity identifier in the solicitation.

* * * * *

4.1804 [Amended]

■ 11. Amend section 4.1804 by removing from paragraph (a)(1) ''Data Universal Numbering System Number'' and adding ''Unique Entity Identifier'' in its place.

PART 9—CONTRACTOR QUALIFICATIONS

■ 12. Amend section 9.404 by revising paragraph (b)(6) to read as follows:

9.404 System for Award Management Exclusions.

* * * * *

(b) * * *

(6) Unique Entity Identifier;

* * * * *

PART 12—ACQUISITION OF COMMERCIAL ITEMS

12.301 [Amended]

■ 13. Amend section 12.301 by removing from paragraphs (d)(1) and (2) ''DUNS Number'' and adding ''unique entity identifier'' in their places.

PART 19—SMALL BUSINESS PROGRAMS

19.704 [Amended]

■ 14. Amend section 19.704 by removing from the introductory text of paragraph (a) ''must include'' and adding ''shall include'' in its place; and removing from paragraphs (a)(10)(v) and (vi) ''DUNS number'' and adding ''unique entity identifier'' in their places.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 15. Revise section 52.204–6 to read as follows.

52.204–6 Unique Entity Identifier.

As prescribed in 4.607(b), insert the following provision:

Unique Entity Identifier (Date)

(a) *Definitions.*

Electronic Funds Transfer (EFT) indicator, as used in this provision, means a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the commercial, non-profit, or Government entity to establish additional System for Award Management records for identifying alternative EFT accounts (see subpart 32.11) for the same entity.

Unique entity identifier, as used in this provision, means a number or other identifier used to identify a specific commercial, non-profit, or Government entity. See *www.sam.gov* for the designated entity for establishing unique entity identifiers.

(b) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation ''Unique Entity Identifier'' followed by the unique entity

identifier that identifies the Offeror's name and address exactly as stated in the offer. The Offeror also shall enter its EFT indicator, if applicable.

(c) If the Offeror does not have a unique entity identifier, it should contact the entity designated at SAM for establishment of the unique entity identifier directly to obtain one. The Offeror should be prepared to provide the following information:

(1) Company legal business name.

(2) Tradestyle, doing business, or other name by which your entity is commonly recognized.

(3) Company physical street address, city, state and Zip Code.

(4) Company mailing address, city, state and Zip Code (if separate from physical).

(5) Company telephone number.

(6) Date the company was started.

(7) Number of employees at your location.

(8) Chief executive officer/key manager.

(9) Line of business (industry).

(10) Company Headquarters name and address (reporting relationship within your entity).

(End of provision)

■ 16. Amend section 52.204–7 by—

■ a. Revising the date of the provision;

■ b. Amending paragraph (a) by—

■ i. Removing the definitions ''Data Universal Numbering System (DUNS) number'' and ''Data Universal Numbering System +4 (DUNS+4)'';

■ ii. Adding, in alphabetical order, the definition ''Electronic Funds Transfer (EFT) indicator'';

■ iii. Revising paragraph (1) of the definition ''Registered in the System for Award Management (SAM) database''; and

■ iv. Adding, in alphabetical order, the definition ''Unique entity identifier'';

■ c. Removing from paragraph (b)(1) ''the offeror'' and adding ''the Offeror'' in its place; and

■ d. Revising paragraphs (b)(2) and (c).

The revised and added text reads as follows:

52.204–7 System for Award Management.

* * * * *

System for Award Management (DATE)

(a) *Definitions.* As used in this provision—

Electronic Funds Transfer (EFT) indicator means a four-character suffix to the unique entity identifier, the suffix is assigned at the discretion of the commercial, non-profit, or Government entity to establish additional System for Award Management records for identifying alternative EFT accounts (see the FAR at subpart 32.11) for the same entity.

Registered in the System for Award Management (SAM) database means that—

(1) The Offeror has entered all mandatory information, including the unique entity identifier and the EFT indicator, if applicable, the Commercial and Government Entity (CAGE) code, as well as data required by the Federal Funding Accountability and Transparency Act of 2006 (see subpart 4.14) into the SAM database;

* * * * *

Unique entity identifier means a number or other identifier used to identify a specific commercial, non-profit, or Government entity. See *www.sam.gov* for the designated entity for establishing unique entity identifiers.

(b) * * *

(2) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation Unique Entity Identifier followed by the unique entity identifier that identifies the Offeror's name and address exactly as stated in the offer. The Offeror also shall enter its EFT indicator, if applicable. The unique entity identifier will be used by the Contracting Officer to verify that the Offeror is registered in the SAM database.

(c) If the Offeror does not have a unique entity identifier, it should contact the entity designated at SAM for establishment of the unique entity identifier directly to obtain one. The Offeror should be prepared to provide the following information:

(1) Company legal business.

(2) Tradestyle, doing business, or other name by which your entity is commonly recognized.

(3) Company Physical Street Address, City, State, and Zip Code.

(4) Company Mailing Address, City, State and Zip Code (if separate from physical).

(5) Company Telephone Number.

(6) Date the company was started.

(7) Number of employees at your location.

(8) Chief executive officer/key manager.

(9) Line of business (industry).

(10) Company Headquarters name and address (reporting relationship within your entity).

* * * * *

■ 17. Amend section 52.204–10 by—

■ a. Revising the date of the clause; and

■ b. Removing from paragraph (d)(2)(i) ''identifier (DUNS Number)'' and adding ''entity identifier'' in its place.

The revised text reads as follows:

52.204–10 Reporting Executive Compensation and First-Tier Subcontract Awards.

* * * * *

Reporting Executive Compensation and First-Tier Subcontract Awards (DATE)

* * * * *

■ 18. Revise section 52.204–12 to read as follows.

52.204–12 Unique Entity Identifier.

As prescribed in 4.607(c), insert the following clause:

Unique Entity Identifier (DATE)

(a) *Definition. Unique entity identifier,* as used in this clause, means a number or other identifier used to identify a specific commercial, non-profit, or Government entity. See *www.sam.gov* for the designated entity for establishing unique entity identifiers.

(b) The Contractor shall ensure that the unique entity identifier is maintained with the entity designated at the System for Award Management (SAM) for establishment of the unique entity identifier throughout the life of the contract. The Contractor shall communicate any change to the unique entity identifier to the Contracting Officer within 30 days after the change, so an appropriate modification can be issued to update the data on the contract. A change in the unique entity identifier does not necessarily require a novation be accomplished.

(End of clause)

■ 19. Amend section 52.204–13 by—

■ a. Revising the date of the clause;

■ b. Amending paragraph (a) by—

■ i. Removing the definitions ''Data Universal Numbering System (DUNS) number'' and ''Data Universal Numbering System +4 (DUNS+4)'';

■ ii. Adding, in alphabetical order, the definition ''Electronic Funds Transfer (EFT) indicator'';

■ iii. Revising paragraph (1) of the definition ''Registered in the System for Award Management (SAM) database''; and

■ iv. Adding, in alphabetical order, the definition ''Unique entity identifier''; and

■ c. Revising paragraph (c)(3).

The revised and added text reads as follows:

52.204–13 System for Award Management Maintenance.

* * * * *

System for Award Management Maintenance (DATE)

(a) * * *

Electronic Funds Transfer (EFT) indicator means a four-character suffix to the unique entity identifier. The suffix is assigned at the discretion of the commercial, non-profit, or Government entity to establish additional System for Award Management (SAM) records for identifying alternative EFT accounts (see the FAR at subpart 32.11) for the same entity.

Registered in the System for Award Management (SAM) database means that—

(1) The Contractor has entered all mandatory information, including the unique entity identifier (if applicable) or the EFT indicator, the Commercial and Government Entity (CAGE) code, as well as data required by the Federal Funding Accountability and Transparency Act of 2006 (see subpart 4.14), into the SAM database;

* * * * *

Unique entity identifier means a number or other identifier used to identify a specific commercial, non-profit, or Government entity. See *www.sam.gov* for the designated entity for establishing unique entity identifiers.

* * * * *

(c) * * *

(3) The Contractor shall ensure that the unique entity identifier is maintained with the entity designated at SAM for establishment of the unique entity identifier throughout the life of the contract. The Contractor shall communicate any change to the unique entity identifier to the Contracting

Officer within 30 days after the change, so an appropriate modification can be issued to update the data on the contract. A change in the unique entity identifier does not necessarily require a novation be accomplished.

* * * * *

■ 20. Amend section 52.204–14 by—

■ a. Revising the date of the clause; and

■ b. Removing from paragraph (f)(1)(i), ''DUNS number'' and adding ''unique entity identifier'' in its place.

The revised text reads as follows:

52.204–14 Service Contract Reporting Requirements.

* * * * *

Service Contract Reporting Requirements (DATE)

* * * * *

■ 21. Amend section 52.204–15 by—

■ a. Revising the date of the clause; and

■ b. Removing from paragraph (f)(1)(i) ''DUNS number'' and adding ''unique entity identifier'' in its place.

The revised text reads as follows:

52.204–15 Service Contract Reporting Requirements for Indefinite-Delivery Contracts.

* * * * *

Service Contract Reporting Requirements for Indefinite-Delivery Contracts (DATE)

* * * * *

■ 22. Amend section 52.212–1 by revising the date of the provision and paragraph (j) to read as follows:

52.212–1 Instructions to Offerors—Commercial Items.

* * * * *

Instructions to Offerors-Commercial Items (DATE)

* * * * *

(j) *Unique entity identifier.* (Applies to all offers exceeding $3,500, and offers of $3,500 or less if the solicitation requires the Contractor to be registered in the System for Award Management (SAM) database.) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation ''unique entity identifier''. The suffix is followed by the unique entity identifier that identifies the Offeror's name and address. The Offeror also shall enter its Electronic Funds Transfer (EFT) indicator, if applicable. The EFT indicator is a four-character suffix to the unique entity identifier assigned at the discretion of the offeror to establish additional SAM records for identifying alternative EFT accounts (see FAR subpart 32.11) for the same entity. If the Offeror does not have a unique entity identifier, it should contact the entity designated at SAM for unique entity identifier establishment directly to obtain one. The offeror should indicate that it is an offeror for a Government contract when contacting the entity designated at SAM for establishing the unique entity identifier.

* * * * *

■ 23. Amend section 52.212–3 by—

■ a. Revising the date of the provision; and

■ b. Removing from paragraph (p) introductory text ''DUNS Number'' and adding ''unique entity identifier'' in its place.

The revised text reads as follows:

52.212–3 Offeror Representations and Certifications-Commercial Items.

* * * * *

Offeror Representations and Certifications-Commercial Items (DATE)

* * * * *

■ 24. Amend section 52.212–5 by revising the date of the clause and paragraphs (b)(4), (b)(6), (b)(7), and (b)(17)(i) to read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items.

* * * * *

Contract Terms and Conditions Required to Implement Statutes or Executive Orders-Commercial Items (DATE)

* * * * *

(b) * * *

__ (4)52.204–10, Reporting Executive Compensation and First-Tier Subcontract Awards (DATE) (Pub. L. 109–282) (31 U.S.C. 6101 note).

* * * * *

__ (6)52.204–14, Service Contract Reporting Requirements (DATE) (Pub. L. 111–117, section 743 of Div. C).

__ (7)52.204–15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (DATE) (Pub. L. 111–117, section 743 of Div. C).

* * * * *

__ (17)(i)52.219–9, Small Business Subcontracting Plan (DATE) (15 U.S.C. 637(d)(4)).

* * * * *

■ 25. Amend section 52.213–4 by revising the date of the clause and paragraph (b)(1)(i) to read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Items).

* * * * *

Terms and Conditions-Simplified Acquisitions (Other Than Commercial Items) (DATE)

* * * * *

(b) * * *

(1) * * *

(i) 52.204–10, Reporting Executive Compensation and First-Tier Subcontract Awards (DATE) (Pub. L. 109–282) (31 U.S.C. 6101 note) (Applies to contracts valued at $25,000 or more).

* * * * *

■ 26. Amend section 52.219–9 by—

■ a. Revising the date of the clause;

■ b. Removing from the introductory text of paragraph (d) ''offeror's'' and adding ''Offeror's'' in its place;

■ c. Removing from paragraph (d)(10) introductory text ''offeror'' and adding ''Offeror'' in its place;

■ d. Removing from paragraph (d)(10)(v) ''DUNS number,'' and ''the offeror's'' and adding ''unique entity identifier,'' and ''the Offeror's'' in their places, respectively; and

■ e. Removing from paragraph (d)(10)(vi) ''DUNS number,'' and adding ''unique entity identifier,'' in its place.

The revised text reads as follows:

52.219–9 Small Business Subcontracting Plan.

* * * * *

Small Business Subcontracting Plan (DATE)

* * * * *

[FR Doc. 2015–29414 Filed 11–17–15; 8:45 am]

BILLING CODE 6820–EP–P

Notices

Federal Register

Vol. 80, No. 222

Wednesday, November 18, 2015

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 and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Information Collection for the National School Lunch Program

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this information collection. This is a revision of a currently approved collection which FNS employs to determine public participation in the National School Lunch Program.

DATES: Written comments must be received on or before January 19, 2016.

ADDRESSES: 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, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Lynn Rodgers-Kuperman, Branch Chief, Program Monitoring, Child Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Alexandria, VA 22302–1594. Comments may also be submitted via fax to the attention of Lynn Rodgers-Kuperman at 703–305–2879 or via email to *Lynn.Rodgers@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov*, and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m., Monday through Friday) at 3101 Park Center Drive, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this information collection should be directed to Lynn Rodgers-Kuperman at the address indicated above or by phone at 703–305–2595.

SUPPLEMENTARY INFORMATION:

Title: 7 CFR part 210, National School Lunch Program.

Forms: FNS–640, FNS–66, FNS–66A, and FNS–828.

OMB Control Number: 0584–0006.

Expiration Date: February 29, 2016.

Type of Request: Revision of a currently approved collection.

Abstract: The Richard B. Russell National School Lunch Act (NSLA), as amended, authorizes the National School Lunch Program (NSLP) to safeguard the health and well-being of the nation's children and provide free or reduced price school lunches to qualified students through subsidies to schools. The United States Department of Agriculture (USDA) provides States with general and special cash assistance and donations of foods to assist schools in serving nutritious lunches to children each school day. Participating schools must serve lunches that are nutritionally adequate and maintain menu and food production records and the latest nutritional analysis to demonstrate compliance with the meal requirements.

Section 10 of the Child Nutrition Act of 1966 (42 U.S.C. 1779) requires the Secretary of Agriculture to prescribe such regulations as deemed necessary to carry out this Act and the NSLA (42 U.S.C. 1751 *et seq.*). Pursuant to that provision, the Secretary has issued 7 CFR part 210, which sets forth policies and procedures for the administration and operation of the NSLP. The Program is administered at the State and school food authority (SFA) levels and operations include the submission of applications and agreements, submission of the number of meals served and payment of claims, submission of data from required monitoring reviews conducted by the State agency, and maintenance of records. State and local operators of the NSLP are required to meet Federal reporting and accountability requirements and are also required to maintain records that include school food service accounts of revenues and expenditures.

In addition, FNS collects program data from the State agencies on Forms FNS–10, Report of School Operations; FNS–13, Annual Report of State Revenue Matching; and FNS–777, Financial Status Report. These forms are approved under OMB Control # 0584–0594, Food Program Reporting System (FPRS), which expires June 30, 2017. The reporting burden associated with these reports is covered under #0584–0594 and is not associated with this information collection. However, the recordkeeping burden is still maintained in this collection.

The reporting and recordkeeping burden associated with this revision is decreased from 11,337,788 to 9,871,395 hours. This change is mainly due to adjustments, the majority of which is the removal of duplicate burden, removal of burden that occurs only once, burden changes for an increase in schools participating in the Program and a decrease in number of School Food Authorities operating the Program, and other program changes.

This information collection is required to administer and operate this program in accordance with the NSLA. All of the reporting and recordkeeping requirements associated with the NSLP are currently approved by the Office of Management and Budget and are in force. This is a revision of the currently approved information collection.

Affected Public: (1) State agencies; (2) School Food Authorities; and (3) schools.

Number of Respondents: 121,210 (56 State agencies (SAs), 19,822 school food authorities (SFAs), and 101,332 schools).

Number of Responses per Respondent: 4.14573.

Total Annual Responses: 502,504.

Reporting Time per Response: 0.703875.

Estimated Annual Reporting Burden: 353,700.

Number of Recordkeepers: 121,210 (56 SAs, 19,822 SFAs, 101,332 schools).

Number of Records per Record Keeper: 406.294827.

Estimated Total Number of Records: 49,246,996.

Recordkeeping Time per Response: 0.19326446.

Total Estimated Recordkeeping Burden: 9,517,694.

Annual Recordkeeping and Reporting Burden: 9,871,395.

Current OMB Inventory for Part 210: 11,337,788.

Difference (change in burden with this renewal): (1,466,393).

Refer to the table below for estimated total annual burden for each type of respondent.

Affected public	Estimated number of respondents	Number of responses per respondent	Total annual responses	Estimated average hours per response	Estimated total burden (hours)
Reporting					
State Agencies	56	122	6,832	7.7762	53,127
School Food Authorities	19,822	15	293,008	0.956653	280,307
Schools	101,332	2	202,664	0.1	20,266
Total Estimated Reporting Burden	121,210		502,504		353,700
Recordkeeping					
State Agencies	56	1419	79,464	1.5913	126,451
School Food Authorities	19,822	20	396,440	4.5380	1,799,045
Schools	101,332	481	48,771,092	0.15567	7,592,199
Total Estimated Recordkeeping Burden	121,210		49,246,996		9,517,694
Total of Reporting and Recordkeeping					
Reporting	121,210	4.14573	502,504	0.703875	353,700
Recordkeeping	121,210	406.294827	49,246,996	0.19326446	9,517,694
Total			49,749,500		9,871,395

Dated: November 9, 2015.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2015–29390 Filed 11–17–15; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comments Request—Erroneous Payments in Child Care Centers Study (EPICCS)

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the general public and other public agencies to comment on this proposed information collection. This is a new collection for the Erroneous Payments in Child Care Centers Study (EPICCS).

DATES: Written comments must be received on or before January 19, 2016.

ADDRESSES: 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, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Written comments may be sent to: Chan Chanhatasilpa, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 1000, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Chan Chanhatasilpa at 703–305–2576 or via email to *Chanchalat.chanhatasilpa@fns.usda.gov.* Comments will also be accepted through the Federal eRulemaking Portal. Go to *http://www.regulations.gov,* and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5:00 p.m. EST, Monday through Friday) at 3101 Park Center Drive, Room 1100, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Chan Chanhatasilpa at 703–305–2115.

SUPPLEMENTARY INFORMATION:

Title: Erroneous Payments in Child Care Centers Study (EPICCS).

Form Number: Not applicable.

OMB Number: 0584—NEW.

Expiration Date: Not Yet Determined.

Type of Request: New collection.

Abstract: The Improper Payments Information Act of 2002, Public Law 107–300, requires the United States Department of Agriculture (USDA) to identify and reduce erroneous payments in various programs, including the Child and Adult Care Food Program (CACFP). The passage of the Improper Payments Elimination and Recovery Act (IPERA) in 2010, Public Law 111–204 amended and enhanced requirements for not only addressing improper payments but also prompting efforts at recovery by requiring annual risk assessments and measurement of improper payments. To comply with IPERA 2010, USDA needs a reliable

measure to estimate erroneous payments for CACFP. The program's benefits are provided in various programs that serve both children and adults in both child care centers and private homes. EPICCS will gather information specific to participating child care centers, both sponsored and independent, and including Head Start centers. EPICCS is planned to leverage the procedures and methodologies used to conduct the Access, Participation, Eligibility and Certification (APEC) Study series to develop reliable estimation models to estimate erroneous payment.

Affected Public: Respondent groups identified include: (1) State CN agencies, (2) CACFP sponsoring organizations, (3) child care centers, and (4) parents/guardians of enrolled children.

Estimated Number of Respondents: The total estimated number of respondents for data collection is 6,325. This includes: 25 administrators at State CN agencies, 450 directors at sponsoring organizations, 450 child care center directors, and 5,400 parents or guardians of enrolled children at CACFP participating child care centers. The number of sponsors, centers, and parents/guardians recruited will be slightly higher to account for non-respondents. The sample will include 150 independent child care centers who act as their own sponsor for the CACFP. As such, they are included in counts of both sponsors and child care centers.

Estimated Number of Responses per Respondent: Administrators at State CN agencies will be expected to provide responses on three occasions. The sponsoring organizations may be contacted up to seven times while the child care centers can be contacted up to eleven times. Parents or guardians of sampled households will be contacted on four occasions. The burden for non-respondents is outlined in the table that follows, and includes the time to complete the review of introductory materials and respond to the recruitment call.

Estimated Total Annual Responses: The total number of responses expected across all respondent categories is 32,272. This includes a total of 16,480 responses for recruitment and review of study information and/or requests, and a total of 15,792 responses for actual data collection (*i.e.* responses survey/interview questions or compiling data for the study).

Estimated Time per Respondent: The estimated time will vary depending on the respondent category. The table that follows outlines the estimated total annual burden for each type of respondent.

Estimated Total Annual Burden on Respondents: The total estimated response time is 12,844 hours.

Table A12-1 Estimates of Respondent Burden

Respondent Category	Respondent Type	Data Collection Activity	Sample Size	Number of Respondents	Frequency of Response	Total Annual Responses	Hours per Response	Total Annual Burden Estimate (Hours)
State	State Program Administrator	Review Introductory Materials	25	25	1	25	0.500	12.5
		Follow-up Call	25	25	1	25	0.250	6.3
	Data Manager	Meal Counts and Claiming Records	25	25	1	25	4.000	100.0
State Subtotal							**4.750**	**118.8**
Sponsor (Includes ICCCs)	County or Local Services Director	Review Introductory Materials	474	474	1	474	0.500	237.0
		Recruitment Call	474	474	1	474	0.500	237.0
		Pre-visit Interview	474	450	1	450	0.500	225.0
		Interact with Data Collector for Records Abstraction	474	450	1	450	0.250	112.5
		Review Introductory Materials for Sponsor Survey	450	450	1	450	0.083	37.4
		Complete Sponsor Survey	450	450	1	450	0.500	225.0
	Data Manager	Meal Counts and Claiming Records	450	450	1	450	2.000	900.0
Sponsor Subtotal							**4.333**	**1,973.9**
Child Care Center	Child Care Center Manager /Director	Review Introductory Package	316 [a]	316	1	316	0.500	158.0
		Recruitment Call	316 [a]	316	1	316	0.500	158.0
		Pre-Visit Interview	450	450	1	450	0.500	225.0
		1st Round Interact with Data Collector for Records Abstraction	474	450	1	450	0.500	225.0
		Interact with Data Collector for Meal Count/Claiming Records	474	450	1	450	0.500	225.0
		Interact with Data Collector for Meal Observations	474	450	1	450	0.250	112.5
		2nd Round Scheduling Call	450	450	1	450	0.083	37.4
		2nd Round Interact with Data Collector for Records Abstraction	450	450	1	450	0.250	112.5
		3rd Round Scheduling Call	450	450	1	450	0.083	37.4
		3rd Round Interact with Data Collector for Records Abstraction	450	450	1	450	0.250	112.5
		Respond to Post-visit Data Request	475	450	1	450	2.000	900.0
Child Care Center Subtotal							**5.416**	**2,303.2**
Household	Parent/Guardian of CACFP Eligible Child	Pre-test Household Survey	8	8	1	8	1.000	8.0
		Test Income Worksheet Methods	9	9	1	9	1.000	9.0
		Review Introductory Materials	6,750	6,750	1	6,750	0.083	560.3
		Recruiting and Appointing Call	6,750	6,750	1	6,750	0.166	1120.5
		Complete Income Worksheet	6,750	5,400	1	5,400	0.500	2,700.0
		Household Survey	6,750	5,400	1	5,400	0.750	4,050.0
Household Subtotal							**1.499**	**8,447.8**
GRAND TOTAL						**32,272**		**12,844**

[a] Sample size for review of the invitation package and recruiting call is decreased since independent child care centers complete this step at the same time as contact is made with them in their role as sponsor.

Dated: November 10, 2015.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2015–29391 Filed 11–17–15; 8:45 am]

BILLING CODE 3410–30–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Notice of Amendment to Agenda for November 23, 2015, Sunshine Act Meeting, Previously Announced in the Board's Notice of November 6, 2015

The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on November 23, 2015, starting at 1:00 p.m. EST in Washington, DC, at the CSB offices located at 1750 Pennsylvania Avenue NW., Suite 910. The agenda for this meeting is amended to include discussion about future public meetings about worker fatigue and Process Safety Management. It is also amended to include a staff presentation and Board vote on a recommendation to the BP Global Executive Board of Directors to implement an incident reporting program. In 2012, a CSB staff evaluation of BP's actions taken in response to that recommendation was calendared for discussion in a public setting. The

recommendation was issued as part of the investigation report of the BP America Refinery explosion in Texas City, Texas, in March 2005, and a vote on the status of that recommendation was tabled at the Board's July 22, 2015, public meeting. An opportunity for public comment will be provided prior to Board vote on the status of this recommendation.

Dated: November 16, 2015.

Kara Wenzel,

Acting General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2015–29593 Filed 11–16–15; 4:15 pm]

BILLING CODE 6350–01–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Economic Analysis (BEA), Department of Commerce.

Title: Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of U.S. Carriers (BE–30) and the Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses (BE–37).

OMB Control Number: 0608–0011.

Form Number: BE–30 and BE–37.

Type of Request: Regular submission.

Number of Responses: BE–30 responses: 280 annually (70 filed each quarter; 62 reporting mandatory data and 8 that would file exemption claims). BE–37 responses: 120 annually (30 filed each quarter; 29 reporting mandatory data, and 1 that would file an exemption claim).

Average Hours per Response: 4 hours is the average for those reporting data and 1 hour is the average for those not reporting data, but hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 1,492 (BE–30 burden hours of 1,024 and BE–37 burden hours of 468).

Needs and Uses: The Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of United States Carriers (BE–30) is a survey that collects data from U.S. ocean freight carriers (owners and operators) whose total covered revenues or total covered expenses incurred outside the United States were $500,000 or more in the previous year or are expected to be $500,000 or more during the current year. The covered revenues are: (1) Revenue on cargo outbound from U.S. ports and the associated shipping weight; (2) revenue on cargo inbound into the United States and the associated shipping weight; (3) revenue on cross-trade cargoes; and (4) charter hire (with crew) and space leasing revenues from foreign residents. The covered expenses are: (1) Fuel expenses in foreign countries; (2) expenses in foreign countries (other than fuel expenses); and (3) charter hire (with crew) and space leasing payments to foreign residents.

The Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses (BE–37) is a survey that collects data from U.S. airline operators engaged in the international transportation of goods and/or passengers and whose total covered revenues or total covered expenses incurred outside the United States were $500,000 or more in the previous year or are expected to be $500,000 or more during the current year. The covered revenues are: (1) Revenue derived from carriage of export freight and express from the United States to points outside the United States; (2) revenue derived from carriage of freight and express originating from, and destined to, points outside the United States; (3) revenue derived from transporting passengers originating from, and destined to, points outside the United States; (4) revenue from transporting passengers to and from the United States and the associated number of passengers; and (5) interline settlement receipts from foreign airline operators. The covered expenses are: (1) Expenses incurred outside the United States for fuel and oil, station and maintenance bases, wages, and other goods and services purchased abroad (except aircraft leasing expenses); (2) aircraft (with crew) leasing expenses; and (3) interline settlement payments to foreign airline operators.

The data are needed to monitor U.S. trade in transport services, to analyze the impact on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in transport services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the transport component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is proposing no additions or modifications to the current BE–30 and BE–37 surveys. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

Affected Public: Businesses or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: November 13, 2015.

Sheleen Dumas,

Departmental PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2015–29417 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Economic Analysis (BEA), Department of Commerce.

Title: Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United States.

OMB Control Number: 0608-0068.

Form Number: BE–9.

Type of Request: Regular submission.

Number of Responses: 180 annually (45 filed each quarter; 44 reporting mandatory data, and 1 that would file an exemption claim).

Average Hours per Response: 6 hours is the average for those reporting data and 1 hour is the average for those not reporting data, but hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 1,060.

Needs and Uses: The Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United

States (BE–9) is a survey that collects data from U.S. offices, agents, or other representatives of foreign airline operators that transport freight and express to or from the United States and whose total covered revenues or total covered expenses were $5 million or more in the previous year or are expected to be $5 million or more during the current year. The covered revenues are freight revenue on merchandise exported from, or imported into, the United States. The covered expenses are expenses incurred in the United States for: (1) Fuel and oil; (2) wages and salaries paid to employees in the United States; (3) agents' and brokers' fees and commissions for arrangement of freight and passenger transportation; (4) aircraft handling and terminal services, aircraft (with crew) leasing expenses, and (5) all other expenses incurred in the United States except aircraft leasing (without crew) expenses.

Respondents are also asked to report: (1) Shipping weights on which freight revenues were earned; (2) the number of passengers transported to/from the United States; and (3) revenues associated with these passengers.

The data are needed to monitor U.S. trade in transport services, to analyze the impact on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in transport services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the transport component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is proposing no additions or modifications to the current BE-9 survey. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

Affected Public: Businesses or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–806.

Dated: November 13, 2015.

Sheleen Dumas,

Departmental PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2015–29415 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Economic Analysis (BEA), Department of Commerce.

Title: Annual Survey of Foreign Ocean Carriers' Expenses in the United States.

OMB Control Number: 0608–0012.

Form Number: BE–29.

Type of Request: Regular submission.

Number of Responses: 80 annually (70 reporting mandatory data, and 10 that would file exemption claims).

Average Hours per Response: 3 hours is the average for those reporting data and 1 hour is the average for those not reporting data, but hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 220.

Needs and Uses: The Annual Survey of Foreign Ocean Carriers' Expenses in the United States (BE–29) is a survey that collects data from U.S. agents of foreign ocean carriers who handle 40 or more port calls in the reporting period by foreign ocean vessels, or have total covered expenses in the reporting period for all foreign ocean vessels handled by the U.S. agent of $250,000 or more. The covered expenses are: (1) Port call services such as pilotage, towing and tugboat services, harbor fees, and berth fees; (2) cargo-related services such as loading, unloading, and storing cargo at U.S. ports; (3) fuels and oils (bunkers) purchased in U.S. ports; (4) other vessel operating expenses such as stores and supplies, vessel repairs, and personnel expenses in the United States; and (5) other expenses such as U.S. agents' and brokers' fees and commissions and expenses related to maintaining U.S. offices, such as rent, advertising, and wages.

The data are needed to monitor U.S. trade in transport services, to analyze the impact on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in transport services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the transport component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is proposing no additions or modifications to the current BE–29 survey. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

Affected Public: Businesses or other for-profit organizations.

Frequency: Annual.

Respondent's Obligation: Mandatory.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202)395–5806.

Dated: November 13, 2015.

Sheleen Dumas,

Departmental PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2015–29416 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1985]

Approval of Expansion of Subzone 50H Tesoro Refining and Marketing Company, LLC, Long Beach, 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 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 Long Beach, California, grantee of Foreign-Trade Zone 50, has made application to the Board to expand Subzone 50H at the facilities of Tesoro Refining and Marketing Company, LLC, located in Long Beach, California, (FTZ Docket B–55–2015, docketed August 18, 2015);

Whereas, notice inviting public comment has been given in the **Federal Register** (80 FR 5198, August 24, 2015) 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 status at the facilities of Tesoro Refining and Marketing Company, LLC, located in Long Beach, California (Subzone 50H), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.13.

Signed at Washington, DC, this 10th day of November 2015.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2015–29459 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1986]

Reorganization of Foreign-Trade Zone 8 (Expansion of Service Area) Under Alternative Site Framework Toledo, Ohio

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 400.2(c)) as an option for the establishment or reorganization of zones;

Whereas, the Toledo-Lucas County Port Authority, grantee of Foreign-Trade Zone 8, submitted an application to the Board (FTZ Docket B–38–2015, docketed June 9, 2015) for authority to expand the service area of the zone to include Erie, Fulton, Ottawa, Paulding and Williams Counties, as described in the application, adjacent to the Toledo, Ohio Customs and Border Protection port of entry;

Whereas, notice inviting public comment was given in the **Federal Register** (80 FR 33479–33480, June 12, 2015) 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 8 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 10th day of November 2015.

Paul Piquado,

Assistant Secretary of Commerce for Enforcement and Compliance, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2015–29476 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

President's Export Council Subcommittee on Export Administration; Notice of Partially Closed Meeting

The President's Export Council Subcommittee on Export Administration (PECSEA) will meet on December 2, 2015, 10 a.m., at the U.S. Department of Commerce, Herbert C. Hoover Building, Room 3884, 14th Street between Pennsylvania and Constitution Avenues NW., Washington, DC. The PECSEA provides advice on matters pertinent to those portions of the Export Administration Act, as amended, that deal with United States policies of encouraging trade with all countries with which the United States has diplomatic or trading relations and of controlling trade for national security and foreign policy reasons.

Agenda

Open Session

1. Opening remarks by the Chairman and Vice Chairman.

2. Opening remarks by the Bureau of Industry and Security.

3. Export Control Reform Update.

4. Presentation of papers or comments by the Public.

Closed Session

5. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 25 participants on a first come, first served basis. To join the conference, submit inquiries to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov* no later than November 25, 2015.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate the distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on February 25, 2015, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 section (10)(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482–2813.

Dated: November 13, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–29495 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 03–1A008]

Export Trade Certificate of Review

ACTION: Notice of Application for an Amended Export Trade Certificate of Review by California Pistachio Export Council (''CPEC''), Application No. 03–1A008.

SUMMARY: The Secretary of Commerce, through the International Trade Administration, Office of Trade and Economic Analysis (OTEA), has received an application for an amended Export Trade Certificate of Review (''Certificate'') from CPEC. This notice summarizes the proposed amendment and seeks public comments on whether the amended Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph E. Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. Sections 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing Title III are found at 15 CFR part 325 (2015). Section 302(b)(1) of the Export Trade Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its application. Under 15 CFR 325.6(a), interested parties may, within twenty days after the date of this notice, submit written comments to the Secretary on the application.

Request for Public Comments: Interested parties may submit written comments relevant to the determination whether an amended Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Office of Trade and Economic Analysis, International Trade Administration, U.S. Department of Commerce, Room 21028, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the amended Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 03–1A008.''

Summary of the Application

Applicant: California Pistachio Export Council, 512 C Street NE., Washington DC 20002.

Contact: Robert I. Schramm, Senior Associate at Schramm, Williams & Associates, Inc., (202)–543–4455.

Application No.: 03–1A008.

Date Deemed Submitted: November 3, 2015.

Proposed Amendment:

1. Remove the following company as Member of the Certificate: Gold Coast Pistachios, Inc.

2. Change the name of the following existing Member: A&P Growers Cooperative, Inc. is now Horizon Marketing Agency in Common Cooperative Inc.

CPEC's proposed amendment of its Export Trade Certificate of Review would result in the following entities as Members under the Certificate:

(a) Keenan Farms, Inc.

(b) Monarch Nut Company

(c) Nichols Pistachio

(d) Primex Farms, LLC

(e) Setton Pistachio of Terra Bella, Inc.

(f) Horizon Marketing Agency in Common Cooperative Inc.

Dated: November 13, 2015.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration.

[FR Doc. 2015–29397 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE221

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Application for one new enhancement of survival permit.

SUMMARY: Notice is hereby given that NMFS has received an application for a new enhancement of survival permit and a request for entry into an associated proposed Programmatic Safe Harbor Agreement (Agreement) between the applicant and NMFS. The proposed Enhancement of Survival Permit and Agreement are intended to promote the survival and recovery of species listed under the Endangered Species Act (ESA). Information NMFS received as a part of the application is available to the public as a matter of public record and is available upon request by contacting the NMFS California Coastal Office in Santa Rosa, California.

DATES: Comments or requests for a public hearing on the action proposed in the application or related matters must be received at the appropriate address or fax number (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on December 18, 2015.

ADDRESSES: You may submit comments on this document and requests for a public hearing, identified by NOAA–NMFS–2015–0149, by either of the following methods:

Electronic Submission: Submit electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0149.* Click the ''Comment Now!'' icon, complete the required fields. Enter or attach your comments.

—OR—

Mail, Email, Fax: Submit written comments and requests for a public hearing to California Coastal Office, NMFS, 777 Sonoma Avenue, Room 325, Santa Rosa, CA 95404. Comments and requests may also be submitted via fax to 707–578–3435 or by email to *WCR_DryCreekValleyPSHA.comments@noaa.gov* (include permit number 20032 in the subject line of the fax or email).

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be

considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Dan Wilson, Santa Rosa, CA (ph.: 707–578–8555), Fax: 707–578–3435, email: *WCR_DryCreekValleyPSHA.comments@noaa.gov*).

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species are covered in this notice:

Chinook salmon (*Oncorhynchus tshawytscha*): Threatened California Coastal (CC).

Coho salmon (*O. kisutch*): Endangered Central California Coast (CCC).

Steelhead (*O. mykiss*): Threatened Central California Coast (CCC).

Authority

Enhancement of Survival Permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR parts 222–227). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Under a Safe Harbor Agreement, participating landowners voluntarily undertake management activities on their property to enhance, restore, or maintain habitat benefiting species listed under the Act (16 U.S.C. 1531 *et seq.*). Safe Harbor Agreements, and the subsequent Enhancement of Survival Permits that are issued pursuant to section 10(a)(1)(A) of the Act, encourage private and other non-Federal property owners to implement conservation efforts for listed species by assuring property owners that they will not be subjected to increased property use restrictions as a result of their efforts to attract listed species to their property or to increase the numbers or distribution of listed species already on their property. Application requirements and issuance criteria for Enhancement of Survival Permits through Safe Harbor Agreements are found in 50 CFR 222.308(b), 222.308(c) and June 17, 1999 (64 FR 32717*).* These permits allow any necessary future incidental take of covered species above the mutually agreed-upon baseline conditions for those species in accordance with the terms and conditions of the permits and accompanying agreements.

An interested party may submit written data, views, arguments, or a request for a hearing with respect to the action proposed in the application or related matters. Anyone requesting a hearing on a matter pursuant to this notice should set out the specific reasons why a hearing on that matter would be appropriate (see **ADDRESSES**). Such hearings are held at the discretion of the Assistant Administrator for Fisheries, NMFS.

Application Received

Permit 20032

The Sonoma County Water Agency (Applicant) is requesting an Enhancement of Survival Permit and approval of the associated proposed Agreement that was developed by NMFS and the Applicant. The Enhancement of Survival Permit will facilitate implementation of the Agreement that is expected to promote the recovery of the Covered Species on non-federal properties within Dry Creek below Warm Springs Dam, a tributary to the Russian River in Sonoma County, California. The proposed duration of the Agreement and the associated Enhancement of Survival Permit is 35 years. The proposed Enhancement of Survival Permit would authorize the incidental taking of the Covered Species associated with routine viticulture activities and the potential future return of any property included in the Agreement to the Elevated Baseline Conditions. Under this Agreement, individual landowners (Cooperators) may include their properties by entering into a Cooperative Agreement with the Applicant. Each Cooperative Agreement will specify the restoration and/or enhancement, and management activities to be carried out on that specific property and a timetable for implementing those activities. All Cooperative Agreements will be reviewed by NMFS to determine whether the proposed activities will result in a net conservation benefit for the Covered Species and meet all required standards of the Safe Harbor Policy (64 FR 32717). Upon NMFS approval, the Applicant will issue a Certificate of Inclusion to the Cooperator. Each Certificate of Inclusion will extend the incidental take coverage conferred by the Enhancement of Survival permit to the Cooperator. Certificates of Inclusion will be valid for a minimum of 10 years, but no longer than term of the Enhancement of Survival permit.

The Agreement requires that each enrolled property adopt an Elevated Baseline Condition. Elevated Baseline levels for the Covered Species will be determined by completing the Elevated Baseline Habitat Worksheet (Table 1 in Attachment 3 of the Agreement), which will be completed by the Applicant. NMFS will review each Elevated Baseline determination prior to the Applicant issuing a Certificate of Inclusion to the Cooperator. The Agreement also contains a monitoring component that requires the Applicant to ensure that the Cooperators are in compliance with the terms and conditions of the Agreement and that the Elevated Baseline levels of habitat for the Covered Species occurs on the Enrolled Property. Results of these monitoring efforts will be provided to NMFS by the Applicant in annual reports for the duration of the 35-year permit term.

Upon approval of this Agreement, and consistent with the NMFS's Safe Harbor Policy (64 FR 32717), NMFS would issue an Enhancement of Survival Permit to the Applicant. The Enhancement of Survival Permit will authorize those Cooperators who have been issued a Certificate of Inclusion to take Covered Species incidental to the implementation of the management activities specified in the Agreement, incidental to other lawful uses of the property including Routine Viticulture Activities, and to return to baseline conditions if desired. In addition to meeting other criteria, actions to be performed under an Enhancement of Survival Permit must not jeopardize the existence of federally listed species.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the application, associated documents, and comments submitted to determine whether the application meets the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Dated: November 12, 2015.

Perry Gayaldo,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–29409 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Application for Appointment in the NOAA Commissioned Officer Corps

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before January 19, 2016.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to LCDR Madeleine Adler—Chief, NOAA Corps Recruiting, or LT Jeffrey Pereira—NOAA Corps Recruiting Officer; OMAO–CPC–OCMD, 8402 Colesville Road, Suite 500, Silver Spring, MD 20910, ((800)-299–6622), *noaacorps.recruiting@noaa.gov*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection. The NOAA Commissioned Corps is the uniformed component of the National Oceanic and Atmospheric Administration (NOAA), a bureau of the Department of Commerce. Officers serve under Senate-confirmed appointments and Presidential commissions (33 U.S.C. chapter 17, subchapter 1, sections 853 and 854). The NOAA Corps provides a cadre of professionals trained in engineering, earth sciences, oceanography, meteorology, fisheries science, and other related disciplines, who are dedicated to the service of their country and optimization of NOAA's missions to ensure the economic and physical well-being of the Nation.

NOAA Corps officers serve in assignments throughout NOAA, as well as in each of NOAA's Line Offices (National Environmental Satellite, Data, and Information Service, National Ocean Service, National Weather Service, Office of Oceanic and Atmospheric Research and Office of Planning, Programming and Integration).

Persons wishing to be considered for a NOAA Corps Commission must submit a complete application package, including NOAA Form 56–42, at least three letters of recommendation, and official transcripts. A personal interview must also be conducted. Eligibility requirements include a bachelor's degree with at least 48 credit hours of science, engineering or other disciplines related to NOAA's missions (including either calculus or physics), excellent health, normal color vision with uncorrected visual acuity no worse than 20/400 in each eye (correctable to 20/20) and ability to complete 20 years of active duty commissioned service prior to their 62nd birthday.

II. Method of Collection

Applicants must utilize the E-recruit electronic application process (*https://cpc.omao.noaa.gov/erecruit/login.jsp*) and then submit paper forms via mail. An in-person interview is also required.

III. Data

OMB Control Number: 0648–0047.

Form Number(s): NOAA 56–42 and NOAA 56–42A.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 150.

Estimated Time per Response: Written applications, 5 hours; interviews, 90 minures; references, 15 minutes.

Estimated Total Annual Burden Hours: 1,088.

Estimated Total Annual Cost to Public: $10,875 in recordkeeping, recording and travel costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 13, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–29405 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD294

Fisheries of the Exclusive Economic Zone Off Alaska; Application for an Exempted Fishing Permit

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

ACTION: Notice; receipt of application for exempted fishing permit.

SUMMARY: This notice announces receipt of an exempted fishing permit (EFP) application from the Alaska Seafood Cooperative (AKSC). If granted, this permit would allow up to five AKSC-member Amendment 80 vessels to conduct experimental fishing in two subareas of the Bering Sea that are closed to fishing with trawl gear. Under the permit, experimental fishing with non-pelagic trawl gear would be authorized in Reporting Area 516 of Zone 1 that is otherwise closed to all trawl gear and the Red King Crab Savings Area (RKCSA) that is otherwise closed to non-pelagic trawl gear. The AKSC would collect data on crab prohibited species catch (PSC) rates during commercial groundfish fishing operations inside the Area 516 seasonal closure, the RKCSA, and adjacent areas that are currently open to non-pelagic trawling. The objective of the EFP is to evaluate PSC rates and overall catch of target species in the above-mentioned closed areas compared with the areas currently open to fishing with trawl gear. This experiment has the potential to promote the objectives of the Magnuson-Stevens Fishery Conservation and Management Act.

DATES: Submit comments on this EFP application on or before December 15, 2015.

The North Pacific Fishery Management Council (Council) will

consider the EFP application at its meeting to be held December 9, 2015, through December 15, 2015, in Anchorage, AK.

ADDRESSES: The Council meeting will be held at the Anchorage Hilton Hotel, 500 W. 3rd Avenue, Anchorage, AK, 99501. The agenda for the Council meeting is available at *http://legistar2.granicus.com/npfmc/meetings/2015/12/932_A_North_Pacific_Council_15–12–07_Meeting_Agenda.pdf.*

You may submit comments on this document, identified by NOAA–NMFS–2015–0138, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA–NMFS–2015–0138,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the EFP application and the categorical exclusion under the National Environmental Policy Act are available from the Alaska Region, NMFS Web site at *http://alaskafisheries.noaa.gov/.*

FOR FURTHER INFORMATION CONTACT: Jeff Hartman, 907–586–7442.

SUPPLEMENTARY INFORMATION: NMFS manages the domestic groundfish fisheries in the Bering Sea and Aleutian Islands management area (BSAI) under the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP), which the Council prepared under the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing the BSAI groundfish fisheries appear at 50 CFR parts 600 and 679. The FMP and the implementing regulations, § 600.745(b) and § 679.6, allow the NMFS Regional Administrator to authorize, for limited experimental purposes, fishing that would otherwise be prohibited. Procedures for issuing EFPs are contained in the implementing regulations.

Background

BSAI groundfish harvests are managed subject to annual limits on groundfish and PSC. Pacific halibut, Pacific herring, Pacific salmon and steelhead, king crab (including red king crab), and Tanner crab are prohibited species under the FMP. Participants in the BSAI non-pelagic trawl fisheries catch PSC incidentally—primarily crab and halibut.

The directed red king crab pot fishery is one of the most important shellfish fisheries in the Bering Sea. Current regulations for harvesting red king crab in the crab pot fishery may be found in 50 CFR part 680. Red king crab is also caught incidentally as PSC in Bering Sea groundfish non-pelagic trawl fisheries. PSC (including red king crab) in the non-pelagic trawl fisheries must be minimized to the extent practicable and if caught, immediately returned to the ocean with a minimum of injury.

The Council and NMFS have implemented FMP amendments, dating back to the 1980s and 1990s to reduce the amount of red king crab PSC in trawl fisheries, including the BSAI non-pelagic trawl fishery. For example, the Area 516 red king crab seasonal closure for all trawl gear (FMP Amendment 10) was implemented in 1987 (52 FR 8592, March 19, 1987). FMP amendment 37, (61 FR 65985, December 16, 1996) was implemented in 1997, to create the red king crab savings area (RKCSA) along with other measures to conserve concentrations of Bristol Bay red king crab. The management and structure of the non-pelagic trawl fisheries in the Bering Sea have changed since these red king crab closure areas were implemented. In 2007, NMFS implemented Amendment 80 to the FMP (72 FR 52668, September 14, 2007). Amendment 80 established a catch share program to allocate specific non-pelagic groundfish species among specific defined participants (the Amendment 80 sector) and facilitate the formation of Amendment 80 cooperatives among those participants. The Amendment 80 sector is comprised of 19 active vessels in 2015, and is the largest component of the non-pelagic trawl fishery. With the implementation of Amendment 80 to the FMP in 2008, vessels operating in Amendment 80 cooperatives were able to develop tools to reduce incidental catch of crab PSC.

Since the implementation of Amendment 80, participants in Amendment 80 cooperatives have reduced the amount of red king crab bycatch through improved fishing practices that are possible now that participants in the Amendment 80 cooperative receive an allocation of specific groundfish species. These exclusive allocations provide opportunities for Amendment 80 cooperative participants to slow or otherwise change their fishing operations to avoid red king crab bycatch. These modified fishing practices are not practicable when vessels are not provided an exclusive harvest allocation and are racing with other vessels to harvest their groundfish as soon as possible.

Although Amendment 80 cooperatives have undoubtedly helped to reduce red king crab PSC in the sector's target fisheries, a combination of closed areas and PSC limits currently regulate red king crab PSC in trawl fisheries, including the Amendment 80 sector. For example, the Area 516 of Zone 1 in the Bering Sea sub area closes annually to all trawl gear, including Amendment 80 vessels from March 15 through June 15, § 679.22(a)(2).

Regulations for groundfish fishing in the RKCSA, § 679.22(a)(3), close directed fishing for non-pelagic trawl gear in a portion of the Bering sea subarea defined in Figure 11 to 50 CFR part 679. Non-pelagic trawl gear is used by all Amendment 80 vessels in the Bering Sea.

PSC limits for red king crab (§ 679.21(e)(1)(i)) specify the annual PSC allowance of red king crab for all trawl vessels while engaged in directed fishing for groundfish in Zone 1. Approximately 50 percent of the Zone 1 red king crab PSC limit is apportioned to the Amendment 80 sector, and distributed as an allowance of crab to each Amendment 80 cooperative. In 2015, the Zone 1 red king crab PSC allowance for the AKSC is 30,834 animals.

The Zone 1 red king crab PSC allowance, allowed the Amendment 80 cooperatives to assign voluntary, vessel-level apportionments of PSC to vessels fishing in Zone 1. With these voluntary apportionments, vessel owners and operators in the sector began to share information about individual vessel PSC rates and avoid areas with high PSC rates for red king crab. The primary result of the improved crab avoidance and management tools is that AKSC and the remaining Amendment 80 sector vessels have consistently stayed well

under the Zone 1 red king crab PSC allowance. While the potential exists for crab PSC allowances and closure areas to constrain allocated catch in some Amendment 80 target fisheries, the Amendment 80 sector continues to actively explore how to further reduce crab PSC while preserving target fishery harvest opportunities.

Exempted Fishing Permit Application

On October 2, 2015, the AKSC, an Amendment 80 cooperative, submitted an application for an EFP. The EFP would allow up to five AKSC-member Amendment 80 vessels to conduct field tests in two subareas of the Bering Sea that are closed to trawl directed fisheries. Those two subareas are Reporting Area 516 of Zone 1, which is closed to all trawl gear § 679.22(a)(2), and the RKCSA, which is closed to non-pelagic trawl gear under § 679.22(a)(3). If granted, this EFP would allow AKSC to collect data on crab bycatch rates during commercial fishing operations on five groundfish fishing vessels (targeting mostly flatfish) inside the Area 516 seasonal closure, the RKCSA, and adjacent areas that are currently open to non-pelagic trawl gear. The principle objective of the EFP is to evaluate whether flatfish and other groundfish trawling in the above-mentioned closed areas under the existing PSC allowance for crab would result in reduced PSC rates for crab or other species, or a change in overall catch of target species compared with the status quo. This data will inform assessment of the effectiveness of these two crab closures.

The applicant proposes to begin EFP fishing in early February 2016 and end by mid-May 2016. EFP fishing would begin again in late January 2017 and end by mid-May 2017. The EFP would be in place over two winter/spring seasons to increase the chance that data collections will occur in different environmental conditions that are expected to affect crab and flatfish abundance and location.

To ensure data are available for valid comparisons of catch rates inside and outside the closed areas, participating vessels would fish both inside the closed areas and in adjacent areas outside the closed areas (as proportionally as possible) over the course of their Zone 1 rock sole and yellowfin sole fishing each year of the EFP. Adjacent areas against which rates inside the closed areas will be assessed will be selected based on similarities in the general depth and type of substrates that were test trawled in the RKCSA and Area 516 closures. To help ensure differences in bycatch rates reflect differences in relative abundance rather than the attributes of trawl gear used, the vessels participating in the EFP will keep their ground gear configuration (*e.g.* size of trawl net and width of footropes) as consistent as possible inside and outside of the closed areas.

Under the EFP, sea samplers would be required for monitoring and data collection. Sea samplers are NMFS-certified observers that conduct activities under an EFP rather than normal observer activities on an Amendment 80 vessel.

The sea samplers will conduct a census of all crab for all EFP tows inside the red king crab closed areas and in adjacent areas outside the red king crab closed areas. The census data will include a record of size and sex of each individual. Temperature and depth data will be collected by sea samplers for each tow. Sea samplers will also collect fishing operational information such as tow speed and tow length. AKSC will compare catch rates on different EFP vessels when fishing in similar areas to evaluate the degree to which individual differences in a specific vessel are impacting catch rates.

To ensure observer sampling duties are undisturbed, expanded crab data collection under the census will be conducted in a manner that is completely separate from current observer sampling protocols. To accomplish this, the crab census will occur after all the catch passes over the vessel's flow scale and the observer has completed all sampling of unsorted catch for all Bering Sea EFP hauls.

The five vessels authorized to participate in this EFP would be required to comply with all the aggregate target species allocations that apply to the rest of the Amendment 80 sector, and would operate under the Amendment 80 crab and halibut PSC allowances available through membership in the AKSC. These allowances will apply to all EFP and non-EFP fishing during the year.

Under the EFP, the AKSC and the member EFP vessels would be limited to the amount of aggregate groundfish allocations currently in regulation at 50 CFR part 679. Further, the amount of red king crab PSC accrued by the AKSC and under the EFP would not exceed the AKSC's 2016 or 2017 red king crab allowance. All other crab limits and halibut mortality limits will continue to apply to the EFP activities, and are subject to review and approval by NMFS.

At the end of EFP fishing in 2016, AKSC would be required to submit to NMFS a preliminary report of the EFP results on PSC use inside and outside of the closed areas and by target fishery. At the end of EFP fishing in 2017, a final, comprehensive EFP report would be submitted.

The proposed action would exempt participating AKSC vessels from selected 50 CFR part 679 closed areas and PSC handling requirements. Should the Regional Administrator issue a permit based on this EFP application, the conditions of the permit will be designed to minimize PSC, and any potential for biasing estimates of groundfish or PSC. Vessels participating in EFP fishing would be exempt from, at minimum, the following regulations:

1. Closure to directed fishing by trawl gear in Reporting Area 516 of Zone 1 in the Bering Sea Subarea from March 15 through June 15, at § 679.22(a)(2).

2. closure to directed fishing by non-pelagic trawl gear in the RKCSA at § 679.22(a)(3).

3. that the operator of each vessel, after allowing for sampling by an observer, return all prohibited species, or parts thereof, to the sea immediately, with a minimum of injury, regardless of its condition at § 679.21(b)(2)(ii).

The EFP would be valid upon issuance in 2016 until either the end of designated EFP fishing in 2017 or until the AKSC Zone 1 red king crab PSC allowance is reached in areas of the BSAI open to directed fishing by the Amendment 80 cooperatives. EFP-authorized fishing activities would not be expected to change the nature or duration of the groundfish fishery, gear used, or the amount or species of fish caught by the Amendment 80 cooperatives.

The fieldwork that would be conducted under this EFP is not expected to have a significant impact on the human environment as detailed in the categorical exclusion prepared for this action (see **ADDRESSES**).

In accordance with § 679.6, NMFS has determined that the application warrants further consideration and has forwarded the application to the Council to initiate consultation. The Council is scheduled to consider the EFP application during its December 2015 meeting, which will be held at the Anchorage Hilton Hotel, Anchorage, AK. The EFP application will also be provided to the Council's Scientific and Statistical Committee for review at the December Council meeting. The applicant has been invited to appear in support of the application.

Public Comments

Interested persons may comment on the EFP application at the December 2015 Council meeting during public testimony. Information regarding the

meeting is available at the Council's Web site at *http://alaskafisheries.noaa.gov/npfmc/council.htm.* Comments also may be submitted directly to NMFS (see **ADDRESSES**) by the end of the comment period (see **DATES**). Copies of the application and categorical exclusion are available for review from NMFS (see **ADDRESSES**).

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

Dated: November 13, 2015.

Emily H. Menashes,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2015–29451 Filed 11–17–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket ID: USA–2015–0004]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by December 18, 2015.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and Omb Number: Exchange Official Personnel Folder; Exchange Form 1100–106 ''Identification & Privilege Card Application''; OMB Control Number: 0702–XXXX.

Type of Request: Existing collection in use without an OMB Control Number.

Number of Respondents: 2,500.

Responses per Respondent: 1.

Annual Responses: 2,500.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 625.

Needs and Uses: The information collection requirement is necessary to provide a repository of the records, reports of personnel actions, and the documents and papers required in connection with these actions effected during an employee's service with the Army and Air Force Exchange Service (Exchange). Records provide the basic source of factual data about a person's employment with the agency and have various uses by the Exchange personnel office, including screening qualifications of employees, determining status, eligibility, and employee's rights and benefits, computing length of service and other information needed to provide personnel services.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: November 12, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–29401 Filed 11–17–15; 8:45 am]

BILLING CODE 5001–06–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Notice

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of the Government in the Sunshine Act (5 U.S.C. 552b), and the Defense Nuclear Facilities Safety Board's (Board) regulations implementing the Government in the Sunshine Act, notice is hereby given of the Board's closed meeting described below.

DATES: 1:00 p.m.–3:00 p.m., December 1, 2015.

ADDRESSES: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Room 425, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Mark Welch, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The meeting will be closed to the public. No participation from the public will be considered during the meeting.

Status

Closed. During the closed meeting, the Board Members will discuss issues dealing with potential Recommendations to the Secretary of Energy. The Board is invoking the exemption to close a meeting described in 5 U.S.C. 552b(c)(3) and 10 CFR 1704.4(c). The Board has determined that it is necessary to close the meeting since conducting an open meeting is likely to disclose matters that are specifically exempted from disclosure by statute. In this case, the deliberations will pertain to potential Board Recommendations which, under 42 U.S.C. 2286d(b) and (h)(3), may not be made publicly available until after they have been received by the Secretary of Energy or the President, respectively.

MATTERS TO BE CONSIDERED: The meeting will proceed in accordance with the closed meeting agenda which is posted on the Board's public Web site at *www.dnfsb.gov.* Technical staff may present information to the Board. The Board Members are expected to conduct deliberations regarding potential Recommendations to the Secretary of Energy.

Dated: November 13, 2015.

Joyce L. Connery,

Chairman.

[FR Doc. 2015–29497 Filed 11–16–15; 11:15 am]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

Notice Expanding an Experiment Under the Experimental Sites Initiative; Federal Student Financial Assistance Programs Under Title IV of the Higher Education Act of 1965, as Amended

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary is expanding the Competency-Based Education experiment, which was announced in a previous **Federal Register** notice, to provide additional flexibility in how institutions provide Federal student aid to students who are enrolled in competency-based education programs, including providing waivers and modifications to statutory and regulatory requirements designed to support competency-based education programs that charge a flat fee for a period of time rather than charging by course or by competency. The expansion of the Competency-Based Education experiment provides two additional sets of waivers that are available to both institutions currently approved for the experiment and institutions that may be approved based on their submission of a letter of interest. These sets of waivers are described in this notice below, under ''The Experiment.''

In a **Federal Register** notice published on July 31, 2014, the Secretary invited postsecondary educational institutions (institutions) that participate in the student financial assistance programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA), to apply to participate in institutionally-based experiments, including the Competency-Based Education experiment, under the Experimental Sites Initiative (ESI).

DATES: Institutions that have not already received approval to participate in the Competency-Based Education experiment must submit a letter of interest following the instructions included in this notice. Letters of interest must be received by the Department no later than January 19, 2016 in order for an institution to receive priority to be considered for participation in the experiment. Letters received after January 19, 2016 may still, at the discretion of the Secretary, be considered for participation.

The Department will contact those institutions that have already received approval to participate in the Competency-Based Education experiment to determine which of the three sets of waivers, discussed below in the ''The Experiment'' section of this notice, the institution wishes to apply to their competency-based education programs. Based upon each institution's response, the Department will amend the institution's Program Participation Agreement (PPA) to reflect the specific waivers and modifications to statutory or regulatory provisions included in the set of waivers chosen by the institution.

ADDRESSES: Letters of interest must be submitted by electronic mail to the following email address: *experimentalsites@ed.gov.* The subject line of the email should read ''ESI 2015—Competency-Based Education.'' For formats and other required information, see ''Instructions for Submitting Letters of Interest'' under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Warren Farr, U.S. Department of Education, Federal Student Aid, 830 First Street NE., Washington, DC 20002. Telephone: (202) 377–4380 or by email at: *Warren.Farr@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Instructions for Submitting Letters of Interest

Letters of interest for the Competency-Based Education experiment should take the form of a PDF attachment to an email message as described in the **ADDRESSES** section of this notice. The letter of interest should be on institutional letterhead and be signed by at least two officials of the institution—one of these officials should be the institution's financial aid administrator, and the other should be an academic official of the institution who is familiar with the institution's competency-based educational programs. The letter of interest must include the institution's official name and Department of Education Office of Postsecondary Education Identification (OPEID), as well as a mailing address, email address, FAX number, and telephone number of a contact person at the institution. The letter should indicate which of the three sets of waivers, discussed below in the ''The Experiment'' section of this notice, the institution wishes to apply to their competency-based education programs.

Background

The Secretary, under the Experimental Sites Initiative (ESI) authority of section 487A(b) of the HEA, published a **Federal Register** notice (79 FR 44429) dated July 31, 2014 (July 31, 2014, notice), inviting institutions to participate in four experiments that would waive certain statutory and regulatory requirements related to the title IV, HEA programs. One of those experiments was the Competency-Based Education experiment.

Under the Competency-Based Education experiment, the Secretary provided limited waivers of certain statutory and regulatory requirements to remove some of the time-based restrictions to the disbursement of student assistance under title IV of the HEA (title IV aid) so that funds are available to a student to pay institutional charges as the student progresses through a program at the student's own pace. Specifically, the Secretary allowed for the disbursement of title IV aid for direct costs as soon as the student completed a required number of competencies, regardless of how many weeks of instructional time have elapsed, and for disbursement of title IV aid for indirect costs at regular calendar intervals, regardless of how many competencies the student had completed, all within award maximums. The Secretary also modified the requirements for monitoring satisfactory academic progress to permit institutions to evaluate a student's pace in a competency-based education program by calculating competencies completed over calendar time, rather than by dividing the hours the student completed by the hours the student attempted. Detailed information regarding these requirements is provided in the Competency-Based Education Experiment Reference Guide, which is available at: *https://experimentalsites.ed.gov/exp/guidance.html*.

In the July 31, 2014, notice, the Secretary described the application, selection, reporting, and evaluation requirements for the Competency-Based Education experiment. All of those requirements remain in effect regardless of which set of waivers, as described in this notice, is chosen by an institution.

Since the publication of the July 31, 2014, notice, the Department has learned that there are challenges associated with the waivers discussed in that notice for institutions that charge students who are enrolled in competency-based programs a set amount for a defined period of time, as opposed to charging an amount for each competency. This is often referred to as a ''subscription period model.'' Some institutions have suggested that financial aid for programs that charge using subscription periods rather than by competency can be administered more effectively by using term-based disbursements, with flexibilities to allow students to begin and complete their competencies outside of the start and end dates of terms, rather than using a nonterm model as described in the July 31, 2014, notice.

Other institutions stated that they were primarily interested in the satisfactory academic progress waivers

noted in the July 31, 2014, notice and did not need the full set of waivers included in that notice.

Selection

For institutions that, in response to this notice, submit letters of interest for the Competency-Based Education experiment, the Secretary's process for selecting participating institutions will remain the same as was described in the July 31, 2014, notice.

The Experiment

Background

The Department's regulations at 34 CFR 668.4(a) and (b) describe requirements for payment periods for eligible programs that measure progress in credit hours and use standard or nonstandard terms. A term is a period during which all classes are scheduled to begin and end within a set timeframe.

The Department's regulations for satisfactory academic progress at 34 CFR 668.34 require institutions to measure a student's progress at least once annually, though an institution is permitted to check more often. Those regulations also require an institution to determine a student's academic progress pace by dividing the cumulative number of hours the student has successfully completed by the cumulative number of hours the student has attempted.

Some institutions offering competency-based programs charge students using ''subscription periods,'' in which the institution charges the student a single fee for all of the student's competency-based instruction during each subscription period. In some instances, students begin and complete a subscription period within the dates of the term. However, because competency-based programs are generally self-paced, the requirement under a term-based program that coursework must begin and end within the timeframe of the term is often a significant impediment to the students enrolled in such programs.

Description

In response to the above, the Secretary is expanding the current Competency-Based Education experiment to provide two additional sets of statutory and regulatory waivers. Institutions must choose a single set of waivers from among the three sets available that will apply to all of the competency-based education programs that it includes under the experiment. The sets of waivers are as follows:

(1) *Split Disbursement:* This set of waivers includes all of the disbursement, satisfactory academic progress, and Return of Title IV Funds waivers described in the July 31, 2014, notice and explained in the Competency-Based Education Experiment Reference Guide.

(2) *Satisfactory Academic Progress Only:* A second set of waivers will include only the waivers to the satisfactory academic progress requirements described in the July 31, 2014, notice and explained in the Competency-Based Education Experiment Reference Guide.

(3) *Subscription Period Disbursement:* The third set of waivers is intended for institutions offering competency-based programs using subscription periods and is described below.

Under the Subscription Period Disbursement set of waivers, the institution may include in its determination of a student's enrollment status competencies that begin prior to the start of the subscription period, as long as it does not include those competencies in enrollment status for two different payment periods. Institutions will disburse title IV aid based on the student's anticipated enrollment for a subscription period (which is equivalent to a payment period) rather than requiring completion of a specific number of competencies prior to making subsequent disbursements of title IV aid. While an institution will determine a student's title IV aid amounts based on the student's anticipated enrollment status, the institution will be required to perform a satisfactory academic progress evaluation for the student at the end of each subscription period (payment period) to ensure that the student has completed the appropriate number of competencies in that payment period, given the student's enrollment status.

Program Eligibility: An institution participating in the Competency-Based Education experiment could choose to use the Subscription Period Disbursement set of waivers only if it charges students in a competency-based education program using subscription periods, as described above.

Payment Periods: Subscription periods under this set of waivers will be considered to be term-based payment periods, as payment periods are defined under 34 CFR 668.4(a) and (b). Institutions disbursing under this set of waivers will generally follow existing rules for standard and nonstandard terms, as appropriate, except that nonstandard terms that are not substantially equal will have the same payment periods for Direct Loans as they do for Pell Grants, with similar proration based on the length of the payment period.

Enrollment Status: For each payment period, students will be assigned by the institution an enrollment status (full-time, half-time, three-quarter time, less than half-time) based on the student's expected enrollment in and completion of competencies for the payment period. After consulting with the student, the institution will determine the student's enrollment status based on a realistic assessment by the institution of the number of competencies that the student will complete during the payment period. However, unlike under existing regulations for standard and nonstandard term programs, an institution will not be permitted to count a unique competency or course toward a student's enrollment status for more than one payment period.

In addition, under this set of waivers, a student's enrollment status may not be changed for title IV purposes once it has been established for the payment period, except that an institution must increase a student's enrollment status to reflect any competencies completed by the student during the payment period that were not originally assigned to that payment period or to a previous payment period. If the additional competencies that were completed in the payment period were expected to be completed in a subsequent payment period(s), an adjustment to the student's enrollment status for that subsequent payment period(s) is required.

For Pell Grant purposes, students will still be required to begin working on at least the number of competencies used in the determination of the student's enrollment status for each payment period. Therefore, to use this set of waivers, an institution must have a mechanism for determining that a student has been participating in a competency during a payment period.

Satisfactory Academic Progress: As in the Split Disbursement set of waivers, the Subscription Period Disbursement set of waivers will modify the statutory and regulatory requirements for monitoring satisfactory academic progress so that an institution will be required to evaluate a student's pace by using competencies completed over calendar time, rather than by dividing a student's completed credit hours by attempted credit hours. However, two additional requirements will be added for institutions using Subscription Period Disbursement.

First, the institution must evaluate a student's satisfactory academic progress after every subscription period (payment period), rather than at least once annually, even if the program is more than one academic year in length.

Second, the institution must evaluate a student's pace using two separate measures:

(1) The student's progress for the payment period immediately prior to the evaluation, calculated using the number of credit hours or equivalents completed over the number of credit hours or equivalents included in the student's enrollment status for that payment period; and

(2) The student's cumulative rate of progress, calculated by dividing the aggregate number of credit hours or equivalents completed as of the end of the payment period by the total number of credit hours or equivalents expected to be completed as of the end of that payment period in order for the student to complete the program within the maximum timeframe. The maximum timeframe is based on the published length of the program, expressed in calendar time (*i.e.,* weeks, months, years).

To make satisfactory academic progress under the payment period measure, a student must complete the minimum number of credit hours or equivalents associated with the enrollment status that was assigned to the student for the payment period under review. For example, if an institution's definition of a ''full-time academic workload'' in a competency-based education program is 12 semester hours and a student enrolled in that program is assigned a full-time enrollment status in a payment period, the student would need to complete competencies with an equivalent of at least 12 semester hours in that payment period to make satisfactory academic progress. Similarly, if a student in the same program is assigned a half-time enrollment status in a payment period, the student would need to complete at least 6 semester hours in that payment period in order to make satisfactory academic progress.

For its evaluation of a student's cumulative rate of progress, the institution could use different standards for students on different enrollment tracks—for example, there could be a different maximum timeframe for a student on a half-time enrollment track, for whom the normal time for completion of the program is longer than for a student on a full-time enrollment track.

If a student fails either of the two satisfactory academic progress evaluations, the student will have failed to make satisfactory academic progress and will, based on the institution's satisfactory academic progress policies, either be assigned to a financial aid warning period or immediately lose eligibility for title IV funds. Institutions will have the same flexibility to establish options for appeals, probation periods, and academic plans as they do under the current regulations.

Return of title IV Funds (R2T4): Under the Subscription Period Disbursement set of waivers, R2T4 calculations will be required, and will follow the normal requirements under 34 CFR 668.22 when a student withdraws.

Waivers

For all of the competency-based education programs that it offers under the experiment, the institution must select one of the following sets of waivers.

(1) *Split Disbursement:*

• This set of waivers was described in the July 31, 2014, notice and explained in the Competency-Based Education Experiment Reference Guide.

(2) *Satisfactory Academic Progress Only:*

• This set of waivers includes only the waivers to the satisfactory academic progress requirements described in the July 31, 2014, notice and explained in the Competency-Based Education Experiment Reference Guide.

(3) *Subscription Period Disbursement:*

• 34 CFR 668.4(a), to the extent that the regulation requires the coursework undertaken within a standard term or a nonstandard term to begin within the term start and end dates.

• 34 CFR 668.4(b), to the extent that the regulation requires the coursework undertaken within a nonstandard term to begin within the term start and end dates.

• HEA section 484(c) and 34 CFR 668.34(a)(3)(ii), (a)(5)(ii), and (b), related to the timeframe when the institution must determine whether a student is making satisfactory academic progress and the method by which an institution must calculate the pace of a student's academic progression.

• 34 CFR 685.303(d)(5), to the extent that the regulations provide that Direct Loan proceeds must be disbursed in substantially equal installments. The modification will require the institution to make disbursements of Direct Loan funds in accordance with the provisions of the Pell Grant program under the same rules used in the calculation of disbursement amounts in the Pell Grant program under 34 CFR 690.63.

• 34 CFR 690.80(b)(2)(i), which permits an institution to recalculate a student's enrollment status during a payment period after the student has begun all of the coursework for the payment period.

All other provisions and regulations of the title IV student assistance programs will remain in effect.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. 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 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 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.

Delegation of Authority: The Secretary of Education has delegated authority to Jamienne S. Studley, Deputy Under Secretary, to perform the functions and duties of the Assistant Secretary for Postsecondary Education.

Program Authority: HEA, section 487A(b); 20 U.S.C. 1094a(b).

Dated: November 13, 2015.

Jamienne S. Studley,

Deputy Under Secretary.

[FR Doc. 2015–29437 Filed 11–17–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Nuclear Energy Advisory Committee

AGENCY: Office of Nuclear Energy, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Nuclear Energy Advisory Committee (NEAC). The Federal Advisory Committee Act (Pub. L. 94–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Friday, December 11, 2015, 8:30 a.m.–4:00 p.m.

ADDRESSES: Westin Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Bob Rova, Designated Federal Officer, U.S. Department of Energy, 19901 Germantown Rd., Germantown, MD 20874; telephone (301) 903–9096; email: *Robert.rova@nuclear.energy.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Nuclear Energy Advisory Committee (NEAC), formerly the Nuclear Energy Research Advisory Committee (NERAC), was established in 1998 by the U.S. Department of Energy (DOE) to provide advice on complex scientific, technical, and policy issues that arise in the planning, managing, and implementation of DOE's civilian nuclear energy research programs. The committee is composed of 17 individuals of diverse backgrounds selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to nuclear energy.

Purpose of the Meeting: To inform the committee of recent developments and current status of research programs and projects pursued by the Department of Energy's Office of Nuclear Energy and receive advice and comments in return from the committee.

Tentative Agenda: The meeting is expected to include presentations that cover such topics as an update on activities for the Office of Nuclear Energy. In addition, there will be presentations by Nuclear Energy Advisory Committee subcommittees. The agenda may change to accommodate committee business. For updates, one is directed the NEAC Web site: *http://energy.gov/ne/services/nuclear-energy-advisory-committee.*

Public Participation: Individuals and representatives of organizations who would like to offer comments and suggestions may do so on the day of the meeting, Friday, December 11, 2015. Approximately thirty minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but is not expected to exceed 5 minutes. Anyone who is not able to make the meeting or has had insufficient time to address the committee is invited to send a written statement to Bob Rova, U.S. Department of Energy 1000 Independence Avenue SW., Washington, DC 20585, or email: *robert.rova@nuclear.energy.gov.*

Minutes: The minutes of the meeting will be available by contacting Mr. Rova at the address above or on the Department of Energy, Office of Nuclear Energy Web site at *http://energy.gov/ne/services/nuclear-energy-advisory-committee.*

Issued in Washington, DC, on November 12, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–29434 Filed 11–17–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Advanced Scientific Computing Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Advanced Scientific Computing Advisory Committee (ASCAC). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES:

Wednesday, December 9, 2015 8:30 a.m.–5:30 p.m.;

Thursday, December 10, 2015 8:30 a.m.–12:00 p.m.

ADDRESSES: American Geophysical Union (AGU), 2000 Florida Avenue NW., Washington, DC 20009–1277.

FOR FURTHER INFORMATION CONTACT: Christine Chalk, Office of Advanced Scientific Computing Research; SC–21/Germantown Building; U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–1290; Telephone (301) 903–7486.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: To provide advice and guidance on a continuing basis to the Office of Scientific Computing Research and to the Department of Energy on scientific priorities within the field of advanced scientific computing research.

Purpose of the Meeting: This meeting is the semi-annual meeting of the Committee.

Tentative Agenda Topics:

- View from Germantown
- Report from the Next Generation Networking for Science Committee of Visitors
- Information on the National Strategic Computing Initiative
- Update on Exascale project activities
- Summary of workshops on technologies ''beyond exascale''
- Program response to report from Subcommittee on the Office of Scientific and Technical Information (OSTI)
- Technical presentations
- Public Comment (10-minute rule)

The meeting agenda includes a report from the Committee of Visitors on the Next Generation Networking for Science program; an update on the budget, accomplishments and planned activities of the Advanced Scientific Computing Research program; a program response to the report from the Subcommittee on the Office of Scientific and Technical Information; an update on exascale computing project activities; information on recent workshops exploring potential technologies ''beyond exascale''—such as quantum computing and neom orphic computing; a technical presentation from an exascale researcher in Computer Science; and an opportunity for comments from the public. The meeting will conclude at noon on December 10, 2015. Agenda updates and presentations will be posted on the ASCAC Web site prior to the meeting: *http://science.energy.gov/ascr/ascac/.*

Public Participation: The meeting is open to the public. Individuals and representatives of organizations who would like to offer comments and suggestions may do so during the meeting. Approximately 30 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but will not exceed 10 minutes. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Those wishing to speak should submit your request at least five days before the meeting. Those not able to attend the meeting or who have insufficient time to address the committee are invited to send a written statement to Christine Chalk, U.S. Department of Energy, 1000 Independence Avenue SW., Washington DC 20585, email to *Christine.Chalk@science.doe.gov.*

Minutes: The minutes of this meeting will be available within 90 days on the Office of Advanced Scientific Computing Web site at *http://science.energy.gov/ascr/ascac/.*

Issued at Washington, DC, on November 12, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–29429 Filed 11–17–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

National Nuclear Security Administration

Defense Programs Advisory Committee

AGENCY: Office of Defense Programs, National Nuclear Security Administration, Department of Energy.

ACTION: Notice of closed meeting.

SUMMARY: This notice announces a closed meeting of the Defense Programs Advisory Committee (DPAC). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of meetings be announced in the **Federal Register**. Due to national security considerations, under section 10(d) of the Act and 5 U.S.C. 552b(c), the meeting will be closed to the public and matters to be discussed are exempt from public disclosure under Executive Order 13526 and the Atomic Energy Act of 1954, 42 U.S.C. 2161 and 2162, as amended.

DATES: December 3, 2015, 8:30 a.m. to 5:00 p.m. and December 23, 2015, 8:30 a.m. to 5:00 p.m.

ADDRESSES: U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Loretta Martin, Office of RDT&E (NA–113), National Nuclear Security Administration, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, (202) 586–7996.

SUPPLEMENTARY INFORMATION:

Background: The DPAC provides advice and recommendations to the Deputy Administrator for Defense Programs on the stewardship and maintenance of the Nation's nuclear deterrent.

Purpose of the Meeting: The purpose of this meeting of the DPAC is to discuss the final draft of the classified report to be provided to the National Nuclear Security Administration in response to the charge to the Committee. This meeting corresponds to the one previously announced for October 22–23, 2015, in Washington, DC, which had to be postponed.

Type of Meeting: In the interest of national security, the meeting will be closed to the public. The Federal Advisory Committee Act, 5 U.S.C., App. 2, section 10(d), and the Federal Advisory Committee Management Regulation, 41 CFR 102–3.155, incorporate by reference the Government in the Sunshine Act, 5 U.S.C. 552b, which, at 552b(c)(1) and (c)(3) permits closure of meetings where restricted data or other classified matters will be discussed. Such data and matters will be discussed at this meeting.

Tentative Agenda: Day 1—Welcome, discussion and editing of draft report; Day 2—Discussion and editing of draft report, reconciliation of input, (tentative) acceptance of report; conclusion.

Public Participation: There will be no public participation in this closed meeting. Those wishing to provide written comments or statements to the Committee are invited to send them to Loretta Martin at the address listed above.

Minutes: The minutes of the meeting will not be available.

Issued in Washington, DC, on November 12, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–29430 Filed 11–17–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: November 19, 2015, 10:00 a.m.

PLACE: Room 2C, 888 First Street NE., Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda * Note—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400. For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's Web site at *http://www.ferc.gov* using the eLibrary link, or may be examined in the Commission's Public Reference Room.

1021ST—MEETING, REGULAR MEETING, NOVEMBER 19, 2015, 10:00 A.M.

Item No.	Docket No.	Company
	Administrative	
A–1	AD16–1–000	Agency Administrative Matters.
A–2	AD16–7–000	Customer Matters, Reliability, Security and Market Operations.
A–3	AD07–13–009	2015 Report on Enforcement.
A–4	AD16–12–000	Energy Storage Panel.
	Electric	
E–1	RM15–2–000	Third-Party Provision of Primary Frequency Response Service.
E–2	AD14–14–000	Price Formation in Energy and Ancillary Services Markets Operated by Regional Transmission Organizations and Independent System Operators.
E–3	RM16–1–000	Reactive Power Requirements for Non-Synchronous Generation.
E–4	ER15–861–004	California Independent System Operator Corporation.
E–5	ER15–2281–000, ER15–2282–001, ER15–2283–000	Nevada Power Company, Sierra Pacific Power Company, PacifiCorp.
E–6	OMITTED.	
E–7	RM15–3–001	Revisions to Public Utility Filing Requirements.
E–8	RM11–12–001	Availability of E-Tag Information to Commission Staff.
E–9	RM15–7–000	Revisions to Emergency Operations Reliability Standards.

1021ST—MEETING, REGULAR MEETING, NOVEMBER 19, 2015, 10:00 A.M.—Continued

Item No.	Docket No.	Company
	RM15–12–000	Revisions to Undervoltage Load Shedding Reliability Standards.
	RM15–13–000	Revisions to the Definition of ''Remedial Action Scheme'' and Related Reliability Standards.
E–10	RM15–16–000	Transmission Operations Reliability Standards and Interconnection Reliability Operations and Coordination Reliability Standards.
E–11	ER11–4081–001	Midwest Independent Transmission System Operator, Inc.
E–12	ER11–4081–002	Midwest Independent Transmission System Operator, Inc.
E–13	ER15–698–000	Northern States Power Company, a Minnesota corporation.
	ER15–698–001	Northern States Power Company, a Wisconsin corporation.
E–14	ER15–2292–000	Idaho Power Company.
E–15	ER12–2399–003	PJM Interconnection, L.L.C. and American Transmission Systems, Inc.
E–16	OMITTED.	
E–17	ER15–2260–001, EL14–24–000	PJM Interconnection, L.L.C.
E–18	EL14–26–000	New York Independent System Operator, Inc.
E–19	EL14–23–000	ISO New England Inc.
E–20	ER15–2295–000	Southwest Power Pool, Inc.
E–21	OMITTED.	
E–22	ER15–572–003	New York Transco, LLC.
E–23	ER15–2550–000	Rancho Cucamonga Municipal Utility.
E–24	ER15–2588–000	Eastside Power Authority.
E–25	ER12–39–000, ER12–39–001	Seminole Electric Cooperative, Inc. and Florida Municipal Power Agency v. Florida Power Corporation.
	EL13–63–000, EL13–63–001, EL14–90–000	Seminole Electric Cooperative, Inc. and Florida Municipal Power Agency v. Duke Energy Florida, Inc.
	ER13–1356–000, ER13–1356–001, ER14–1832–000, ER15–1618–000.	Duke Energy Florida, Inc.
E–26	EL08–14–010	Black Oak Energy, L.L.C., EPIC Merchant Energy, L.P. and SESCO Enterprises, L.L.C. v. PJM Interconnection, L.L.C.
E–27	ER12–1384–001, ER12–1385–002, ER12–1386–001, ER12–1387–001, ER12–1388–001, ER12–1390–001, EL11–57–002, (Consolidated).	Entergy Arkansas, Inc., Entergy Gulf States Louisiana, L.L.C., Entergy Louisiana, LLC, Entergy Mississippi, Inc., Entergy New Orleans, Inc., Entergy Texas, Inc., Louisiana Public Service Commission v. Entergy Corporation, Entergy Services, Inc., Entergy Louisiana, LLC, Entergy Arkansas, Inc., Entergy Mississippi, Inc., Entergy New Orleans, Inc., Entergy Gulf States Louisiana, LLC, and Entergy Texas, Inc.
E–28	ER10–2001–004	Entergy Services, Inc.
E–29	ER10–2156–004	Consumers Energy Company.
E–30	ER12–1653–005	New York Independent System Operator, Inc.
E–31	ER15–2272–000	California Independent System Operator Corporation.
E–32	ER14–2017–001	California Independent System Operator Corporation.
E–33	EL15–83–000	Joint Consumer Representatives v. PJM Interconnection, L.L.C.
E–34	EL10–55–002	Louisiana Public Service Commission v. Entergy Corporation, Entergy Services, Inc., Entergy Louisiana, L.L.C., Entergy Arkansas, Inc., Entergy New Orleans, Inc., Entergy Mississippi, Inc., Entergy Gulf States Louisiana, LLC, and Entergy Texas, Inc.
E–35	EL15–32–001	North Carolina Waste Awareness and Reduction Network, Inc. v. Duke Energy Carolinas, LLC and Duke Energy Progress, Inc.
E–36	EL15–47–001	NextEra Desert Center Blythe, LLC v. California Independent System Operator Corporation.
E–37	EL10–86–004	Jeffers South, LLC v. Midwest Independent Transmission System Operator, Inc.
E–38	EL12–98–001, EL12–98–002	Hudson Transmission Partners, LLC v. New York Independent System Operator, Inc.
E–39	EL15–25–001	New England Power Generators Association, Inc. v. ISO New England Inc.
E–40	EL15–62–000	Chevron U.S.A. Inc.
E–41	EF15–8–000	Western Area Power Administration.
E–42	OMITTED.	
E–43	TS15–1–000	City of Alexandria, Louisiana.
E–44	ER05–1056–009	Chehalis Power Generating, L.P.
E–45	ER14–1050–002, EL14–52–001	ISO New England Inc. and New England Power Pool.
E–46	ER14–2419–003, EL14–52–002	ISO New England Inc.
E–47	ER15–2623–000, ER15–2625–000	Nevada Power Company.
	Gas	
G–1	RP15–1022–001	Alliance Pipeline L.P.
G–2	IS14–607–000, IS14–608–000, IS14–609–000, IS14–610–000	Zydeco Pipeline Company LLC.

1021ST—MEETING, REGULAR MEETING, NOVEMBER 19, 2015, 10:00 A.M.—Continued

Item No.	Docket No.	Company
G–3	IS09–348–004, IS09–395–004, IS10–204–002, IS10–491–000, IS09–348–006, IS09–395–006, IS10–204–004, IS10–491–003.	BP Pipelines (Alaska) Inc.
	IS09–384–004, IS10–205–003, IS10–476–001, IS09–384–006, IS10–205–005, IS10–476–003.	ConocoPhillips Transportation Alaska Inc.
	IS09–391–004, IS09–177–005, IS10–200–002, IS10–547–000, IS09–391–006, IS09–177–007, IS10–200–004, IS10–547–002.	ExxonMobil Pipeline Company.
	IS09–176–004, IS07–41–005, IS08–53–005, IS10–52–001, OR10–3–001, IS10–490–000, IS11–3–000, IS09–176–006, IS07–41–007, IS08–53–007, IS10–52–003, OR10–3–004, IS10–490–002 , IS11–3–002.	Unocal Pipeline Company.
	IS10–54–001, IS10–496–000, IS10–54–003, IS10–496–003	Koch Alaska Pipeline Company, L.L.C.
G–4	OR15–53–000	Enterprise TE Products Pipeline Company LLC.
G–5	TS13–3–001	KPC Pipeline, LLC.
	Hydro	
H–1	P–13351–021	Marseilles Land and Water Company.
H–2	P–6142–008	Kevin Drone.
H–3	P–2106–068	Pacific Gas and Electric Company.
H–4	P–5–101	Confederated Salish and Kootenai Tribes Energy Keepers, Incorporated.
H–5	P–2280–020	Seneca Generation, LLC.
H–6	P–14628–006	Minneapolis Leased Housing Associates IV, Limited Partnership.
H–7	HB81–09–2–003, P–12252–033	Hudson River-Black River Regulating District.
	P–13–032	Green Island Power Authority and Albany Engineering Corp.
	P–2047–059, P–2318–052, P–2482–099, P–2554–072	Erie Boulevard Hydropower L.P.
	P–2385–028	FH Opco LLC.
	P–2609–045	Curtis/Palmer Hydroelectric Co.
	P–2934–027	New York State Electric & Gas Corp.
	P–4226–006	Fort Miller Associates.
	P–4684–069	GR Catalyst One., LLC,.
	P–5276–063	Northern Electric Power Co. and Niagara Mohawk Power Corp.
	P–5461–050	South Glens Falls Limited Partnership and Niagara Mohawk Power Corp.
	P–6032–074	Albany Engineering Corp.
H–8	P–1025–086	Safe Harbor Water Power Corporation.
	Certificates	
C–1	OMITTED.	
C–2	CP11–161–002	Tennessee Gas Pipeline, L.L.C.
C–3	CP15–100–000	National Fuel Gas Supply Corporation and National Fuel Gas Supply, LLC.
C–4	CP14–555–000	Dominion Transmission, Inc.
C–5	CP14–513–001	Impulsora Pipeline, LLC.

Issued: November 12, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

A free webcast of this event is available through *www.ferc.gov.* Anyone with Internet access who desires to view this event can do so by navigating to *www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the free webcasts. It also offers access to this event via television in the DC area and via phone bridge for a fee. If you have any questions, visit *www.CapitolConnection.org* or contact Danelle Springer or David Reininger at 703–993–3100.

Immediately following the conclusion of the Commission Meeting, a press briefing will be held in the Commission Meeting Room. Members of the public may view this briefing in the designated overflow room. This statement is intended to notify the public that the press briefings that follow Commission meetings may now be viewed remotely at Commission headquarters, but will not be telecast through the Capitol Connection service.

[FR Doc. 2015–29509 Filed 11–16–15; 11:15 am]

BILLING CODE 6717–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, 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.: 011550–014.

Title: ABC Discussion Agreement.

Parties: Hamburg-Süd, King Ocean Services Limited, Seafreight Line, Ltd., and Seaboard Marine, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment would add Crowley Caribbean Services, LLC as a party to the agreement.

Agreement No.: 011741–020.

Title: U.S. Pacific Coast-Oceania Agreement.

Parties: ANL Singapore Pte Ltd./CMA CGM S.A.; Hamburg-Sud; and Hapag-Lloyd AG.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1200 19th Street NW.; Washington, DC 20036.

Synopsis: The amendment would delete Mexico from the scope of the agreement, delete obsolete references to Maersk Line, correct the address of ANL, increase the maximum capacity of vessels that can be deployed in each string, adjust the allocation of slots on the PSW string, revise references to Australian law to reflect a change in the name of the relevant Australian statute, add a minimum level of service in Appendix A, and update Appendix C.

Agreement No.: 011961–020.

Title: The Maritime Credit Agreement.

Parties: Maersk Line A/S; China Shipping Container Lines Co. Ltd.; Cosco Container Lines Company Limited; Hanjin Shipping Co., Ltd.; Kawasaki Kisen Kaisha Ltd.; United Arab Shipping Company; Wallenius Wilhelmsen Logistics AS; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1200 19th Street NW.; Washington, DC 20036.

Synopsis: The amendment deletes Independent Container Line Ltd. as a party to the Agreement.

Agreement No.: 012128–004.

Title: Southern Africa Agreement.

Parties: Maersk Line A/S and MSC Mediterranean Shipping Company, S.A.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1200 19th Street NW.; Washington, DC 20036.

Synopsis: The Amendment would revise Article 5.1(b) to suspend operation of the additional vessel.

Agreement No.: 012267–002.

Title: COSCON/CSCL Vessel Sharing and Slot Exchange Agreement.

Parties: China Shipping Container Lines Co., Ltd. and China Shipping Container Lines (Hong Kong) Co. Ltd. (collectively CSCL); COSCO Container Lines Company, Limited.

Filing Party: Patricia M. O'Neill, Esq.; Blank Rome, LLP; Watergate; 600 New Hampshire Avenue NW.; Washington, DC 20037.

Synopsis: The amendment adds Malaysia, Panama, and the U.S. Gulf Coast to the geographic scope of the agreement.

Agreement No.: 012334–001.

Title: Hyundai Glovis/Hoegh Transpacific Westbound Space Charter Agreement.

Parties: Hoegh Autoliners AS and Hyundai Glovis Co. Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Conner; 1200 19th Street NW.; Washington, DC 20036.

Synopsis: The amendment adds Korea to the geographic scope of the agreement and makes the agreement a two-way buy/sell agreement rather than a one-way sale of space from Hyundai Glovis to Hoegh.

Agreement No.: 012371.

Title: CMA CGM/COSCON Slot Exchange Agreement Indian Subcontinent-Middle East-Mediterranean Sea-North Europe and North West European Continent-US East Coast.

Parties: CMA CGM S.A. and COSCO Container Lines Company, Limited.

Filing Party: Draughn B. Arbona, Esq; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: The agreement authorizes COSCON to charter space to CMA CGM in the trade between Belgium, Germany, Netherlands and France on the one hand, and the U.S. East Coast on the other hand, and CMA CGM to charter space to COSCON in the trade between North Europe, the Mediterranean, the Middle East and the Indian Subcontinent.

Agreement No.: 012372.

Title: CMA CGM/COSCON Slot Exchange Agreement Asia-U.S. West Coast.

Parties: CMA CGM S.A. and COSCO Container Lines Company, Limited.

Filing Party: Draughn B. Arbona, Esq; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: The agreement authorizes the parties to charter space to/from one another in the trade between China (including Hong Kong), Malaysia, Vietnam, South Korea and Canada on the one hand, and the U.S. West Coast on the other hand.

By Order of the Federal Maritime Commission.

Dated: November 13, 2015.

Karen V. Gregory,

Secretary.

[FR Doc. 2015–29454 Filed 11–17–15; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 3, 2015.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Debra J. Erickson, Lakeland Shores, Minnesota, individually and as co-trustee of the Bank Stock Family Trust Created Under the David B. Erickson Revocable Trust dated May 12, 2010,* Hudson, Wisconsin (Gary D. Vander Vorst, Hudson, Wisconsin, Co-Trustee), to acquire voting shares of Freedom Bancorporation, Inc. (''Freedom BC''), Lindstrom, Minnesota, and thereby indirectly acquire voting shares of Lake Area Bank, Lindstrom, Minnesota.

In addition, the Descendants Separate Trust CLE Irrev Tr FBO DBE FBO Ashley B. Erickson, the Descendants Separate Trust CLE Irrev Tr FBO DBE FBO Bradley D. Erickson, and the Descendants Separate Trust CLE Irrev Tr FBO DBE FBO Grady L. Erickson, all of Hudson, Wisconsin (Gary D. Vander Vorst, trustee of the trusts), have applied to retain voting shares of Freedom BC and thereby remain members of the Erickson Family Shareholder Group, which controls Freedom BC.

Board of Governors of the Federal Reserve System, November 13, 2015.

Margaret McCloskey Shanks,

Deputy Secretary of the Board.

[FR Doc. 2015–29439 Filed 11–17–15; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0235; Docket No. 2015–0001; Sequence 13]

General Services Administration Acquisition Regulation; Information Collection; Federal Supply Schedule Pricing Disclosures

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division is submitting a request to the Office of Management and Budget (OMB) to review and approve an extension of a previously approved information collection requirement regarding General Services Administration Acquisition Regulation clause 552.238–75, Price Reductions, otherwise known as the Price Reductions clause. The requested extension has been renamed ''Federal Supply Schedule Pricing Disclosures'' because it now includes a burden estimate for Commercial Sales Practices disclosures. The information collected is used to establish and maintain Federal Supply Schedule pricing and price related terms and conditions.

DATES: Submit comments on or before: January 19, 2016.

ADDRESSES: Submit comments identified by Information Collection 3090–0235, Federal Supply Schedule Pricing Disclosures, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0235, Federal Supply Schedule Pricing Disclosures.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0235, Federal Supply Schedule Pricing Disclosures'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street, NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 3090–0235, Federal Supply Schedule Pricing Disclosures.

Instructions: Please submit comments only and cite Information Collection 3090–0235, Federal Supply Schedule Pricing Disclosures, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Matthew McFarland, General Services Acquisition Policy Division, 202–690–9232 or *gsar@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA's Federal Supply Schedule (FSS) program, commonly known as the GSA Schedules program or Multiple Award Schedule (MAS) program, provides federal agencies with a simplified process for acquiring commercial supplies and services. The FSS program is the Government's preeminent contracting vehicle, accounting for approximately 10 percent of all federal contract dollars, with approximately $33 billion in purchases made through the program in fiscal year 2014.

GSA is requesting an extension of a previously approved information collection requirement related to one of the major components of the FSS program, General Services Administration Acquisition Regulation (GSAR) clause 552.238–75, Price Reductions, otherwise known as the Price Reductions clause. However, this requested extension has been renamed ''Federal Supply Schedule Pricing Disclosures'' because it now includes a burden estimate for Commercial Sales Practices disclosures.

FSS Pricing Practices

GSA establishes price reasonableness on its FSS contracts by comparing a contractor's prices and price-related terms and conditions with those offered to their other customers. Through analysis and negotiations, GSA establishes a favorable pricing relationship in comparison to one of the contractor's customers (or category of customers) and then maintains that pricing relationship for the life of the contract. In order to carry out this practice, GSA collects pricing information through Commercial Sales Practices (CSP) disclosures and enforces the pricing relationship through General Services Administration Acquisition Regulation (GSAR) clause 552.238–75, Price Reductions, commonly known as the Price Reductions clause (PRC).

Commercial Sales Practices (CSP): In accordance with GSAR 515.408(a)(2), offerors must submit information in the Commercial Sales Practices Format provided in the solicitation, following the instructions at GSAR Figure 515.4–2, or submit information in their own format. In addition to when an offer is submitted, CSP disclosures are also required prior to executing bilateral modifications for exercising a contract option period, adding items to the contract, or increasing pricing under the Economic Price Adjustment clause (GSAR 552.216–70).

Price Reductions Clause (PRC): GSAR 538.273(b)(2) prescribes the PRC for use in all FSS solicitations and contracts. The clause is intended to ensure the Government maintains its price/discount (and/or term and condition) advantage in relation to the contractor's customer (or category of customer) upon which the FSS contract is based. The basis of award customer (or category of customer) is identified at the conclusion of negotiations and noted in the contract. Thereafter, the PRC requires FSS contractors to inform the contracting officer of price reductions within 15 calendar days. Per GSAR 552.238–75(c)(1),

> A price reduction shall apply to purchases under this contract if, after the date negotiations conclude, the Contractor—
>
> (i) Revises the commercial catalog, pricelist, schedule or other document upon which contract award was predicated to reduce prices;
>
> (ii) Grants more favorable discounts or terms and conditions than those contained in the commercial catalog, pricelist, schedule or other documents upon which contract award was predicated; or
>
> (iii) Grants special discounts to the customer (or category of customers) that formed the basis of award, and the change disturbs the price/discount relationship of the Government to the customer (or category of customers) that was the basis of award.

41 U.S.C. 152(3)(B) requires FSS ordering procedures to ''result in the lowest overall cost alternative to meet the needs of the Federal Government.'' CSP disclosures and the PRC ensure GSA meets this objective by giving it insight into a contractor's pricing practices, which is proprietary information that can only be obtained directly from the contractor.

Information Collection Changes and Updates

GSA has revised this information collection by adding CSP disclosure burden estimates, renaming the information collection, and updating figures.

Including the CSP Disclosure Burden: GSA is adding CSP disclosure burden estimates to this information collection because of comments received for its Transactional Data Reporting proposed rule (GSAR case 2013–G504), published in the **Federal Register** at 80 FR 11619, on March 4, 2015. GSA proposed to amend the GSAR to include a clause that would require FSS vendors to report transactional data from orders and prices paid by ordering activities. The new clause would be paired with changes to the basis of award monitoring, or ''tracking customer,'' requirement of the existing Price Reductions clause, resulting in a burden

reduction for participating FSS contractors. The proposed rule also noted, ''. . . GSA would maintain the right throughout the life of the FSS contract to ask a vendor for updates to the disclosures made on its [CSP] format . . . if and as necessary to ensure that prices remain fair and reasonable in light of changing market conditions.''

In comments received regarding the proposed rule, industry respondents indicated retaining CSP disclosures would cancel out any burden reduction achieved by eliminating the PRC tracking customer requirement. Specifically, respondents were concerned that CSP disclosures still force them to monitor their commercial prices, which ultimately causes the associated burden for both disclosure requirements. In response, GSA agrees the burden of the PRC and CSP is related and is therefore including CSP disclosure burden estimates in this information collection extension request.

Renaming the Information Collection: GSA is changing the information collection name from ''Price Reductions Clause'' to ''Federal Supply Schedule Pricing Disclosures'' to more accurately reflect the scope of the information collected.

Updated Figures: The following figures were updated for the current information collection:

- Increased the number of FSS contracts and vendors from 19,000 FSS contracts held by 16,000 vendors to 20,094 FSS contracts were held by 17,302 vendors.
- Increased the number of price reduction modifications from 1,560 to 2,148.
- Decreased the number of GSA OIG pre-award audits from an average of 70 to 59.
- Increased the estimated annual time burden from 868,920 hours to 1,324,343 hours.
- Increased the estimated annual cost burden; the new estimated annual cost burden is $90,055,353. The 2012 information collection did not provide a cost burden estimate, but if the same hourly rate ($68) was applied to the 2012 time burden, the 2012 cost burden would have been $59,086,560.

B. Annual Reporting Burden

This information collection applies to all companies that held, or submitted offers for, FSS contracts. In fiscal year 2014:

- 20,094 contracts were active, including 1,411 contracts that were awarded and 2,213 contracts that ended over that time period.
- 17,302 companies held FSS contracts (some companies held more than one contract).
- 3,464 offers were submitted for FSS contracts.

However, the number of responses consists of the number of CSP disclosures and price reduction notifications made in FY2014, as well as the average number of GSA Office of Inspector General audits performed between fiscal years 2012 and 2014.

Heavier Lifts and Lighter Lifts

FSS contracts are held by a diverse set of companies, which vary in terms of business size, offerings, and FSS sales volume. For example, in fiscal year 2014:

- 32.8 percent, or 5,673 companies, reported $0 in FSS contracts.
- 5.6 percent, or 975 companies, accounted for 80 percent of all FSS sales.
- The top 20 percent of FSS contractors (in terms of FY2014 sales) accounted for 95.7 percent of FSS sales.
- Only 2.6 percent of FSS contractors reported more than $1 million in FSS sales.

In general, a contractor's FSS sales volume will have the greatest effect on the associated burden of these requirements, although the number and type of offerings, and business structure, can also be significant factors. As shown by the above figures, a relatively small number of FSS contractors account for the vast majority of FSS sales and accordingly, likely bear a heavier burden for these requirements. Conversely, the majority of FSS vendors, which are typically small businesses with lower sales volume, absorb a lighter burden for these requirements.

To account for the differences among FSS contractors, GSA is utilizing the Pareto principle, or ''80/20 rule,'' which states 80 percent of effects comes from 20 percent of the population. Accordingly, GSA is separating FSS contractors among those that have a ''heavier lift'' (20 percent) from those that have a ''lighter lift'' (80 percent). Contractors with heavier lifts are those with the characteristics that lead to increased burden—more sales volume, higher number of contract items, more complex offerings, more transactions, more complex transactions, and/or intricate business structures. This methodology is used for several components of the burden analysis.

Cost Burden Calculation

The estimated cost burden for respondents was calculated by multiplying the burden hours by an estimated cost of $68/hour ($50/hour with a 36 percent overhead rate).

Price Reductions Clause

For this information collection clearance, GSA attributes the PRC-related burden to training, compliance systems, and audits, as well as a burden associated with notifying GSA of price reductions within 15 calendar days after their occurrence.

Training: FSS contractors provide training to their employees to ensure compliance with FSS pricing disclosure requirements. In FY2014, there were 17,302 contractors, 3,460 (20 percent) with a heavier lift and 13,842 (80 percent) with a lighter lift. Contractors within the heavier lift category may need to develop formal training programs and conduct training for numerous divisions and offices, while contractors in the lighter lift category may have no need for training design and administration due to having as few as one person responsible for PRC compliance.

Training—Heavier Lift

Total Annual Responses: *3,460*
Average Hours per Response: *40*
Total Time Burden (Hours): *138,400*
Total Cost Burden: *$9,411,200*

Training—Lighter Lift

Total Annual Responses: *13,842*
Average Hours per Response: *20*
Total Time Burden (Hours): *276,840*
Total Cost Burden: *$18,825,120*

Compliance Systems: FSS contractors must develop systems to control discount relationships with other customers/categories of customer to ensure the basis of award pricing relationship is not disturbed. In response to the 2012 information collection request, the Coalition for Government Procurement provided the results from a survey it conducted among its members regarding the PRC burden. The Coalition survey results attributed 1,100 burden hours to developing compliance systems. However, GSA believes this figure is only attributable to heavier lift contractors and should be allocated over the 20-year life of an FSS contract because a significant part of a burden is the effort to establish a compliance system that will be used over the life of the contract. GSA is attributing a total of 600 burden hours to compliance systems for contractors with a lighter lift and is also allocating that burden over a 20-year period. The results are an annual 55-hour burden for heavier lift contractors (1,100 hours divided by 20 years) and an annual 30-hour burden for

lighter lift contractors (600 hours divided by 20 years).

In FY2014, there were 17,302 contractors, 3,460 (20 percent) with a heavier lift and 13,842 (80 percent) with a lighter lift:

Compliance Systems—Heavier Lift

Total Annual Responses: *3,460*
Average Hours per Response: *55*
Total Time Burden (Hours): *190,322*
Total Cost Burden: *$12,940,400*

Compliance Systems—Lighter Lift

Total Annual Responses: *13,842*
Average Hours per Response: *30*
Total Time Burden (Hours): *415,248*
Total Cost Burden: *$28,237,680*

Audits: The GSA Office of Inspector General (OIG) performed an average of 59 pre-award audits of FSS contracts between FY2012 and FY2014, according to the OIG's Semiannual Congressional Reports over that time period. Respondents to a 2012 Coalition for Government Procurement survey estimated that approximately 440–470 hours were spent preparing for audits involving the PRC; the 455 hour figure is the median point in the range:

GSA OIG Audits

Total Annual Responses: *59*
Average Hours per Response: *455*
Total Time Burden (Hours): *26,845*
Total Cost Burden: *$1,825,460*

Price Reduction Notifications: 2,148 price reduction modifications were completed in FY14, with each modification requiring a notification from the contractor. In a survey conducted among GSA FSS contracting officers, respondents estimated it took an average of 4.25 hours to complete a price reduction modification. GSA believes FSS contractors bear a similar burden for this task and is therefore using the same burden estimate.

Price Reduction Notifications

Total Annual Responses: *2,148*
Average Hours per Response: *4.25*
Total Time Burden (Hours): *9,129*
Total Cost Burden: *$620,772*

Commercial Sales Practices Disclosures

The CSP burden results from disclosures required of any contractor submitting an offer for an FSS contract or modifying an FSS contract to increase prices, add items and Special Item Numbers, or exercise options. GSA attributed a negotiations burden to the PRC in the previous information collection, but is now including that burden within the CSP disclosure estimates.

The burden estimates for CSP disclosures are based upon the estimates provided by respondents to the GSA FSS contracting officer survey. While the 77 survey respondents provided estimates regarding the amount of time it takes FSS contracting officers to complete CSP-related tasks, GSA believes FSS contractors bear a similar burden for these tasks and is therefore using the same burden estimates.

Pre-award Disclosures: In FY2014, contractors submitted 3,464 offers for FSS contracts, with 693 (20 percent) offerors having a heavier lift (20 percent) and 2,771 (80 percent) with a lighter lift:

Pre-award Disclosures—Heavier Lift

Total Annual Responses: *693*
Average Hours per Response: *41.48*
Total Time Burden (Hours): *28,746*
Total Cost Burden: *$1,954,704*

Pre-award Disclosures—Lighter Lift

Total Annual Responses: *2,771*
Average Hours per Response: *32.41*
Total Time Burden (Hours): *89,808*
Total Cost Burden: *$6,106,951*

Price Increase Modifications: In FY2014, 2,509 price increase modifications were processed, including 502 (20 percent) with a heavier lift and 2,007 (80 percent) with a lighter lift:

Price Increases—Heavier Lift

Total Annual Responses: *502*
Average Hours per Response: *10.45*
Total Time Burden (Hours): *5,246*
Total Cost Burden: *$356,721*

Price Increases—Lighter Lift

Total Annual Responses: *2,007*
Average Hours per Response: *9.71*
Total Time Burden (Hours): *18,404*
Total Cost Burden: *$1,251,485*

Adding Items and Special Item Numbers (SINs): In FY2014, 6,861 modifications to add contract items or SINs were processed, including 1,372 (20 percent) with a heavier lift and 5,489 (80 percent) with a lighter lift:

Addition Modifications—Heavier Lift

Total Annual Responses: *1,372*
Average Hours per Response: *11.13*
Total Time Burden (Hours): *15,270*
Total Cost Burden: *$1,038,384*

Addition Modifications—Lighter Lift

Total Annual Responses: *5,489*
Average Hours per Response: *10.65*
Total Time Burden (Hours): *58,458*
Total Cost Burden: *$3,975,134*

Exercising Options: In FY2014, 2,237 modifications to exercise options were processed, including 447 (20 percent) with a heavier lift and 1,790 (80 percent) with a lighter lift:

Option Modifications—Heavier Lift

Total Annual Responses: *447*
Average Hours per Response: *26.14*
Total Time Burden (Hours): *11,685*
Total Cost Burden: *$794,551*

Option Modifications—Lighter Lift

Total Annual Responses: *1,790*
Average Hours per Response: *22.32*
Total Time Burden (Hours): *39,953*
Total Cost Burden: *$2,716,790*

Total Annual Burden

The total estimated burden imposed by Federal Supply Schedule pricing disclosures is as follows:

Estimated Annual Time Burden (Hours)

Price Reductions Clause: *1,056,774*
CSP Disclosures: *267,569*
Total Annual Time Burden: *1,324,343*

Estimated Annual Cost Burden

Price Reductions Clause: *$71,860,632*
CSP Disclosures: *$18,194,721*
Total Annual Cost Burden: *$90,055,353*

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies Of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0235, Price Reductions Clause, in all correspondence.

Dated: November 12, 2015.

Jeffrey A. Koses,

Director, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2015–29396 Filed 11–17–15; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare

Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed changes to the currently approved information collection project: *''Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Comparative Database.''* In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on August 11, 2015 and allowed 60 days for public comment. AHRQ received one substantive comment from the public.

The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by December 18, 2015.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Consumer Assessment of Healthcare Providers and Systems (CAHPS) Clinician and Group Survey Comparative Database

The CAHPS Clinician and Group Survey (''the CAHPS CG Survey'') is a tool for collecting standardized information on patients' experiences with physicians and staff in outpatient medical practices, enabling clinicians and administrators to assess and improve patients' experiences with medical care. The CAHPS CG survey is a product of the CAHPS® program, which is funded and administered by AHRQ. AHRQ works closely with a consortium of public and private research organizations to develop and maintain surveys and tools to advance patient-centered care. CAHPS® is a registered trademark of AHRQ. In 1999, the CAHPS Consortium began work on a survey that would assess patients' experiences with medical groups and clinicians. The CAHPS Consortium developed a preliminary instrument known as the CAHPS Group Practices Survey (G–CAHPS), with input from the Pacific Business Group on Health, whose Consumer Assessment Survey established a precedent for this type of instrument.

In August 2004, AHRQ issued a notice in the **Federal Register** inviting organizations to test the CAHPS CG Survey. These field-test organizations were crucial partners in the evolution and development of the instrument, and provided critical data illuminating key aspects of survey design and administration. In July 2007 the CAHPS CG Survey was endorsed by the National Quality Forum (NQF), an organization established to standardize health care quality measurement and reporting. The endorsement represents the consensus of many health care providers, consumer groups, professional associations, purchasers, Federal agencies, and research and quality organizations. The CAHPS CG Survey and related toolkit materials are available on the CAHPS Web site at *https://cahps.ahrq.gov/surveys-guidance/cg/instructions/index.html.* Since its release, the survey has been used by thousands of physicians and medical practices across the U.S.

The current CAHPS Consortium includes AHRQ, the Centers for Medicare & Medicaid Services (CMS), RAND, Yale School of Public Health, and Westat.

AHRQ developed the database for CAHPS CG Survey data following the CAHPS Health Plan Database as a model. The CAHPS Health Plan Database was developed in 1998 in response to requests from health plans, purchasers, and CMS for comparative data to support public reporting of health plan ratings, health plan accreditation and quality improvement (OMB Control Number 0935–0165, expiration 5/31/2017). Demand for comparative results from the CG Survey has grown as well, and therefore AHRQ developed a dedicated CAHPS Clinician and Group Database to support benchmarking, quality improvement, and research (OMB Control Number 0935–0197, expiration 06/30/2015).

The CAHPS Database contains data from AHRQ's standardized CAHPS Surveys which provide comparative measures of quality to health care purchasers, consumers, regulators, and policy makers. The CAHPS Database also provides data for AHRQ's annual National Healthcare Quality and Disparities Report.

Health systems, medical groups and practices that administer the CAHPS Clinician & Group Survey according to CAHPS specifications can participate in this project. A health system is a complex of facilities, organizations, and providers of health care in a specified geographic area. A medical group is defined as a medical group, Accountable Care Organization (ACO), State organization or some other grouping of medical practices. A practice is an outpatient facility in a specific location whose physicians and other providers share administrative and clinical support staff. Each practice located in a building containing multiple medical offices is considered a separate practice.

The goal of this project is to renew the CAHPS CG Database. This database will continue to update the CAHPS CG Database with the latest results of the CAHPS CG Survey. These results consist of 34 items that measure 5 areas or composites of patients' experiences with physicians and staff in outpatient medical practices. This database:

(1) Allows participating organizations to compare their survey results with those of other outpatient medical groups;

(2) Provides data to medical groups and practices to facilitate internal assessment and learning in the quality improvement process; and

(3) Provides information to help identify strengths and areas with potential for improvement in patient care. The five composite measures are:

- Getting Timely Appointments, Care, and Information
- How Well Providers Communicate With Patients
- Helpful, Courteous, and Respectful Office Staff
- Care Coordination
- Patients' Rating of the Provider

The collection of information for the CAHPS CG Database for Clinicians and Groups is being conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services; quality measurement and improvement; and health surveys and database development 42 U.S.C. 299a(a)(1), (2) and (8).

Method of Collection

To achieve the goal of this project, the following activities and data collections will be implemented:

(1) Registration Form—The purpose of this form is to determine the eligibility status and initiate the registration process for participating organizations seeking to voluntarily submit their CAHPS CG Survey data to the CAHPS CG Database. The point of contact (POC) at the participating organization (or parent organization) will complete the

form. The POC is either a corporate-level health care manager or a survey vendor who contracts with a participating organization to collect the CAHPS CG Survey data.

(2) Data Use Agreement—The purpose of this DUA is to obtain authorization from participating organizations to use their voluntarily submitted CAHPS CG Survey data for analysis and reporting according to the terms specified in the Data Use Agreement (DUA). The POC at the organization will complete the form. Vendors do not sign the DUA.

(3) Data Submission—The number of submissions to the database may vary each year because medical groups and practices may not administer the survey and submit data each year. Data submission is typically handled by one POC who either is a health system, medical group or practice or a survey vendor who contracts with the medical group or practice to collect their data. After the POC has completed the Registration Form and the Data Use Agreement, they will submit their patient-level data from the CAHPS CG Survey to the CAHPS CG Database. Data on the organizational characteristics such as ownership, number of patient visits per year, medical specialty, and information related to survey administration such as mode, dates of survey administration, sample size, and response rate, which are collected as part of CAHPS CG Survey operations are also submitted. Each submission will consist of 3 data files: (1) A Group File that contains information about the group ownership and size of group, (2) a Practice File containing type of practice, the practice ownership and affiliation (*i.e.,* commercial, hospital or integrated delivery system, insurance company, university or medical school, community health center, VA or military) and number of patient visits per year, and (3) a Sample File that contains one record for each patient surveyed, the date of visit, survey disposition code and information about survey completion.

Survey data from the CAHPS CG Database is used to produce four types of products: (1) An online reporting of results available to the public on the CAHPS Database Web site; (2) individual participant comparative reports that are confidential and customized for each participating organization that submits their data, (3) an annual Chartbook that presents summary-level results in a downloadable PDF file; and (4) a dataset available to researchers for additional analyses.

Information for the CAHPS CG Database has been collected by AHRQ through its contractor Westat on an annual basis since 2010. Participating organizations are asked to voluntarily submit their data to the CAHPS CG Database each year. The data is cleaned with standardized programs, then aggregated and used to produce comparative results. In addition, reports are produced that compare the participating organizations' results to the database in a password-protected section of the CAHPS CG Database online reporting system.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours for the respondent to participate in the CAHPS CG Database. The 20 POCs in exhibit 1 are the number of estimated vendors. The 240 POCs in exhibit 1 are the number of estimated participating Health/Medical entities.

Each vendor will register online for submission. The online Registration form will require about 5 minutes to complete. The data use agreement will be completed by the 240 participating Health/Medical entities. Vendors do not sign DUAs. The DUA requires about 3 minutes to sign and return by fax, mail or to upload directly in the submission system. Each submitter will provide a copy of their questionnaire and the survey data file in the required file format. Survey data files must conform to the data file layout specifications provided by the CAHPS CG Database. The number of data submissions per POC will vary because some may submit data for multiple practices, while others may submit data for only one. Once a data file is uploaded the file will be automatically checked to ensure it conforms to the specifications and a data file status report will be produced and made available to the submitter. Submitters will review each report and will be expected to fix any errors in their data file and resubmit if necessary. It will take about one hour to complete each file submission. The total burden is estimated to be 454 hours annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses for each POC	Hours per response	Total burden hours
Registration Form	20	1	5/60	2
Data Use Agreement	240	1	3/60	12
Data Files Submission	440	1	1	440
Total	700	NA	NA	454

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete the submission process. The cost burden is estimated to be $18,613 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Registration Form	20	2	39.75[a]	$80
Data Use Agreement	240	12	86.88[b]	$1043
Data Files Submission	20	440	39.75[c]	$17,490

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Total	280	454	NA	$18,613

* National Compensation Survey: Occupational wages in the United States May 2014, ''U.S. Department of Labor, Bureau of Labor Statistics.'' a) and c) Based on the mean hourly wages for Computer Programmer (15–1131). b) Based on the mean hourly wage for Chief Executives (11–1011). *http://www.bls.gov/oes/current/oes_nat.htm#15–0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2015–29440 Filed 11–17–15; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10433]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *December 18, 2015:*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395–5806 *OR*

Email: *OIRA_submission@omb.eop.gov*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Initial Plan Data Collection to Support Qualified Health Plan (QHP) Certification and Other Financial Management and Exchange Operations; *Use:* As required by the CMS–9989–F, Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange Establishment Rule), published on March 27, 2012, each Exchange must assume responsibilities related to the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an Exchange, a health insurance issuer must have its health plans certified as QHPs by the Exchange.

A QHP must meet certain minimum certification standards, such as those pertaining to essential community providers, essential health benefits, and actuarial value. In order to meet those standards, the Exchange is responsible for collecting data and validating that QHPs meet these minimum requirements as described in the Exchange rule under 45 CFR parts 155 and 156, based on the Affordable Care Act, as well as other requirements determined by the Exchange. In

addition to data collection for the certification of QHPs, the reinsurance and risk adjustment programs outlined by the Affordable Care Act, detailed in 45 CFR part 153, as established by CMS–9975–F, Patient Protection and Affordable Care Act; Standards for Reinsurance, Risk Corridors, and Risk Adjustment (77 FR 17220), published in March 23, 2012, have general information reporting requirements that apply to issuers, group health plans, third party administrators, and plan offerings outside of the Exchanges. Subsequent regulations for these programs including the final HHS Notice of Benefit and Payment Parameters for 2014 and the Program Integrity: Exchange, Premium Stabilization Programs, and Market Standards; Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 provide further reporting requirements. *Form Number:* CMS–10433 (OMB Control Number 0938–1187); *Frequency:* Annually; *Affected Public:* States and Private Sector; *Number of Respondents:* 26,951; *Number of Responses:* 26,951; *Total Annual Hours:* 235,153. (For questions regarding this collection contact Leigha Basini at 301–492–4380.)

Dated: November 12, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–29343 Filed 11–17–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–M–1707, FDA–2015–M–2218, FDA–2015–M–2217, FDA–2015–M–2497, FDA–2015–M–2219, FDA–2015–M–2499, FDA–2015–M–2634, FDA–2015–M–2584, FDA–2015–M–2618, FDA–2015–M–2739, FDA–2015–M–2740, and FDA–2015–M–2964]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

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–2015–M–1707, FDA–2015–M–2218, FDA–2015–M–2217, FDA–2015–M–2497, FDA–2015–M–2219, FDA–2015–M–2499, FDA–2015–M–2634, FDA–2015–M–2584, FDA–2015–M–2618, FDA–2015–M–2739, FDA–2015–M–2740, and FDA–2015–M–2964 for ''Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications.'' 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: Melissa Torres, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–5576.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will

continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from July 1, 2015, through September 30, 2015. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JULY 1, 2015, THROUGH SEPTEMBER 30, 2015

PMA No., docket No.	Applicant	Trade name	Approval date
P930016/S044, FDA–2015–M–1707	AMO Manufacturing USA, LLC	STAR S4 IR Exciter Laser System and iDesign WaveScan Studio System.	5/6/2015
P120024, FDA–2015–M–2218	Aesculap Implant Systems, LLC	activL® Artificial Disc	6/11/2015
P140021, FDA–2015–M–2217	Roche Diagnostics Operations, Inc	Elecsys® Anti-HCV II Immunoassay and Elecsys® PreciControl Anti-HCV.	6/11/2015
P140009, FDA–2015–M–2497	St. Jude Medical Neuromodulation	Brio Neurostimulation System	6/12/2015
P140025, FDA–2015–M–2219	Ventana Medical Systems, Inc	VENTANA ALK (D5F3) CDx Assay	6/12/2015
P140031, FDA–2015–M–2499	Edwards Lifesciences, LLC	SAPIEN 3™ Transcatheter Heart Valve and Accessories.	6/17/2015
P040024/S073, FDA–2015–M–2634	Galderma Laboratories L.P.	Restylane Lyft with Lidocaine	7/1/2015
H080004, FDA–2015–M–2584	Integrum AB	Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA).	7/16/2015
P140028, FDA–2015–M–2618	Boston Scientific Corporation	Innova™ Vascular Self-Expanding Stent System.	7/21/2015
P140013, FDA–2015–M–2739	Minerva Surgical, Inc	Minerva™ Endometrial Ablation System.	7/27/2015
P140012, FDA–2015–M–2740	ReShape Medical, Inc	ReShape Integrated Dual Balloon System.	7/28/2015
P140008, FDA–2015–M–2964	Apollo Endosurgery, Inc	ORBERA™ Intragastric Balloon System.	8/5/2015

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29450 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0530]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Tropical Disease Priority Review Vouchers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by December 18, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Guidance for Industry on Tropical Disease Priority Review Vouchers.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Tropical Disease Priority Review Vouchers—OMB Control Number 0910–NEW

Section 1102 of the Food and Drug Administration Amendments Act (FDAAA) adds new section 524 to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360n). Section 524 is designed to encourage development of new drug or biological products for prevention and treatment of certain tropical diseases affecting millions of people throughout the world and makes provisions for awarding priority review vouchers for future applications to sponsors of tropical disease products. By enacting section 524, Congress intended to stimulate new drug development for drugs to treat certain tropical diseases for which there are no or few available treatments by offering additional incentives for obtaining FDA approval for pharmaceutical treatments for these diseases. Under section 524, a sponsor of a human drug application for a

qualified tropical disease may be eligible for a voucher that can be used to obtain a priority review for any application submitted under section 505(b)(1) of the FD&C Act (21 U.S.C. 355(b)(1)) or section 351 of the Public Health Service Act (the PHS Act). The guidance explains to internal and external stakeholders how FDA intends to implement the provisions of section 524, and provides information on using the priority review vouchers and on transferring priority review vouchers to other sponsors.

Under the guidance, sponsors of certain tropical disease drug product applications submitted under section 505(b)(1) of the FD&C Act and section 351 of the PHS Act may request a priority review voucher. Based on inquiries and discussions with industry about section 524, we estimate that we will receive annually approximately five requests from five sponsors, and that each request will take approximately 8 hours to prepare and submit to FDA.

The guidance also states that sponsors should notify FDA of their intent to use a priority review voucher, including the date on which the sponsor intends to submit the application, at least 90 days before use. We estimate that we will receive annually approximately five notifications of intent to use a voucher from five sponsors, and that each notification will take approximately 8 hours to prepare and submit to FDA.

The guidance also permits the transfer of a priority review voucher from one sponsor to another, and states that each transfer should be documented with a letter of transfer. We estimate that we will receive approximately two letters indicating the transfer of a voucher from two application holders, and two letters from two new voucher owners acknowledging the transfer, and that it will take approximately 8 hours to prepare and submit each letter to FDA.

In the **Federal Register** of October 20, 2008 (73 FR 62298), FDA published a 60-day notice requesting public comment on the proposed collection of information. The comments we received did not pertain to the information collection that would result from the guidance (that is, the four types of submissions estimated in table 1).

FDA estimates the burden of this collection of information as follows:

Description of Respondents: Sponsors submitting applications under section 505(b)(1) of the FD&C Act or section 351 of the PHS Act.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance for Industry on Tropical Disease Priority Review Vouchers	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Priority Review Voucher Request	5	1	5	8	40
Notifications of Intent To Use a Voucher	5	1	5	8	40
Letters Indicating the Transfer of a Voucher Letter	2	1	2	8	16
Acknowledging the Receipt of a Transferred Voucher	2	1	2	8	16
Total					112

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: November 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29406 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0286]

Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidance assists sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products. This guidance finalizes the draft guidance issued on April 1, 2013.

DATES: Submit either electronic or written comments on Agency 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–2013–D–0286] for Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants; Guidance for Industry; Availability. 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6483, Silver Spring, MD 20993–0002, 301–796–0970; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants.'' This guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by CDER and CBER. For the purposes of this guidance, ''formal meeting'' includes any meeting that is requested by a sponsor or applicant following the request procedures provided in this guidance and includes meetings conducted in any format (*i.e.,* face to face, teleconference, or videoconference).

The Biologics Price Competition and Innovation Act of 2009 amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). The Biosimilar User Fee Act of 2012 (BsUFA), enacted as part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize a new user fee program for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the new user fee program. The performance goals, which are set forth in a letter from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives,[1] include meeting management goals for formal meetings that occur between FDA and sponsors or applicants during the development phase of a biosimilar biological product. This guidance describes the Agency's current thinking on how it intends to interpret and apply certain provisions of BsUFA, and also provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products.

This guidance reflects a unified approach to all formal meetings between sponsors or applicants and FDA for biosimilar biological product development (BPD) programs. It is intended to assist sponsors and applicants in generating and submitting a meeting request and the associated meeting package to FDA for biosimilar biological products. This guidance does not apply to new drug or abbreviated new drug applications under section 505 of the FD&C Act or to biologics license applications under section 351(a) of the PHS Act.

FDA expects that review staff will participate in many meetings with biosimilar biological product sponsors or applicants who seek guidance relating to the development and review of biosimilar biological products. Because these meetings often will represent critical points in the regulatory process, it is important that there are efficient, consistent procedures for the timely and effective conduct of such meetings. The good meeting management practices in this guidance are intended to provide consistent procedures that will promote well-managed meetings and to ensure that such meetings are scheduled within a reasonable time, conducted efficiently, and documented appropriately. The following five meeting types that occur between sponsors or applicants and FDA staff during the biosimilar BPD phase are described in the guidance: (1) Biosimilar Initial Advisory meeting; (2) BPD Type 1 meeting; (3) BPD Type 2 meeting; (4) BPD Type 3 meeting; and (5) BPD Type 4 meeting.

[1] See *http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM281991.pdf*.

On April 1, 2013 (78 FR 19492), FDA announced the availability of a draft version of this guidance. All comments received during the comment period for the draft guidance have been reviewed and, where appropriate, incorporated into this guidance. As a result of the public comments, information has been added to provide clarity on the process for requesting meetings, including identifying the appropriate meeting type, and the data expectations to support the appropriate meeting type.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on formal meetings between FDA and biosimilar biological product sponsors or applicants. 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.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under OMB control number 0910–0802.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: November 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29455 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0921]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adverse Event Reporting; Electronic Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of the FDA Electronic Submission Gateway (ESG) and the Safety Reporting Portal (SRP) to collect adverse event reports and other safety information for FDA-regulated products.

DATES: Submit either electronic or written comments on the collection of information by January 19, 2016.

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–2012–N–0921 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal.'' 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

II. Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803—OMB Control Number 0910–0645—Revision

The SRP and the ESG are the Agency's electronic systems for collecting, submitting, and processing adverse event reports, product problem reports, and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, the Agency needs to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification process is the first necessary step that allows the Agency to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a)). While adverse event reports submitted to FDA in paper format using Forms FDA 3500, 3500A, 1932, and 1932a, are approved under OMB control numbers 0910–0284 and 0910–0291, this notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, and currently approved under OMB control number 0910–0645.

III. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive several types of adverse event reports electronically via the SRP using rational questionnaires. In this notice, FDA seeks comments on the extension of OMB approval for the existing rational questionnaires; the proposed revision of the existing rational questionnaire for dietary supplements; the proposed revision of the existing rational questionnaire for tobacco products; a proposed new rational questionnaire that will be used for a new safety reporting program for clinical trials and/or investigational use by the Center for Tobacco Products (CTP); and proposed new rational questionnaires that will be used for food, infant formula, and cosmetic adverse event reports.

A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines ''reportable food'' as an ''article of food (other than infant formula or dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals.'' (See section 417(a)(2) of the FD&C Act). The Secretary of Health and Human Services (the Secretary) has delegated to the Commissioner of FDA the responsibility for administering the FD&C Act, including section 417. The Congressionally identified purpose of the RFR is to provide ''a reliable mechanism to track patterns of adulteration in food [which] would support efforts by the Food and Drug Administration to target limited inspection resources to protect the public health'' (121 Stat. 965). We designed the RFR report rational questionnaire to enable FDA to quickly identify, track, and remove from commerce an article of food (other than infant formula and dietary supplements) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. FDA's Center for Food Safety and Applied Nutrition (CFSAN) uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. The data elements for RFR reports remain unchanged in this request for extension of OMB approval.

B. Reports Concerning Experience With Approved New Animal Drugs

Section 512(l) of the FD&C Act (21 U.S.C. 360b(l)) and § 514.80(b) of FDA's regulations (21 CFR 514.80) require applicants of approved new animal drug applications (NADAs) and approved abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects to the Center for Veterinary Medicine (CVM). This continuous monitoring of approved NADAs and ANADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Postapproval marketing surveillance is important because data previously submitted to FDA may no longer be adequate, as animal drug effects can change over time and less

apparent effects may take years to manifest.

If an applicant must report adverse drug experiences and product/manufacturing defects and chooses to do so using the Agency's paper forms, the applicant is required to use Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs'' (see § 514.80(d)). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects by veterinarians and the general public. Collection of information using existing paper forms FDA 2301, 1932, and 1932a is approved under OMB control number 0910–0284.

Alternatively, an applicant may choose to report adverse drug experiences and product/manufacturing defects electronically. The electronic submission data elements to report adverse drug experiences and product/manufacturing defects electronically remain unchanged in this request for extension of OMB approval.

C. Animal Food Adverse Event and Product Problem Reports

Section 1002(b) of the FDAAA directed the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. As part of the effort to fulfill that directive, the Secretary tasked FDA with developing the instrument that would allow consumers to report voluntarily adverse events associated with pet food. We developed the Pet Food Early Warning System rational questionnaire as a user-friendly data collection tool, to make it easy for the public to report a safety problem with pet food. Subsequently, we developed a questionnaire for collecting voluntary adverse event reports associated with livestock food from interested parties such as livestock owners, managers, veterinary staff or other professionals, and concerned citizens. Information collected in these voluntary adverse event reports contribute to CVM's ability to identify adulteration of the livestock food supply and outbreaks of illness associated with livestock food. The Pet Food Early Warning System and the Livestock Food Reports are designed to identify adulteration of the animal food supply and outbreaks of illness associated with animal food to enable us to quickly identify, track, and remove from commerce such articles of food. We use the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses. The electronic submission data elements to report adverse events associated with animal food remain unchanged in this request for extension of OMB approval.

D. Voluntary Tobacco Product Adverse Event and Product Problem Reports

As noted, this notice seeks comments on two items: (1) A revision to the existing rational questionnaire utilized by consumers and concerned citizens to report tobacco product adverse event or product problems, and (2) a proposed new rational questionnaire that will be used for a new safety reporting program for clinical trials and/or investigational use by CTP.

FDA has broad legal authority under the FD&C Act to protect the public health, including protecting Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others. The Family Smoking Prevention and Tobacco Control Act of 2009 (Pub. L. 111–31) (Tobacco Control Act) amended the FD&C Act by creating a new section 909 (21 U.S.C. 387i, Records and Reports on Tobacco Products). Section 909(a) of the FD&C Act (21 U.S.C. 387i(a)) authorizes FDA to establish regulations with respect to mandatory adverse event reports associated with the use of a tobacco product. At this time, FDA collects voluntary adverse event reports associated with the use of tobacco products from interested parties such as health care providers, researchers, consumers, and other users of tobacco products. Information collected in voluntary adverse event reports will contribute to CTP's ability to be informed of, and assess the real consequences of, tobacco product use.

The need for this collection of information derives from our objective to obtain current, timely, and policy-relevant information to carry out our statutory functions. The FDA Commissioner is authorized to undertake this collection as specified in section 1003(d)(2) of the FD&C Act (21 U.S.C. 393(d)(2)).

FDA's CTP has been receiving adverse event and product problem reports through the Safety Reporting Portal since January 2014, when the Safety Reporting Portal for tobacco products first became available to the public. CTP also receives adverse event and product problem reports via paper forms, as approved under OMB control number 0910–0291. The original questionnaire evolved with input from a National Institutes of Health team of human-factors experts, from other regulatory Agencies, and with extensive input from consumer advocacy groups and the general public. The revised CTP questionnaire along with the proposed new Investigator questionnaire build on the foundation of the original rational questionnaire to make the report's data more useful, analyzable, and specific. The change from the original to the new questionnaire is simply a change in wording, to make the question more understandable and specific. In other instances, alterations were made to the long list of values to choose from by the end user in order to include values more pertinent to CTP's current and future data collection needs. In still other instances, questions were removed altogether in an effort to streamline the questionnaire and make it more user-friendly. Finally, we note that users who are unable to submit reports using the electronic system will still be able to provide their information by paper form (by mail or fax) or telephone.

The proposed new rational questionnaire will be used by tobacco product investigators in clinical trials with investigational tobacco products. In addition to the information collected by the existing rational questionnaire for tobacco products, the proposed rational questionnaire will collect identifying information specific to the clinical trial or investigational product such as clinical protocol numbers or other identifying features to pinpoint under which test or protocol the adverse event occurred.

Both CTP voluntary rational questionnaires will capture tobacco-specific adverse event and product problem information from voluntary reporting entities such as health care providers, researchers, consumers, and other users of tobacco products. To carry out its responsibilities, FDA needs to be informed when an adverse event, product problem, or error with use is suspected or identified. When FDA receives tobacco-specific adverse event and product problem information, it will use the information to assess and evaluate the risk associated with the product, and then FDA will take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

E. Dietary Supplement Adverse Event Reports

The Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Pub. L. 109–462, 120 Stat. 3469) amended the FD&C Act with respect to serious adverse event reporting and recordkeeping for dietary supplements and nonprescription drugs marketed without an approved application.

Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa–1(b)(1)) requires the manufacturer, packer, or distributor whose name (under section 403(e)(1) of the FD&C Act (21 U.S.C. 343(e)(1))) appears on the label of a dietary supplement marketed in the United States to submit to FDA all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (Form FDA 3500A) when submitting a serious adverse event report to FDA. In addition, under section 761(c)(2) of the FD&C Act, the submitter of the serious adverse event report (referred to in the statute as the ''responsible person'') is required to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

As required by section 3(d)(3) of the DSNDCPA, FDA issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. The guidance document entitled ''Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act,'' discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides FDA's recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents.

Reporting of serious adverse events for dietary supplements to FDA serves as an early warning sign of potential public health issues associated with such products. Without notification of all serious adverse events associated with dietary supplements, FDA would be unable to investigate and followup promptly, which in turn could cause delays in alerting the public when safety problems are found. In addition, the information received provides a reliable mechanism to track patterns of adulteration in food that supports efforts by FDA to target limited inspection resources to protect the public health. FDA uses the information collected to help ensure that such products are quickly and efficiently removed from the market to prevent foodborne illnesses.

Paper mandatory dietary supplement adverse event reports are submitted to FDA on the MedWatch form, Form FDA 3500A, and paper voluntary reports are submitted on Form FDA 3500. Forms FDA 3500 and 3500A are available as fillable pdf forms. Dietary supplement adverse event reports may be electronically submitted to the Agency via the SRP. This method of submission is voluntary. A manufacturer, packer, or distributor of a dietary supplement who is unable to or chooses not to submit reports using the electronic system will still be able to provide their information by paper MedWatch form, Form FDA 3500A (by mail or fax). There is no change to the mandatory information previously required on the MedWatch form. CFSAN is making available the option to submit the same information via electronic means. However, we are proposing to add a new voluntary question on the mandatory report rational questionnaire and a new voluntary question on the voluntary report rational questionnaire. The text of the new questions is provided in table 1. Finally, we are proposing to change the following data elements from a text box method of response to an individual question and answer method: Race and known allergies.

TABLE 1—PROPOSED NEW QUESTIONS ON THE DIETARY SUPPLEMENT RATIONAL QUESTIONNAIRE

Text of new question	Is response mandatory or voluntary?
Mandatory Report—In the Contact Information section, we propose to add, ''Please provide contact information for you, the person who is filling out this report.''	Voluntary, and only displayed if the person filling out the report is reporting on behalf of a responsible person, such as a contractor, and has not created an account on the SRP.
Voluntary Report—In the Product Information section, we propose to request the ingredients of the suspect and concomitant product(s), as provided on the label of the product(s).	Voluntary.

The reporting and recordkeeping requirements of the FD&C Act for dietary supplement adverse event reports and the recommendations of the guidance document were first approved in 2009 under OMB control number 0910–0635. OMB approved the extension of the 0910–0635 collection of information in February 2013. OMB approved the electronic submission of dietary supplement adverse event reports via the SRP under OMB control number 0910–0645 in June 2013. Burden hours are also reported under OMB control number 0910–0291 reflecting the submission of dietary supplement adverse event reports on the paper MedWatch form, Form FDA 3500A.

F. Food, Infant Formula, and Cosmetic Adverse Event Reports

We are planning proposed new rational questionnaire functionality that will be used for food, infant formula, and cosmetic adverse event reports. Currently, voluntary adverse event reports for such products are submitted on Form FDA 3500, which is available as a fillable pdf form. However, we have not developed rational questionnaires by which these reports may be electronically submitted to us via the SRP. In addition, MedWatch forms, although recently updated with field labels and descriptions to better clarify for reporters the range of reportable products, do not specifically include questions relevant for the analysis of adverse events related to food, infant formula, and cosmetics. The proposed food, infant formula, and cosmetics rational questionnaire functionality will operate in a manner similar to the dietary supplement rational questionnaire and will include specific questions relevant for the analysis of adverse events related to food, infant formula, and cosmetics.

TABLE 2—NEW QUESTIONS ON THE PROPOSED FOOD, INFANT FORMULA, AND COSMETICS RATIONAL QUESTIONNAIRES FOR BOTH SUSPECT AND CONCOMITANT PRODUCTS

Text of new question	Is response mandatory or voluntary?
For food products:	Voluntary.
"Is this a medical food?"	
"If so, what was the diagnosis or reason for use?"	
"How was the product prepared?"	
For infant formula products:	Voluntary.
"What form of the product was used: Concentrate, powder or ready to serve?"	
Is this a specialized infant formula?"	
"If so, what was the diagnosis or reason for use?"	
"How was the product prepared?"	
"What type of water was used to prepare the formula?"	
For cosmetic products:	Voluntary.
"Do you have existing skin conditions?"	
"How soon did symptoms develop after using the product?	
"Did the intensity of the reaction get worse with time?	
"Where did the reaction develop?"	
"What treatments were sought for this adverse event?"	
"What ingredient do you suspect caused the adverse event?"	
"Has the problem resolved?"	
"Does the product label contain a warning or caution statement?"	

IV. Information Collection Burden Estimate

Description of respondents: The respondents to this collection of information include all persons submitting mandatory or voluntary adverse event reports electronically to FDA via the ESG or the SRP regarding FDA-regulated products.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Voluntary Adverse Event Report via the SRP (Other than RFR Reports)	1,786	1	1,786	0.6 (36 minutes)	1,072
Mandatory Adverse Event Report via the SRP (Other than RFR Reports)	636	1	636	1.0	636
Mandatory Adverse Event Report via the ESG (Gateway-to-Gateway transmission)	1,864,035	1	1,864,035	0.6 (36 minutes)	1,118,421
Mandatory and Voluntary RFR Reports via the SRP	1,200	1	1,200	0.6 (36 minutes)	720
Total					1,120,849

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Agency's estimate of the number of respondents and the total annual responses in table 3, Estimated Annual Reporting Burden, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses are based on initial reports. Followup reports, if any, are not counted as new reports. Based on its experience with adverse event reporting, FDA estimates that it will take a respondent 0.6 hour to submit a voluntary adverse event report via the SRP, 1 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. FDA estimates that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910–0284 and 0910–0291. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: November 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–29407 Filed 11–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0407–30D]

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 revision of the approved information collection assigned OMB control number 0990–0407 scheduled to expire on April 30, 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 December 18, 2015.

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) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the OMB control number 0990–0407 and document identifier HHS–OS–0990–0407–30D for reference.

Information Collection Request Title: Think Cultural Health (TCH) Web site Quality Improvement Effort—OMB No. 0990–0407 REVISION—HHS/OS/OMH

Abstract: The Office of Minority Health (OMH), Office of the Secretary (OS), Department of Health and Human Services (HHS) is requesting approval by OMB on a revised data collection. The Think Cultural Health (TCH) Web site is an initiative of the HHS OMH's Center for Linguistic and Cultural Competence in Health Care (CLCCHC), and is a repository of the latest resources and tools to promote cultural and linguistic competency in health and health care. The TCH Web site is unlike other government Web sites in that its suite of e-learning programs affords health and health care professionals the ability to earn continuing education credits through training in cultural and linguistic competency. The revision to this information collection request includes the online Web site registration form, course/unit evaluations specific to the resource or e-learning program course/unit completed, follow up surveys, focus groups, and key informant interviews.

Need and Proposed Use of the Information: The data will be used to ensure that the offerings on the TCH Web site are relevant, useful, and appropriate to their target audiences. The findings from the data collection will be of interest to HHS OMH in supporting maintenance and revisions of the offerings on the TCH Web site.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Type of respondent	Number of respondent	Number responses per respondent	Average burden per response (hours)	Total burden (hours)
Registration Form	Health and Health Care Professionals.	9,460	1.00	3/60	473
Course/unit Evaluation Form	Health and Health Care Professionals.	9,460	1.00	5/60	788
Follow-Up Survey	Health and Health Care Professionals.	4,208	1.00	10/60	701
Follow-Up Survey	Community Health Workers	6	2.00	10/60	2
Focus Groups	Health and Health Care Professionals.	15	1.00	120/60	29
Key Informant Interviews	Health and Health Care Professionals.	13	1.00	60/60	13
Key Informant Interviews	Community Health Workers	25	1.00	60/60	25
Total		23,187			2,031

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2015–29458 Filed 11–17–15; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Special Emphasis Panel; Innovative Development/Use of Technology to Increase HIV Testing and Linkage to Care Efforts in Adolescent Populations.

Date: December 3, 2015.
Time: 1:00 p.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 12, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29377 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR Panel: Fogarty HIV Research Training Program for Low-and Middle-Income Country Institutions.
Date: December 10, 2015.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The St. Regis Washington, DC, 923 16th Street NW., Washington, DC 20006.
Contact Person: Hilary D Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, (301) 594–6377, *sigmonh@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR Panel: Global Infectious Diseases Research Training Program.
Date: December 11, 2015.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: The St. Regis Washington, DC, 923 16th Street NW., Washington, DC 20006.
Contact Person: Hilary D Sigmon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, (301) 594–6377, *sigmonh@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 10, 2015.

Sylvia Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29381 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health And Human Development; 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 section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Maternal and Child Health in Poor Countries: Evidence From Randomized Evaluation.
Date: December 9, 2015.
Time: 11:00 a.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Carla T. Walls, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6898, *wallsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 12, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29376 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; The National Physician Survey of Precision Medicine in Cancer Treatment (NCI)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Janet S. de Moor, Ph.D., MPH, Project Officer, Division of Cancer

Control and Population Sciences, 9609 Medical Center Drive, 3E438, MSC 9764, Rockville, MD, 20850 or call non-toll-free number 240–276–6806 or Email your request, including your address to: *janet.demoor@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: The National Physician Survey of Precision Medicine in Cancer Treatment 0925–NEW, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this study is to investigate the current practice of precision medicine in cancer treatment among medical oncologists in the U.S. This is a nationally representative survey designed to assess oncologists' current and potential use of genomic testing, to inform the development of interventions to facilitate optimal use of genomic testing and to improve patient-physician discussions of the risks, possible benefits, and uncertainties surrounding the use of these tests. Current knowledge of this topic is limited as there are no nationally-representative studies on this topic to date. There are only two non-federal studies two that have examined physicians' knowledge and attitudes regarding somatic genetic and genomic testing. The survey will be administered by mail and web to approximately 1,630 oncology physicians across the U.S. Non-respondents will be invited to complete a follow-back survey to share their reasons for not participating. The study findings will inform NCI of relevant issues and concerns relating to the application of precision medicine to current and future cancer treatment patterns and practice. This information will also inform the development of new funding initiatives to optimize the use of precision medicine in cancer treatment. Additionally, information collected as part of this survey will be used to develop physician educational materials to address barriers to precision medicine in cancer care delivery.

OMB approval is requested for 2 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 261.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Precision Medicine Survey—Pilot Study.	Oncology Physicians	175	1	20/60	58
Precision Medicine Survey—Full Study.	Oncology Physicians	600	1	20/60	200
Follow-back Survey	Oncology Physicians	40	1	5/60	3

Dated: October 28, 2015.

Karla Bailey,

Project Clearance Liaison, NCI, NIH.

[FR Doc. 2015–29382 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Innovation for HIV Vaccine Discovery (R01).

Date: December 10–11, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3G61, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room # 3F30B, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20852–9823, (240) 669–5029, *battlesja@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 12, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29380 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute on Drug Abuse Special Emphasis Panel, November 13, 2015, 01:00 p.m. to November 13, 2015, 05:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD, 20852 which was published in the **Federal Register** on October 22, 2015, 80 FR 64428.

The date of the meeting was changed to December 1, 2015. The meeting is closed to the public.

Dated: November 12, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29379 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health And Human Development; 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 section 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Consortium on Pediatric Trauma.

Date: December 9, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

Contact Person: Joanna Kubler-Kielb, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6916, *kielbj@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 12, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29375 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development, Special Emphasis Panel, Concept Clearance for the concept titled: Systematic Review in Neonatal Medicine.

Date: December 10, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 12, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29374 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: December 7–8, 2015.

Time: December 7, 2015, 9:00 a.m. to 5:00 p.m.

Agenda: NCMRR report and NICHD report; NICHD Training review; Database archive; Research priorities in rehabilitation; National Strategy in Pain Research.

Place: Hyatt Regency Bethesda Hotel, One Bethesda Metro Center, Bethesda, MD 20814.

Time: December 8, 2015, 8:30 a.m. to 12:00 p.m.

Agenda: NIH Center for Complementary and Alternative Medicine, Spinal cord research.

Place: Hyatt Regency Bethesda Hotel, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Ralph M. Nitkin, Ph.D., Deputy Director, National Center for Medical Rehabilitation Research (NCMRR), Director, Biological Sciences and Career Development Program, NCMRR, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6100 Executive Boulevard, Room 2A03, Bethesda, MD 20892–7510, (301) 402–4206, *rn21e@nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.nichd.nih.gov/about/advisory/nabmrr/Pages/index.aspx* where the current roster and minutes from past meetings are posted.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 12, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–29378 Filed 11–17–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2011–0108]

RIN 1601–ZA11

Identification of Foreign Countries Whose Nationals Are Eligible to Participate in the H–2A and H–2B Nonimmigrant Worker Programs

AGENCY: Office of the Secretary, DHS.

ACTION: Notice.

SUMMARY: Under Department of Homeland Security (DHS) regulations, U.S. Citizenship and Immigration Services (USCIS) may approve petitions for H–2A and H–2B nonimmigrant status only for nationals of countries [1] that the Secretary of Homeland Security, with the concurrence of the Secretary of State, has designated by notice published in the **Federal Register**. That notice must be renewed each year. This notice announces that the Secretary of Homeland Security, in consultation with the Secretary of State, is identifying 84 countries whose nationals are eligible to participate in the H–2A program and 83 countries whose nationals are eligible to participate in the H–2B program for the coming year.

DATES: *Effective Date:* This notice is effective January 18, 2016, and shall be without effect at the end of one year after January 18, 2016.

FOR FURTHER INFORMATION CONTACT: Timothy Simmons, Office of Policy, Department of Homeland Security, Washington, DC 20528, (202) 447–4216.

SUPPLEMENTARY INFORMATION:

Background: Generally, USCIS may approve H–2A and H–2B petitions for nationals of only those countries that the Secretary of Homeland Security, with the concurrence of the Secretary of State, has designated as participating countries. Such designation must be published as a notice in the **Federal Register** and expires after one year. USCIS, however, may allow a national from a country not on the list to be named as a beneficiary of an H–2A or H–2B petition based on a determination that such participation is in the U.S. interest. *See* 8 CFR 214.2(h)(5)(i)(F) and 8 CFR 214.2(h)(6)(i)(E).

In designating countries to include on the list, the Secretary of Homeland Security, with the concurrence of the Secretary of State, will take into account factors including, but not limited to: (1) The country's cooperation with respect to issuance of travel documents for citizens, subjects, nationals, and residents of that country who are subject to a final order of removal; (2) the number of final and unexecuted orders of removal against citizens, subjects, nationals, and residents of that country; (3) the number of orders of removal executed against citizens, subjects, nationals, and residents of that country; and (4) such other factors as may serve the U.S. interest. *See* 8 CFR 214.2(h)(5)(i)(F)(1)(i) and 8 CFR 214.2(h)(6)(i)(E)(1). Examples of factors serving the U.S. interest that could result in the non-inclusion of a country or the removal of a country from the list include, but are not limited to, fraud, abuse, and non-compliance with the terms and conditions of the H–2 programs by nationals of that country.

In December 2008, DHS published in the **Federal Register** two notices, ''Identification of Foreign Countries Whose Nationals Are Eligible to Participate in the H–2A Visa Program,'' and ''Identification of Foreign Countries Whose Nationals Are Eligible to Participate in the H–2B Visa Program,'' which designated 28 countries whose nationals are eligible to participate in the H–2A and H–2B programs. *See* 73 FR 77043 (Dec. 18, 2008); 73 FR 77729 (Dec. 19, 2008). The notices ceased to have effect on January 17, 2010 and January 18, 2010, respectively. *See* 8 CFR 214.2(h)(5)(i)(F)(2) and 8 CFR 214.2(h)(6)(i)(E)(3). In implementing these regulatory provisions, the Secretary of Homeland Security, with the concurrence of the Secretary of State, has published a series of notices on a regular basis. *See* 75 FR 2879 (Jan. 19, 2010) (adding 11 countries); 76 FR 2915 (Jan. 18, 2011) (removing Indonesia and adding 15 countries); 77 FR 2558 (Jan. 18, 2012) (adding 5 countries); 78 FR 4154 (Jan. 18, 2013) (adding 1 country); 79 FR 3214 (Jan.17, 2014) (adding 4 countries); 79 FR 74735 (Dec. 16, 2014) (adding 5 countries).

The Secretary of Homeland Security has determined, with the concurrence of the Secretary of State, that 67 countries previously designated in the December 16, 2014 notice continue to meet the standards identified in that notice for eligible countries and therefore should remain designated as countries whose nationals are eligible to participate in both the H–2A and H–2B programs. The Secretary of Homeland Security has determined, however, with the concurrence of the Secretary of State, that Moldova should no longer continue to be designated as an eligible country to participate in the H–2B program because Moldova is not meeting the standards set out in the regulation for the H–2B program participation. See 8 CFR 214.2(h)(6)(i)(E)(1). Specifically, DHS and the Department of State have found that there is a high occurrence of failure to comply with the terms of the H–2B visa among H–2B visa holders from Moldova. Moldova continues to meet the standards set out in the regulation in regard to its participation in the H–2A program; therefore, this determination does not affect participation of nationals of Moldova in the H–2A program. Accordingly, Moldova remains on the list of eligible countries for the H–2A program, but DHS has removed Moldova from the list of eligible countries whose nationals are eligible to participate in the H–2B program.

Further, the Secretary of Homeland Security, with the concurrence of the Secretary of State, has determined that it is now appropriate to add 16 countries whose nationals are eligible to participate in the H–2A and H–2B programs. This determination is made taking into account the four regulatory factors identified above. The Secretary of Homeland Security also considered other pertinent factors including, but not limited to, evidence of past usage of the H–2A and H–2B programs by nationals of the country to be added, as well as evidence relating to the economic impact on particular U.S. industries or regions resulting from the addition or continued non-inclusion of specific countries. In consideration of all of the above, this notice designates for the first time Andorra, Belgium, Brunei, Colombia, Finland, France, Germany, Greece, Lichtenstein, Luxembourg, Malta, Monaco, San Marino, Singapore, Taiwan, and Timor-Leste as countries whose nationals are eligible to participate in the H–2A and H–2B programs.

Designation of Countries Whose Nationals Are Eligible to Participate in the H–2A and H–2B Nonimmigrant Worker Programs

Pursuant to the authority provided to the Secretary of Homeland Security under sections 214(a)(1), 215(a)(1), and 241 of the Immigration and Nationality Act (8 U.S.C. 1184(a)(1), 1185(a)(1), and 1231), I am designating, with the concurrence of the Secretary of State, nationals from the following countries to be eligible to participate in the H–2A nonimmigrant worker program:

Andorra
Argentina
Australia
Austria
Barbados
Belgium
Belize
Brazil

[1] With respect to all references to ''country'' or ''countries'' in this document, it should be noted that the Taiwan Relations Act of 1979, Public Law 96–8, Section 4(b)(1), provides that ''[w]henever the laws of the United States refer or relate to foreign countries, nations, states, governments, or similar entities, such terms shall include and such laws shall apply with respect to Taiwan.'' 22 U.S.C. § 3303(b)(1). Accordingly, all references to ''country'' or ''countries'' in the regulations governing whether nationals of a country are eligible for H–2 program participation, 8 CFR 214.2(h)(5)(i)(F)(1)(i) and 8 CFR 214.2(h)(6)(i)(E)(1), are read to include Taiwan. This is consistent with the United States' one-China policy, under which the United States has maintained unofficial relations with Taiwan since 1979.

Brunei
Bulgaria
Canada
Chile
Colombia
Costa Rica
Croatia
Czech Republic
Denmark
Dominican Republic
Ecuador
El Salvador
Estonia
Ethiopia
Fiji
Finland
France
Germany
Greece
Grenada
Guatemala
Haiti
Honduras
Hungary
Iceland
Ireland
Israel
Italy
Jamaica
Japan
Kiribati
Latvia
Lichtenstein
Lithuania
Luxembourg
Macedonia
Madagascar
Malta
Mexico
Moldova
Monaco
Montenegro
Nauru
The Netherlands
Nicaragua
New Zealand
Norway
Panama
Papua New Guinea
Peru
The Philippines
Poland
Portugal
Romania
Samoa
San Marino
Serbia
Singapore
Slovakia
Slovenia
Solomon Islands
South Africa
South Korea
Spain
Sweden
Switzerland
Taiwan
Thailand
Timor-Leste
Tonga
Turkey
Tuvalu
Ukraine
United Kingdom
Uruguay
Vanuatu

Pursuant to the authority provided to the Secretary of Homeland Security under sections 214(a)(1), 215(a)(1), and 241 of the Immigration and Nationality Act (8 U.S.C. 1184(a)(1), 1185(a)(1), and 1231), I am designating, with the concurrence of the Secretary of State, nationals from the following countries to be eligible to participate in the H–2B nonimmigrant worker program:

Andorra
Argentina
Australia
Austria
Barbados
Belgium
Belize
Brazil
Brunei
Bulgaria
Canada
Chile
Colombia
Costa Rica
Croatia
Czech Republic
Denmark
Dominican Republic
Ecuador
El Salvador
Estonia
Ethiopia
Fiji
Finland
France
Germany
Greece
Grenada
Guatemala
Haiti
Honduras
Hungary
Iceland
Ireland
Israel
Italy
Jamaica
Japan
Kiribati
Latvia
Lichtenstein
Lithuania
Luxembourg
Macedonia
Madagascar
Malta
Mexico
Monaco
Montenegro
Nauru
The Netherlands
Nicaragua
New Zealand
Norway
Panama
Papua New Guinea
Peru
The Philippines
Poland
Portugal
Romania
Samoa
San Marino
Serbia
Singapore
Slovakia
Slovenia
Solomon Islands
South Africa
South Korea
Spain
Sweden
Switzerland
Taiwan
Thailand
Timor-Leste
Tonga
Turkey
Tuvalu
Ukraine
United Kingdom
Uruguay
Vanuatu

This notice does not affect the status of aliens who currently hold valid H–2A or H–2B nonimmigrant status. Persons currently holding such status, however, will be affected by this notice should they seek an extension of stay in H–2 classification, or a change of status from one H–2 status to another. Similarly, persons holding nonimmigrant status other than H–2 status are not affected by this notice unless they seek a change of status to H–2 status.

Nothing in this notice limits the authority of the Secretary of Homeland Security or his or her designee or any other federal agency to invoke against any foreign country or its nationals any other remedy, penalty, or enforcement action available by law.

Jeh Charles Johnson,

Secretary.

[FR Doc. 2015–29373 Filed 11–17–15; 8:45 am]

BILLING CODE 9110–9M–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2015–0073]

Privacy Act of 1974; Department of Homeland Security/U.S. Customs and Border Protection—021 Arrival and Departure Information System

AGENCY: Privacy Office, Department of Homeland Security.

ACTION: Notice of Privacy Act System of Records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update, rename, and reissue a current Department of Homeland Security system of records titled, ''Department of Homeland Security/U.S. Customs and Border Protection-021 Arrival and Departure Information System.'' This system of records allows the Department of Homeland Security/U.S. Customs and Border Protection to collect and maintain records on individuals throughout the immigrant and non-immigrant pre-entry, entry, status management, and exit processes.

The Department of Homeland Security/U.S. Customs and Border Protection is updating this system of records notice to make the following changes/updates: (1) Addition of a new category of records; (2) updated routine uses; and (3) administrative updates to reflect the transfer of the entry-exit program from the Office of Biometric Identity Management, an office within Department of Homeland Security, National Protection and Programs Directorate, to the U.S. Customs and Border Protection in accordance with the Consolidated and Further Continuing Appropriations Act of 2013. With the publication of this updated system of records, the Department of Homeland Security will retire the former version of the system of records titled, ''Department of Homeland Security/National Protection and Programs Directorate—001 Arrival and Departure Information System of Records,'' and complete the transfer of the entry/exit program to U.S. Customs and Border Protection. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

The exemptions for the existing system of records, published in the Final Rule dated December 4, 2009 (74 FR 63944) will continue to be applicable for this updated system of records notice, and this system will be continue to be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before December 18, 2015. This updated system will be effective December 18, 2015.

ADDRESSES: You may submit comments, identified by docket number DHS–2015–0073 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–343–4010.
- *Mail:* Karen L. Neuman, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528–0655.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, please visit *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions, please contact: John Connors, (202) 344–1610, Privacy Officer, U.S. Customs and Border Protection, Privacy and Diversity Office, 1300 Pennsylvania Ave. NW., Washington, DC 20229. For privacy questions, please contact: Karen L. Neuman, (202) 343–1717, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP) proposes to update, rename, and reissue a DHS system of records titled, ''DHS/CBP–021 Arrival and Departure Information System (ADIS) System of Records,'' previously published as ''Department of Homeland Security National Protection and Programs Directorate-001 Arrival and Departure Information System, System of Records'' (78 FR 31955, May 28, 2013). A Final Rule exempting this system of records from certain provisions of the Privacy Act was published on December 4, 2009 (78 FR 63943) and continues to be applicable.

ADIS is a system for the storage and use of biographic, biometric indicator, and encounter data on aliens who have applied for entry, entered, or departed the United States. ADIS consolidates information from various systems in order to provide a repository of data held by DHS for pre-entry, entry, status management, and exit tracking of immigrants and non-immigrants. CBP uses ADIS to determine whether individuals have maintained legal status and to facilitate investigations of the status of individuals who remain in the United States beyond their authorized stay. The information is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information (PII) collected by other federal, state, local, tribal, foreign, or international government agencies.

DHS/CBP is making several updates as it republishes this system of records notice (SORN). First, CBP is adding a new category of records to the system of records. CBP is including Social Security numbers (SSN) as a new category of records, when they are available, to address SSNs that may be contained in immigration status adjustment or other U.S. Citizenship and Immigration Services (USCIS) records. CBP is also adding four new routine uses (A, D, G, and N) that address data sharing for litigation purposes, audits, investigations, and in certain limited instances when there exists a legitimate public interest in disclosing the information. CBP is also adding a new routine use (L) to provide transparency about CBP's sharing of ADIS information with other federal agencies for the purpose of determining proper payment of federal benefits to the subject of the record in accordance with that agency's statutory responsibilities. Finally CBP is making administrative updates to reflect the transfer of the entry/exit program from the legacy United States Visitor Indicator Technology (US–VISIT) to DHS/CBP as mandated by the Consolidated and Further Continuing Appropriations Act of 2013. Additionally, this notice includes non-substantive changes to simplify the formatting and text of the previously published notice.

Consistent with DHS's information-sharing mission, information stored in ADIS may be shared with other DHS components that have a need to know the information to carry out their national security, law enforcement, immigration, intelligence, or other homeland security functions. In addition, information may be shared consistent with applicable exemptions under the Privacy Act, including routine uses set forth in this SORN that provide for sharing with appropriate federal, state, local, tribal, territorial, foreign, or international government agencies.

The exemptions for the existing SORN will continue to be applicable for this updated SORN and this system will continue to be included in DHS's inventory of record systems. In addition to the new routine uses, new category of records, and other changes to this SORN, the Department is requesting comment on the application of the

exemptions to the newly added category of records.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which federal government agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals when systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

Below is the description of the DHS/CBP–021 Arrival and Departure Information System (ADIS), System of Records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)-021.

SYSTEM NAME:

DHS/CBP–021 Arrival and Departure Information System (ADIS).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

CBP maintains ADIS data at DHS/CBP Headquarters in Washington, DC, DHS/CBP data centers in Mississippi and Virginia, and in field offices that receive access to limited data.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals consist of aliens who have applied for entry, entered, or departed from the United States at any time. Although this system primarily consists of records pertaining to alien immigrants (including lawful permanent residents) and non-immigrants, some of these individuals may change status and become United States citizens.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information contained in this system of records includes, but is not limited to:

- Biographic data, such as:
  - Name;
  - Date of birth;
  - Nationality;
  - Social Security number (SSN), when available; and
  - Other personal descriptive data.
- Biometric indicator data, which includes, but is not limited to:
  - Fingerprint identification numbers (FIN);[1] and
  - Encounter identification numbers (EID).
- System-generated identification numbers: ADIS holds data from other DHS and federal agency systems, and identifies/points to the source systems of these records.
- Encounter data, such as:
  - Encounter location;
  - Arrival and departure dates;
  - Flight information;
  - Immigration status changes;
  - Document types;
  - Document numbers;
  - Document issuance information;
  - Address while in the United States; and
  - Narrative information entered by immigration enforcement officers, such as references to:
    - Active criminal immigration enforcement investigations;
    - Immigration enforcement investigations;
    - Immigration status information; and
    - Details from law enforcement or security incidents or encounters.
- Entry or exit data collected by foreign governments in support of their respective entry and exit processes. Generally, records collected from foreign governments relate to individuals who have entered or exited the United States at some time, but in some instances there is no pre-existing ADIS record for the individual.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

6 U.S.C. 202; 8 U.S.C. 1103, 1158, 1201, 1225, 1324, 1357, 1360, 1365a, 1365b, 1372, 1373, 1379, and 1732.

PURPOSE(S):

The purpose of this system is to serve as the primary repository for tracking entry and exit data throughout the immigrant and non-immigrant pre-entry, entry, status management, and exit processes. This data is collected by DHS or other federal or foreign government agencies and is used in connection with DHS missions such as national security, law enforcement, immigration, intelligence, and other DHS mission-related functions. Data is also used to provide associated testing, training, management reporting, planning and analysis, or other administrative purposes. Similar data may be collected from multiple sources to verify or supplement existing data and to ensure a high degree of data accuracy.

Specifically, DHS/CBP uses ADIS data to: (1) Identify lawfully admitted non-immigrants who remain in the United States beyond their period of authorized stay (which may have a bearing on an individual's right or authority to remain in the country, ability to receive or renew a U.S. visa, or to receive governmental benefits); (2) assist DHS in supporting immigration inspection at ports of entry (POE) by providing quick retrieval of biographic and biometric indicator data on individuals who may be inadmissible to the United States; and (3) facilitate the investigation process of individuals who may have violated their immigration status or may be subjects of interest for law enforcement or intelligence purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS consistent with a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;
2. Any employee or former employee of DHS in his/her official capacity;
3. Any employee or former employee of DHS in his/her individual capacity when DOJ or DHS has agreed to represent the employee; or
4. The U.S. or any agency thereof.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration (NARA) or General Services Administration pursuant to records management

[1] Currently, DHS assigns a Fingerprint identification number (FIN) to collected iris images.

inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency or organization for the purpose of performing audit or oversight operations of the system as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. DHS has determined that as a result of the suspected or confirmed compromise, there is a risk of identity theft or fraud, harm to economic or property interests, harm to an individual, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To appropriate federal, state, tribal, local, international, or foreign law enforcement agencies or other appropriate authorities charged with investigating or prosecuting a violation of or enforcing or implementing a law, rule, regulation, or order, when CBP believes the information would assist enforcement of applicable civil and criminal laws, and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To appropriate federal, state, local, tribal, foreign, or international governmental agencies seeking information on the subjects of wants, warrants, or lookouts, or any other subject of interest, for purposes related to administering or enforcing the law, national security, or immigration, when consistent with a DHS mission-related function as determined by DHS.

I. To appropriate federal, state, local, tribal, foreign, or international government agencies charged with national security, law enforcement, immigration, intelligence, or other DHS mission-related functions in connection with the hiring, retention, or vetting by such an agency of an employee, contractor, or visitor; the issuance of a security clearance; the granting of clearance to access a secure facility; the auditing of compliance with any terms of employment or clearance; the reporting of an investigation of such an employee; the letting of a contract; or the issuance of a license, grant, loan, or other benefit by the requesting agency.

J. To an actual or potential party or to his or her attorney for the purpose of negotiation or discussion on such matters as settlement of a case or matter, or discovery proceedings.

K. To federal, state, local, tribal, foreign or international government intelligence or counterterrorism agencies or components when DHS becomes aware of an indication of a threat or potential threat to national or international security, or when such use is to assist in anti-terrorism efforts and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure.

L. To approved federal, state, and local government agencies for any legally mandated purpose in accordance with an authorizing statute and when an approved Memorandum of Agreement or Computer Matching Agreement (CMA) is in place between DHS and the agency.

M. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information, when disclosure is necessary to preserve confidence in the integrity of DHS, or when disclosure is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent the Chief Privacy Officer determines that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

DHS/CBP stores records electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

RETRIEVABILITY:

DHS/CBP retrieves records using a variety of data elements including, but not limited to, name, place and date of arrival or departure, document number, and fingerprint identification number.

SAFEGUARDS:

DHS/CBP safeguards records in this system according to applicable rules and policies, including all applicable DHS automated systems security and access policies. DHS/CBP imposes strict controls to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

The following proposal for retention and disposal is pending approval with the CBP Records Office and the NARA: Testing and training data will be purged when the data is no longer required. Electronic records for which the statute of limitations has expired for all criminal violations or that are older than 75 years, whichever is longer, will be purged.

SYSTEM MANAGER AND ADDRESS:

ADIS System Manager, CBP, U.S. Department of Homeland Security, Washington, DC 20229–1038.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security exempted this system from the notification, access, and amendment procedures of the Privacy Act because it may contain records from a law enforcement system. However, DHS/CBP will consider individual requests to determine whether or not information may be released. Thus, individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the CBP Freedom of Information Act (FOIA) Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''Contacts.''

If an individual believes more than one component maintains Privacy Act records concerning him or her, the individual may submit the request to the Chief Privacy Officer and Chief FOIA Officer, Department of Homeland Security, 245 Murray Drive SW.,

Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records, your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address, and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Chief Privacy Officer and Chief FOIA Officer, *http://www.dhs.gov/foia* or 1–866–431–0486. In addition, you should:

- Explain why you believe the Department would have information on you;
- Identify which component(s) of the Department you believe may have the information about you;
- Specify when you believe the records would have been created; and
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records.

If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without the above information, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

DHS/CBP obtains records about individuals covered by this system directly and by other federal, state, local, tribal, or foreign governments; private citizens; and public and private organizations.

ADIS data may be derived from records related to entry or exit data of foreign countries collected by foreign governments in support of their respective entry and exit processes. Generally, records collected from foreign governments relate to individuals who have entered or exited the United States at some time, but in some instances there is no pre-existing ADIS record for the individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

The Secretary of Homeland Security exempted this system from 5 U.S.C. 552a(c)(3) and (4); (d); (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(5), (e)(8); (f); and (g) pursuant to 5 U.S.C. 552a(j)(2). In addition, the Secretary of Homeland Security has exempted portions of this system from 5 U.S.C. 552a(c)(3); (d); (e)(1), (e)(4)(G), (e)(4)(H); and (f) pursuant to 5 U.S.C. 552a(k)(2). These exemptions apply only to the extent that records in the system are subject to exemption pursuant to 5 U.S.C. 552a(j)(2) and (k)(2).

When this system receives a record from another system exempted in that source system under 5 U.S.C. 552a(j)(2), DHS will claim the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claim any additional exemptions set forth here.

Jonathan R. Cantor,

Deputy Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2015–29445 Filed 11–17–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2015–0065]

National Infrastructure Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of an Open Federal Advisory Committee Meeting.

SUMMARY: The National Infrastructure Advisory Council will meet Tuesday, December 1, 2015, at the Navy League Building, 2300 Wilson Blvd. Arlington, VA 22201. This meeting will be open to the public.

DATES: The National Infrastructure Advisory Council will meet on December 1, 2015 from 12:30 p.m.–3:30 p.m. EST. The meeting may close early if the committee has completed its business. For additional information, please consult the National Infrastructure Advisory Council Web site, *www.dhs.gov/NIAC,* or contact the National Infrastructure Advisory Council Secretariat by phone at (703) 235–2888 or by email at *NIAC@hq.dhs.gov.*

ADDRESSES: Navy League Building, 2300 Wilson Blvd. Arlington, VA 22201. Members of the public will register at the table at the door to the meeting room. For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION, CONTACT**: below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Council as listed in the ''Summary'' section below. Comments must be submitted in writing no later than 12:00 p.m. on November 27,2015, in order to be considered by the Council in its meeting. The comments must be identified by ''DHS–2015–0065,'' and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting written comments.
- *Email: NIAC@hq.dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* (703)235–9707.
- *Mail:* Ginger Norris, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0612, Washington, DC 20598–0607.

Instructions: All written submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Written comments received will be posted without alteration at *www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the National Infrastructure Advisory Council, go to *www.regulations.gov.* Enter ''NIAC'' in the search line and the Web site will list all relevant documents for your review.

Members of the public will have an opportunity to provide oral comments on the topics on the meeting agenda below, and on any previous studies issued by the National Infrastructure Advisory Council. We request that comments be limited to the issues and studies listed in the meeting agenda and previous National Infrastructure Advisory Council studies. All previous National Infrastructure Advisory Council studies can be located at *www.dhs.gov/NIAC.* Public comments may be submitted in writing or presented in person for the Council to consider. Comments received by Ginger Norris after 11:30 a.m. on December 1, 2015, will still be accepted and reviewed by the members, but not necessarily by the time of the meeting. In-person presentations will be limited to three minutes per speaker, with no more than 15 minutes for all speakers. Parties interested in making in-person

comments should register on the Public Comment Registration list available at the meeting location no later than 15 minutes prior to the beginning of the meeting.

FOR FURTHER INFORMATION CONTACT: Ginger Norris, National Infrastructure Advisory Council, Alternate Designated Federal Officer, Department of Homeland Security, (703) 235–2888.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The National Infrastructure Advisory Council shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors.

The NIAC will meet to discuss issues relevant to critical infrastructure security and resilience as directed by the President.

The meeting will commence at 12:30 p.m. EST. At this meeting, the council will receive a presentation on Water Resilience and Applying Lessons Learned From Post Event Recovery. The council will also receive updates on the status of the Water Resilience Working Group and past NIAC Recommendations. The Council will discuss and deliberate the CEO report recommendations clarification. All presentations will be posted no later than one week prior to the meeting on the Council's public Web page—*www.dhs.gov/NIAC.*

Public Meeting Agenda

I. Opening of Meeting

II. Roll Call of Members

III. Opening Remarks and Introductions

IV. Approval of Meeting Minutes

V. Status of Past NIAC Recommendations

VI. Water Resilience—Applying Lessons Learned From Post Event Recovery

VII. Status Update on Water Resilience Working Group

VIII. Public Comment

IX. CEO Report Recommendation Clarification Discussion

X. Closing Remarks

Dated: November 9, 2015.

Ginger Norris,

Alternate Designated Federal Officer for the National Infrastructure Advisory Council.

[FR Doc. 2015–29372 Filed 11–17–15; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2015–0058]

Chemical Security Assessment Tool (CSAT)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: 60-Day notice and request for comments; Revision of Information Collection Request: 1670–0007.

SUMMARY: The Department of Homeland Security (DHS or the Department), National Protection and Programs Directorate (NPPD), Office of Infrastructure Protection (IP), Infrastructure Security Compliance Division (ISCD), will submit the following Information Collection Request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until January 19, 2016. This process is conducted in accordance with 5 CFR 1320.8.

ADDRESSES: Interested persons are invited to submit comments on the proposed information collection through the Federal eRulemaking Portal at *http://www.regulations.gov.* All submissions received must include the words ''Department of Homeland Security'' and the docket number DHS–2015–0058. Except as provided below, comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Comments that include trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI),[1] Sensitive Security Information (SSI),[2] or Protected Critical Infrastructure Information (PCII)[3] should not be submitted to the public regulatory docket. Please submit such comments separately from other comments in response to this notice. Comments containing trade secrets, confidential commercial or financial information, CVI, SSI, or PCII should be appropriately marked and packaged in accordance with applicable requirements and submitted by mail to the DHS/NPPD/IP/ISCD CFATS Program Manager at the Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0610, Arlington, VA 20528–0610. Comments must be identified by docket number DHS–2015–0058.

SUPPLEMENTARY INFORMATION: Section 550 of the Homeland Security Appropriations Act of 2007, Public Law 109–295 (2006), provided the Department with the authority to regulate the security of high-risk chemical facilities. On April 9, 2007, the Department issued an Interim Final Rule (IFR), implementing this statutory mandate at 72 FR 17688. In December 2014, the President signed into law the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014 (the CFATS Act of 2014), Public Law 113–254, which authorized the Chemical Facility Anti-Terrorism Standards program in the Homeland Security Act of 2002, as amended, Public Law 107–296.[4]

The CFATS regulations (available at 6 CFR part 27) govern the security at covered chemical facilities that have been determined by the Department to be at high risk for terrorist attack. See 6 CFR part 27. CFATS represents a national-level effort to minimize terrorism risk to such facilities. Its design and implementation balance maintaining economic vitality with securing facilities and their surrounding communities. The regulations were designed, in collaboration with the private sector and other stakeholders, to take advantage of protective measures already in place and to allow facilities to employ a wide range of tailored measures to satisfy the regulations' Risk-Based Performance Standards (RBPS).

The Department collects the core regulatory data necessary to implement CFATS through the portions of the Chemical Security Assessment Tool (CSAT) covered under this collection. For more information about CFATS and CSAT, you may access *www.dhs.gov/chemicalsecurity.* The current information collection for CSAT (IC

[1] For more information about CVI see 6 CFR 27.400 and the CVI Procedural Manual at *http://www.dhs.gov/xlibrary/assets/chemsec_cvi_proceduresmanual.pdf.*

[2] For more information about SSI see 49 CFR part 1520 and the SSI Program Web page at *http://www.tsa.gov.*

[3] For more information about PCII see 6 CFR part 29 and the PCII Program Web page at *http://www.dhs.gov/protected-critical-infrastructure-information-pcii-program.*

[4] Section 2 of the CFATS Act of 2014 adds a new Title XXI to the Homeland Security Act of 2002. Title XXI contains new sections numbered 2101 through 2109. Citations to the Homeland Security Act of 2002 throughout this document reference those sections of Title XXI. In addition to being found in amended versions of the Homeland Security Act of 2002, those sections of Title XXI can also be found in section 2 of the CFATS Act of 2014, or in 6 U.S.C. 621–629.

1670–0007) will expire on April 30, 2016.[5]

The Department's Methodology in Estimating the Burden for the Top-Screen

Number of Respondents

The current information collection estimated that 2,500 respondents would submit a Top-Screen annually. That estimate, which is taken from the 2007 CFATS Regulatory Assessment,[6] was derived by averaging the estimated number of respondents that would complete a Top-Screen during calendar year (CY) 2012–2014 that had not previously submitted a Top-Screen. In actuality, during CY 2012–2014, there were 2,574 respondents (*i.e.,* chemical facilities of interest) that submitted a Top-Screen for the first time. This information is displayed in Table 1 below:

TABLE 1—TOP-SCREEN RESPONDENTS

[Estimated versus actual]

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total	Average annual
Estimated number of Top-Screen respondents in the current information collection.	2,500	2,500	2,500	7,500	2,500.
Total Number of Respondents ..	412	1,434	728	2,574	858 (rounded).

Because the annual average of 858 respondents is less than half of the annual number of respondents estimated in the 2007 CFATS Regulatory Evaluation for CY 2012–2014 (*i.e.,* 2,500), the Department will revise the estimated number of respondents for this instrument to 1,000 respondents annually.

Estimated Time per Respondent

In the current information collection, the estimated time per respondent to prepare and submit a Top-Screen is 11.25 hours. This estimate assumed that the majority of the burden associated with the Top-Screen was outside of the Department's ability to quantitatively measure. However, by using the data collected during CY 2012–2014, the Department was able to measure the duration a respondent was logged into the Top-Screen application. Based upon actual historical data, the Department determined that 95% percent of respondents, who submitted Top-Screens, were logged into the CSAT Top-Screen application for no more than 1.2 hours (72 minutes). In response to previous comments provided by stakeholders in the last round of public comments on this Information Collection, the Department estimates that for every hour a respondent is logged into the CSAT Top-Screen application, the respondent spends an average of four hours in preparation.[7] Therefore, for the purposes of this notice, the Department's estimated time per respondent to submit a Top-Screen is 6 hours [1.2 hours + (1.2 hours × 4 hours)]. To account for the anticipated resubmission by respondents, the Department further estimates that 50 percent of the respondents will submit two Top-Screens.[8]

The Department expects to implement a revised Top-Screen with the approval of this information collection. The Department expects that as a result of the revised Top-Screen respondents will spend about approximately the same amount of time logged into the CSAT Top-Screen application as Top-Screen users have, historically. The revised Top-Screen will: (1) Streamline the entry of information about chemicals of interest (COI) into CSAT; (2) add new questions to assist respondents in identifying the COI related security issue(s); (3) include questions currently asked in the current Security Vulnerability Assessment (SVA) and Alternative Security Program (ASP) Instrument; and (4) utilize geospatial technology to identify area of highest quantity.

The Department also collects supporting documentation from approximately half of the respondents. Based upon the Department's day-to-day informal discussions with respondents, the Department believes that a reasonable burden for the gathering and provision of supporting documentation is 0.25 hours.

Annual Burden Hours

The annual burden hours for the Top-Screen is [6 hours × 1,000 respondents × 1.5 responses per respondent], which equals 9,000 hours. The annual burden hours to submit supporting documentation is 125 hours [0.25 hours × 500 respondents × one response per respondent].

Therefore, the Department estimates that the total annual burden hours for the Top-Screen is 9,125 hours [9,000 hours + 125 hours]. The rounded estimate is 9,200 hours.

Total Burden Cost (Capital/Startup)

The Department provides access to CSAT free of charge and the Department assumes that each respondent already has access to the internet for basic business needs.

As mentioned previously in this notice, the Department expects to revise the Top-Screen when this information collection is approved. The revised Top-Screen will enable the Department to begin using an improved tiering methodology that incorporates the relevant elements of risk, which was mandated by Section 2102(e)(2) of the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014 (the CFATS Act of 2014). As a result of the development of the new tiering methodology, the Department is considering requesting chemical facilities of interest that have chemical holdings at or above the screening

[5] The current information collection for CSAT may be found at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201303-1670-001*

[6] See Section 3 and Table 6 of the 2007 CFATS Regulatory Assessment, *http://www.regulations.gov/#!documentDetail;D=DHS-2006-0073-0116.*

[7] The comments and the Department's response are described in the 30-day notice the Department published for this Information Collection in March of 2013 (*http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201303-1670-001*)

[8] The Department analyzed the amount of time a respondent was logged into CSAT when submitting an initial Top-Screen versus an additional Top-Screen and determined that while there was a slight difference in the burden per response (*i.e.,* Additional Top-Screens took on average 15% less time). The Department, for the purposes of this notice, opted not to break out the initial and subsequent Top-Screens to analyze the minimal burden difference.

threshold quantities on Appendix A of CFATS to complete the Top-Screen, even if the facility has previously completed a Top-Screen and been determined not to be high-risk. Between the effective date of CFATS in June 2007 and December 2014, the Department has received Top-Screens from approximately 36,930 unique facilities. Therefore the Department estimates that there will be a one-time capital/startup cost of $15,005,397.60 [36,930 facilities × 6 hours × $67.72 (average hourly wage rate for Site Security Officers)]. The rounded estimate is $15,005,400.

Total Recordkeeping Burden

A respondent that has submitted a Top-Screen may or may not be determined by the Department to present a high level of security risk. Only respondents that present a high level of security risk are required to keep records mandated by CFATS.

For respondents that ultimately are determined not to present a high level of security risk, the Department estimates any CFATS recordkeeping burden to be de minimis.

For respondents that are determined to present a high level of security risk, the Top-Screen recordkeeping burden is accounted for within the recordkeeping burden estimate for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of the Site Security Plan,'' discussed later in this notice. The recordkeeping burden estimate for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of the Site Security Plan'' accounts for all records respondents are required to maintain under CFATS because the Department assumes that respondents maintain their Top-Screen records and any other required records in the same manners, formats, and locations as they maintain their SSP/ASP records.

Total Annual Burden Cost

The 2007 CFATS Regulatory Evaluation assumes that Site Security Officers are responsible for submitting Top-Screens. For the purpose of this notice, the Department maintains this assumption.

Therefore, to estimate the total annual burden, the Department multiplied the annual burden of 9,125 hours by the average hourly wage rate of Site Security Officers of $67.72 per hour [9] and then added the one-time startup cost. Therefore, the total annual burden cost for the Top-Screen instrument is $15,623,342.60 [9,125 total annual burden hours x $67.72 per hour + $15,005,397.60]. The rounded estimate is $15,623,400.

The Department's Methodology in Estimating the Burden for the Security Vulnerability Assessment (SVA) & Alternative Security Program (ASP) Submitted in Lieu of the Security Vulnerability Assessment

Number of Respondents

The current information collection estimated that 740 respondents would complete an SVA/ASP annually during CY 2012–2014 that had not previously submitted an SVA/ASP. The number of respondents was derived by a two-step process. The first step estimated the expected number of SVAs/ASPs by multiplying the estimated number of Top-Screens in each CY by the percentage of Top-Screens that resulted in a determination by the Department that an SVA or ASP in lieu of an SVA must be submitted by a respondent (*i.e.,* a covered chemical facility). When the current information collection was approved in September of 2014, that rate was 29.6 percent. The estimated number of SVAs or ASPs in lieu of SVAs that must be submitted by respondents was then averaged. See the table below for estimates.

TABLE 2—SVA/ASP RESPONDENT ESTIMATES IN CURRENT INFORMATION COLLECTION BASED ON TOP-SCREEN RESPONDENTS

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total	Average annual
Estimated number of Top-Screen Respondents in the current information collection	2,500	2,500	2,500	7,500	2,500
Estimated number of SVA/ASP Respondents in the current information collection	740	740	740	2,220	740

In actuality, during CY2012–2014, there were 633 respondents (*i.e.,* chemical facilities of interest) that submitted an SVA/ASP for the first time. This information is displayed in Table 3 below:

TABLE 3—SVA/ASP RESPONDENTS

[Estimated versus actual]

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total
Estimated number of SVA/ASP respondents in the current information collection	740	740	740	2,220
Actual Number of Respondents	136	315	182	633

The Department is satisfied that the methodology to estimate the number of respondents is reasonable because the percentage of Top-Screens that resulted in a determination by the Department that an SVA or ASP in lieu of an SVA was relatively stable. Historical data from the Department during CY 2012–2014 revealed that the percentage of Top-Screens that subsequently resulted in a determination that an SVA or ASP in lieu of an SVA must be submitted by

[9] The average hourly wage rate was based on an average hourly wage rate of $47.21 with a benefits multiplier of 1.43. The $47.21 rate was based on 2014 dollars using the Consumer Price Index (CPI). U.S. Department of Labor, Bureau of Labor Statistics; ''Table 24. Historical Consumer Price Index for All Urban Consumers (CPI–U): U. S. city average, all;'' Annual Average; July 2015. Available at: *http://www.bls.gov/cpi/tables.htm,* last accessed on September 9, 2015.

a respondent was 21.1 percent. This is a small change from the previous percentage of 29.6 percent. The estimated number of SVAs or ASPs in lieu of SVAs that must be submitted by respondents was determined by CY and then averaged. Therefore, for the purposes of this notice, the number of SVA/ASP respondents is 211 [1,000 Top-Screen Respondents x 0.211]. The Department opted to not round the estimate. See table below.

TABLE 4—SVA/ASP RESPONDENTS ESTIMATES IN THIS NOTICE BASED ON TOP-SCREEN RESPONDENTS

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total	Average annual
Estimated number of Top-Screen responses in this notice	1,000	1,000	1,000	3,000	1,000
Estimated number of SVA/ASP responses in this notice	211	211	211	633	211

Estimated Time per Respondent

The current information collection estimated the time per respondent for preparing and submitting an SVA/ASP to be 65 hours. This estimate assumed that the majority of the burden associated with the SVAs/ASPs was outside of the Department's ability to quantitatively measure. However, by using the data collected during CY 2012–2014, the Department was able to measure the duration a respondent was logged into the SVA/ASP application. Based upon actual historical data, the Department determined that 95 percent of respondents who submitted SVAs were logged into the CSAT SVA/ASP application for no more than 5.3 hours.

The Department expects to implement a revised SVA/ASP with the approval of this information collection. The Department expects that as a result of the revised SVA/ASP respondents will spend 90 percent less time logged into the SVA/ASP application because the revised SVA/ASP will (1) have duplicative questions removed that exist in the SSP/ASP; (2) a few questions will be moved to the Top-Screen to support the improved tiering methodology; and (3) the attack scenarios and related questions will also be removed.

In response to previous comments provided by stakeholders in the last round of public comments on this Information Collection, the Department estimates that for every hour a respondent is logged into the CSAT SVA/ASP application, it spends an average of four hours in preparation. Therefore, for the purpose of this notice, the Department's estimated time per respondent to submit an SVA/ASP is 2.65 hours [(5.3 hours × 0.1) + (5.3 hours × 0.1) × 4 hours].[10]

During CY 2012–2014, for every initial submission of an SVA, respondents generally submit two additional SVA/ASPs. However, the Department believes that the reasons for this higher than expected resubmission rate have been addressed and will not be repeated. Therefore, the Department anticipates that only 50 percent of the respondents will submit two SVA/ASPs.[11]

The Department also collects supporting documentation from approximately half of the respondents. Based upon the Department's day-to-day informal discussions with respondents, the Department believes that a reasonable burden for gathering and provision of supporting documentation is 0.25 hours per respondent.

Annual Burden Hours

The annual burden hours for an SVA/ASP is 838.725 hours [211 respondents × 2.65 hours × 1.5 responses per respondent].

The annual burden estimate to obtain supporting documentation is 26.375 hours [0.25 hours × 211 respondents × 0.5 × 1 response per respondent].

Therefore, the Department estimates that the total annual burden in hours for the SVA/ASP is 865.10 hours [838.725 hours + 26.375 hours]. The rounded estimate is 900 hours.

Total Burden Cost (Capital/Startup)

The Department provides access to CSAT free of charge, and the Department assumes that each respondent already has access to the internet for basic business needs. Therefore, for the purposes of this notice, the Department estimates that there are no capital/startup costs.

Total Recordkeeping Burden

A respondent that has submitted an SVA/ASP may or may not be determined by the Department to present a high level of security risk. Only respondents that present a high level of security risk have a recordkeeping requirement.

For respondents that ultimately are determined not to present a high level of security risk, the Department estimates any CFATS recordkeeping burden to be de minimis.

For respondents that are determined to present a high level of security risk, the SVA recordkeeping burden is accounted for within the recordkeeping burden estimate for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of the Site Security Plan,'' discussed later in this notice. The recordkeeping burden estimate for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of the Site Security Plan'' accounts for all records respondents are required to maintain under CFATS because the Department assumes that respondents maintain their Top-Screen records and any other required records in the same manners, formats, and locations as they maintain their SSP/ASP records.

Total Annual Burden Cost

The 2007 CFATS Regulatory Evaluation assumes that Site Security Officers will be responsible for submitting SVA/ASPs. For the purpose of this notice, the Department maintains this assumption.

The total annual burden cost for the SVA/ASP is $58,584.57 [865.10 total annual burden hours × $67.72 (average hourly wage rate for Site Security Officers)]. The rounded estimate is $58,600.

The Department's Methodology in Estimating the Burden for Site Security Plan (SSP) & Alternative Security Program (ASP) Submitted in Lieu of the Site Security Plan

Number of Respondents

The current information collection estimated that 486 respondents would complete an SSP/ASP annually during CY 2012–2014 that had not previously submitted an SSP/ASP. In actuality, during CY2012–2014, there were 336 respondents that submitted an SSP/ASP

[10] The numerical value of 0.1 is used to reflect that 90% reduction of time a respondent is expected to be logged into the CSAT SVA/ASP.

[11] The Department analyzed the amount of time a respondent was logged into CSAT when submitting an initial SVA/ASP versus an additional SVA/ASP and determined that additional SVAs/ASPs took 3% more time on average than initial SVAs/ASPs. The Department, for the purposes of this notice, opted not to break out the initial and subsequent SVAs/ASPs to analyze the minimal burden difference.

for the first time.[12] This information is displayed in Table 5 below:

TABLE 5—SSP/ASP RESPONDENTS

[Estimated versus actual]

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total
Estimated number of SSP/ASP respondents in the current information collection	486	486	486	1,458
Actual Number of Respondents	0	118	218	336

The Department expects to revise both the SVA/ASP and the SSP/ASP with this information collection. One of the expected outcomes of revisions is that potentially 100 percent of respondents to the SVA/ASP will be a respondent of the SSP/ASP, due to the improved tiering methodology that will be implemented by the Department using data collected through the Top-Screen instrument. The Department anticipates both greater accuracy in the initial tiering determination and also substantially greater confidence in the tiering result. Hence, while the Department reserves the right and ability to conduct a second tiering as described in 6 CFR 27.220, the Department anticipates relying on the results of initial tiering determination for the second tiering unless the Department identifies a reason for not doing so on a case by case basis. An important benefit of this approach is that the lengthy tiering process will be streamlined for the majority of respondents that previously would have been required to complete a second survey in order to receive a final determination of not high risk. These facilities would have to only complete the Top-Screen to get to the same determination. For the purpose of estimating the number of respondents that will complete an SSP/ASP in this notice, the Department will make it equal to the number of SVA/ASP respondents, 211 respondents, because all SVA/ASP respondents will be expected to subsequently complete the SSP/ASP.

The Department considered modifying the number of SSP/ASP respondents to account for submissions of SSPs due to requirements of Section 2102 of the Homeland Security Act of 2002, which among other actions, modifies CFATS by adding a new process by which a respondent, assigned to (risk-based) Tier 3 or Tier 4 by the Department, can meet its regulatory requirement to draft and implement a Site Security Plan through a new process called the ''Expedited Approval Program.'' The Department ultimately has not has opted to not adjust the number of respondents because: (1) Most Tier 3 and Tier 4 facilities have approved SSPs; and (2) to date the Department has received few notifications from Tier 3 and Tier 4 facilities indicating that they plan to use the Expedited Approval Program.

Estimated Time per Respondent

The current information collection estimated the time per respondent for preparing and submitting a SSP/ASP to be 225 hours. This estimate assumed that the majority of the burden associated with the SSPs/ASPs is outside of the Department's ability to quantitatively measure. However, by using the data during CY 2012–2014, the Department was able to measure the duration a respondent was logged into the SSP/ASP application. The Department determined that 95 percent of respondents who submitted SSPs were logged into the CSAT SSP/ASP application for no more than 12.5 hours.

As mentioned earlier in this notice, the Department expects to revise the SSP/ASP when this information collection is approved. The Department expects that as a result of the revised SSP/ASP respondents will spend 70 percent less time logged into the SSP/ASP application because the SSP/ASP will (1) have duplicative and unnecessary questions removed that exist in the SVA/ASP (*e.g.,* questions related to asset identification in the SSP) and import relevant answers from the SVA/ASP, and (2) reorganize the SSP/ASP questions in a streamlined process based upon the Department's experience with respondents over the past several years. The reorganization of SSP/ASP questions will allow the Department to also remove repetitive questions

In response to previous comments provided by stakeholders in the last round of public comments on this Information Collection, the Department estimates that for every hour a respondent is logged into the CSAT SSA/ASP application, it spends an average of four hours in preparation. Therefore, for the purpose of this notice, the Department's estimated time per respondent to submit an SSP/ASP is 18.75 hours. [(12.5 hours × 0.3) + ((12.5 hours × 0.3) × 4 hours)].[13] The rounded estimate is 18.75 hours.

As mentioned earlier in this notice, there was a higher than expected resubmission of SSP/ASPs. In fact during CY 2012–2014, there were 2,721 SSP/ASPs resubmitted. The vast majority of the resubmissions were submitted by respondents who has submitted an initial SSP/ASP prior to CY 2012. To account for the increased resubmission of SSP/ASPs by respondents, the Department estimates that each respondent will submit an additional SSP/ASP.[14]

The Department also collects supporting documentation from approximately half of the respondents. Based upon the Department's day-to-day informal discussions with respondents, the Department believes that a reasonable burden for the gathering and provision of supporting documentation is 0.25 hours per respondent.

Annual Burden Hours

The annual burden hours for SSP/ASP submission is 7,912.50 hours [18.75 hours × 211 SSP/ASP

[12] Between 2012 and 2014, the Department made substantial progress in addressing the number of SSP/ASPs received prior to 2012 from covered chemical facilities. The Department received 2,721 SVA/ASPs during CY2012 through CY2014 (*i.e.,* 103 revised SSP/ASP in 2012, 1,026 revised SSP/ASPs in 2013, and 1,592 SSP/ASPs in 2014). The Department accounts for the cost of resubmitted SVA/ASPs in the next section titled, ''Estimated Time Per Respondent.''

[13] The numerical value of 0.3 is used to reflect that 70% reduction of time a respondent is expected to be logged into the CSAT SSP/ASP.

[14] The Department analyzed the amount of time a respondent was logged into CSAT when submitting an initial SSP/ASP versus an additional SSP/SVP and determined that additional SVA/ASPs took 14% less time on average than initial SSP/ASPs. The Department, for the purposes of this notice, opted not to break out the initial and subsequent SSP/ASPs to analyze the minimal burden difference.

respondents × 2 response per respondent].

The annual burden hours for obtaining supporting documentation is 26.3750 hours [0.25 hours × (0.5 × 211 SSP/ASP respondents) × (one response per respondent)].

Therefore, the Department estimates that the total annual burden hours for SSP/ASP submission is 7,938.8750 hours [7,912.50 hours + 26.3750 hours]. The rounded estimate is 8,000 hours.

Total Burden Cost (Capital/Startup)

The Department provides access to CSAT free of charge, and the Department assumes each respondent already has access to the internet for basic business needs. Therefore, for the purposes of this notice, the Department estimates that there are no capital/startup costs.

Total Recordkeeping Burden

The recordkeeping burden estimate for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of the Site Security Plan'' accounts for the recordkeeping burden high-risk chemical facilities are required to maintain under CFATS, including SSP and ASP records because the Department assumes that respondents maintain their records and any other required records in the same manners, formats, and locations as they maintain their SSP/ASP records. Therefore, the Department believes it is reasonable to estimate the recordkeeping burden for all respondents under the recordkeeping burden for the ''Site Security Plan (SSP) and Alternative Security Program (ASP) submitted in lieu of the Site Security Plan.''

Records maintained under CFATS, including SSP/ASP records and other records listed at 6 CFR 27.255, may be kept in electronic or paper formats as long as they are reasonably protected. For the purpose of this notice, the Department assumes that all respondents will purchase a locked filing cabinet to maintain records at a cost of $350 each. In addition, respondents that use paper records will also incur the cost of additional paper and printer ink/toner. The Department assumes an additional box of paper ($50) and additional printer ink/toner supplies ($200). Thus, the physical cost related to record keeping for each SSP/ASP respondent is $600 (*i.e.,* $350 for the filing cabinet plus $250 for paper and toner) for the first year and $250 per year for the second and third year. Thus, the annual average cost, for physical costs related to paper-based recordkeeping, is $367 per SSP/ASP.

TABLE 6—SSP/ASP PAPER-BASED RECORDKEEPING COSTS

	Locked filing cabinet cost	Paper and ink/toner Cost	Year 1 cost	Year 2 cost	Year 3 cost	Average annual cost
SSP/ASP	$350	$250	$600	$250	$250	$367 (rounded).

The Department assumes that clerical staff will spend 48 hours per year (four hours per month) maintaining records, such as filing, binding, etc. For the purpose of this notice the Department used the wage rate of $37.51 per hour.[15] Thus, the Department estimates the labor related to paper-based recordkeeping burden is $1,800.48 per SSP/ASP [48 hours × $37.51].

Alternatively, although it is not required, businesses may keep their records electronically. Under this scenario, the Department maintains its assumption that a small number of respondents (*i.e.,* 5 percent) will purchase a computer loaded with basic spreadsheet software. For the purpose of this notice, the Department assumes that 5 percent of respondents will purchase a computer and printer to maintain records at a total cost of $1,000. Thus, the annual average cost for physical costs related to electronic-based recordkeeping is $333 (rounded) per SSP/ASP.

The Department assumes that there will be a larger time commitment for updating records and inputting data into a spreadsheet. Hence, the Department maintains its estimate of six hours per month to maintain electronic records. Thus, the Department estimates the labor related to electronic-based recordkeeping burden is $2,700.72 [72 hours × $37.51 (average hourly wage rate for clerical staff)].

Therefore, for the purposes of this notice, the Department estimates that the annual recordkeeping burden is $438,744.116 [($367 + $1,800.48) × (0.95 × 211 SSP/ASP respondents) + [($333 + $2,700.72) × (0.05 × 211 SSP/ASP respondents)]. The rounded estimate is $438,800.

Total Annual Burden Cost

The total annual burden cost for the SSP/ASP is $976,364.731 [7,938.8750 hours multiplied by $67.72 (average hourly wage rate for Site Security Officers) + $438,744.116 (total annual recordkeeping burden)]. The rounded estimate is $976,400.

The Department's Methodology in Estimating the Burden for the Helpdesk

Number of Respondents

The Department evaluated the historical data to determine if the current information collection estimate of 15,000 respondents continued to be an appropriate estimate for Helpdesk. During CY 2012–2014, the Helpdesk accepted 30,452 calls and 12,246 emails.

TABLE 7—HELPDESK RESPONDENTS

[Estimated versus actual]

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total	Average annual
Estimated number of Respondents in current information collection.	15,000	15,000	15,000	45,000	15,000.

[15] The average hourly wage rate was based on an average hourly wage rate of $26.15 with a benefits multiplier of 1.43. The $37.51 rate was based on 2014 dollars using the Consumer Price Index (CPI). U.S. Department of Labor, Bureau of Labor Statistics; ''Table 24. Historical Consumer Price Index for All Urban Consumers (CPI–U): U.S. city average, all;'' Annual Average; July 2015. Available at: *http://www.bls.gov/cpi/tables.htm,* last accessed on September 9, 2015.

TABLE 7—HELPDESK RESPONDENTS—Continued

[Estimated versus actual]

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total	Average annual
Actual number of Respondents (phone calls and e-mails).	9,530	15,802	17,366	42,698	14,233 (rounded).

The actual average annual number of respondents for this time period was 14,233 respondents (calls and emails). The Department will maintain the estimated number of respondents of 15,000, based on actual historical data.

Estimated Time per Respondent

The Department evaluated the historical data to determine if the estimated time per respondent of 0.17 hours (10 minutes) continued to be an appropriate estimate. During CY 2012–2014, the actual average Helpdesk call averaged less than eight minutes.

TABLE 8—HELPDESK CALL TIME AVERAGES

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014
Actual Average Call Time (minutes)	7:38	8:09	7:15

The Department does not have any information about the average amount of time it took respondents to type and send the 12,246 emails during CY 2012–2014.

Therefore, for the purpose of this notice, the Department has maintained the estimated time per respondent of 0.17 hours.

Annual Burden Hours

The annual burden hours for the Helpdesk will be 2,550 hours [0.17 hours × 15,000 respondents].

Total Burden Cost (Capital/Startup)

Contacting the CFATS Helpdesk is free, and the Department assumes that each respondent already has a phone and/or access to the internet for basic business needs. Therefore, for the purposes of this notice, the Department estimates that there are no capital/startup costs.

Total Recordkeeping Burden

There is no recordkeeping burden when contacting the CSAT Helpdesk.

Total Annual Burden Cost

The total burden for the Helpdesk is $172,686 [2,550 annual burden hours × $67.72 (average hourly rate for Site Security Officers)]. The rounded estimate is $172,700.

The Department's Methodology in Estimating the Burden for the User Registration

Number of Respondents

The current information collection estimated 625 respondents would complete the user registration process annually. That estimate is based on the assumption that the number of respondents for User Registration will be one-fourth of the number of respondents for the Top-Screen. During CY 2012–2014, the actual number was 3033 respondents.

TABLE 9—USER MANAGEMENT RESPONDENTS

[Estimated versus actual]

	Year 1 CY 2012	Year 2 CY 2013	Year 3 CY 2014	Total	Average annual
Estimated number of Respondents in current information collection	625	625	625	1,875	625
Actual number of Respondents	510	1704	819	3033	1,011

The Department expects the actual number of respondents to fluctuate. However, for the purposes of this notice the Department estimates the number of respondents is 1000 annually.

Estimated Time per Respondent

In the current information collection, the estimated time per respondent is two hours. The Department will maintain the assumption that two hours is an adequate amount of time for the respondent to (1) complete the online CSAT User Registration process, and subsequently (2) collect and submit the necessary signatures on the user access agreement.

Annual Burden Hours

The annual burden estimate for User Registration is 2,000 hours [2 hours × 1000 respondents].

Total Burden Cost (Capital/Startup)

The Department assumes that each respondent already has a fax capability and access to the internet for basic business needs. However, the Department expects to be revising the CSAT User Management application to reduce the burden on respondents and improve the functionality of the CSAT User Management application. The Department expects that there will be a one-time burden for all existing CSAT Users when the CSAT User Management application is updated. The Department expects the one-time burden to be 0.17 hours (10 minutes) per CSAT user. As of September 2015, there were 24,630 active CSAT accounts; therefore, the Department estimates that there will be a capital/startup cost of $283,550.4120 [24,630 Active CSAT users × 0.17 hours × $67.72 (average hourly rate for Site

Security Officers)]. The rounded estimate is $283,600.

Total Recordkeeping Burden

There is no recordkeeping burden for submitting a User Registration application.

Total Annual Burden Cost

The total burden for User Registration is $418,990.4120 [2,000 annual burden hours × $62.72 (average hourly rate for Site Security Officers) + $283,550.4120 (Capital/Startup Burden Cost)]. The rounded estimate is $419,000.

The Department's Methodology in Estimating the Burden for Identification of Additional Facilities and Assets At Risk

Number of Respondents

The Department may collect information from each respondent of a SSP/ASP under this instrument. Respondents are not required to provide this information to the Department for purposes of complying with any portion of CFATS. The Department estimates the number of respondents to this instrument will be equal to the number of respondents to the SSP/ASP, or 211 respondents.

Estimated Time per Respondent

This instrument will request information from covered chemical facilities about their chemical of interest supply and distribution chain or other information about their business operations to allow the Department to potentially identify either potential chemical facilities of interest or potential assets at risk at the covered chemical facility. Participation in this collection will be voluntary and respondents will not be required to provide this information to the Department for purposes of complying with any portion of CFATS. The Department expects the estimated time per respondent is 0.17 hours (10 minutes).

Annual Burden Hours

The annual burden estimate is 35.87 hours [0.17 hours × 211 respondents]. The rounded estimate is 40 hours.

Total Burden Cost (Capital/Startup)

The Department expects a one-time burden for covered chemical facilities with an approved SSP/ASP. There are approximately 3000 covered chemical facilities regulated under CFATS.[16] Therefore, the Department estimates that there will be a one-time capital/startup cost of $34,537.20 [3000 covered chemical facilities × 0.17 hours × $67.72 (average hourly wage rate for Site Security Officers)]. The rounded estimate is $34,600.

Total Recordkeeping Burden

There is no recordkeeping burden for this instrument.

Total Annual Burden Cost

The total burden for the identification of additional potential chemical facilities of interest and assets at risk is $36,966.3164 [35.87 annual burden hours × $67.72 (average hourly rate for Site Security Officers) + $34,537.20 (Capital/Startup Burden Cost)]. The rounded estimate is $37,000.

OMB is particularly interested in comments that:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Analysis:

Agency: Department of Homeland Security, National Protection and Programs Directorate, Office of Infrastructure Protection, Infrastructure Security Compliance Division.

Title: Chemical Security Assessment Tool.

OMB Number: 1670–0007.

Instrument: CSAT Top-Screen.

Frequency: ''On occasion'' and ''Other.''

Affected Public: Business or other for-profit.

Number of Respondents: 1,000 respondents (estimate).

Estimated Time per Respondent: 6.00 hours.

Total Burden Hours: 9,200 hours.

Total Burden Cost (capital/startup): $15,005,400.

Total Recordkeeping Burden: $0.

Total Burden Cost: $15,623,400.

Instrument: Security Vulnerability Assessment and Alternative Security Program submitted in lieu of the Security Vulnerability Assessment.

Frequency: ''On occasion'' and ''Other.''

Affected Public: Business or other for-profit.

Number of Respondents: 211 respondents.

Estimated Time per Respondent: 2.65 hours.

Total Burden Hours: 900 hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost: $58,600.

Instrument: Site Security Plan and Alternative Security Program submitted in lieu of the Site Security Plan.

Frequency: ''On occasion'' and ''Other.''

Affected Public: Business or other for-profit.

Number of Respondents: 211 respondents.

Estimated Time per Respondent: 18.75 hours.

Total Burden Hours: 8,000 hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $438,800.

Total Burden Cost: $976,400.

Instrument: CFATS Helpdesk.

Frequency: ''On occasion'' and ''Other.''

Affected Public: Business or other for-profit.

Number of Respondents: 15,000 respondents.

Estimated Time per Respondent: 0.17 hours.

Total Burden Hours: 2,550 annual burden hours.

Total Burden Cost (capital/startup): $0.

Total Recordkeeping Burden: $0.

Total Burden Cost: $172,700.

Instrument: CSAT User Registration.

Frequency: ''On occasion'' and ''Other.''

Affected Public: Business or other for-profit.

Number of Respondents: 1000 respondents.

Estimated Time per Respondent: 2 hours.

Total Burden Hours: 2,000 hours.

Total Burden Cost (capital/startup): $283,600.

Total Recordkeeping Burden: $0.

Total Burden Cost: $419,000.

Instrument: Identification of Facilities and Assets At Risk.

Frequency: ''On occasion'' and ''Other.''

Affected Public: Business or other for-profit.

Number of Respondents: 211 respondents.

[16] The number of covered chemical facilities fluctuates. For the purposes of this notice 3,000 represents a reasonable estimate to estimate the burden this instrument could impose.

Estimated Time per Respondent: 0.17 hours.

Total Burden Hours: 40 hours.

Total Burden Cost (capital/startup): $34,600.

Total Recordkeeping Burden: $0.

Total Burden Cost: $37,000.

Dated: October 30, 2015.

Scott Libby,

Deputy Chief Information Officer, National Protection and Programs Directorate, Department of Homeland Security.

[FR Doc. 2015–29457 Filed 11–17–15; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5903–N–01]

Notice of Single Family Loan Sales (SFLS 2016–1)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of sales of mortgage loans.

SUMMARY: This notice announces HUD's intention to competitively sell certain unsubsidized single family mortgage loans, in a sealed bid sale offering called SFLS 2016–1, without Federal Housing Administration (FHA) mortgage insurance. This notice also generally describes the bidding process for the sale and certain persons who are ineligible to bid. This is the first sale offering of Fiscal Year (FY) 2016 and the sale will be held on November 18, 2015.

DATES: For this sale action, the Bidder's Information Package (BIP) was made available to qualified bidders on October 21, 2015. Bids for the 2016–1 sale will be accepted on the Bid Date of November 18, 2015 (Bid Date). HUD anticipates that award(s) will be made on or about November 19, 2015 (the Award Date).

ADDRESSES: To become a qualified bidder and receive the BIP, prospective bidders must complete, execute, and submit a Confidentiality Agreement and a Qualification Statement acceptable to HUD. Both documents are available via the HUD Web site at: *http://www.hud.gov/sfloansales* or via: *http://www.verdiassetsales.com.*

Please mail and fax executed documents to Verdi Consulting, Inc.: Verdi Consulting, Inc., 8400 Westpark Drive, 4th Floor, McLean, VA 22102, Attention: HUD SFLS Loan Sale Coordinator, Fax: 1–703–584–7790.

FOR FURTHER INFORMATION CONTACT: John Lucey, Director, Asset Sales Office, Room 3136, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–8000; telephone 202–708–2625, extension 3927. Hearing- or speech-impaired individuals may call 202–708–4594 (TTY). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: HUD announces its intention to sell in SFLS 2016–1 certain unsubsidized non-performing mortgage loans (Mortgage Loans) secured by single family properties located throughout the United States. A listing of the Mortgage Loans is included in the due diligence materials made available to qualified bidders. The Mortgage Loans will be sold without FHA insurance and with servicing released. HUD will offer qualified bidders an opportunity to bid competitively on the Mortgage Loans.

The Loans will be offered in two pool types. The Department will offer national loan pools for bid and will also offer regionally-based pools, with additional purchaser requirements, that are called the Neighborhood Stabilization Outcome pools. Three of these Neighborhood Stabilization Outcome pools will be designated for bidding by qualified non-profit or unit of local government entities only. These pools are located in Tampa, Florida, Chicago, Illinois, and the state of Massachusetts.

The Bidding Process

The BIP describes in detail the procedure for bidding in SFLS 2016–1. The BIP also includes a standardized non-negotiable Conveyance, Assignment and Assumption Agreement (CAA Agreement). Qualified bidders will be required to submit a deposit with their bid. Deposits are calculated based upon each qualified bidder's aggregate bid price.

HUD will evaluate the bids submitted and determine the successful bid, in terms of the best value to HUD, in its sole and absolute discretion. If a qualified bidder is successful, the qualified bidder's deposit will be non-refundable and will be applied toward the purchase price. Deposits will be returned to unsuccessful bidders.

This notice provides some of the basic terms of sale. The CAA Agreement, which is included in the BIP, provides comprehensive contractual terms and conditions. To ensure a competitive bidding process, the terms of the bidding process and the CAA Agreement are not subject to negotiation.

Due Diligence Review

The BIP describes how qualified bidders may access the due diligence materials remotely via a high-speed Internet connection.

Mortgage Loan Sale Policy

HUD reserves the right to remove Mortgage Loans from SFLS 2016–1 at any time prior to the Award Date. HUD also reserves the right to reject any and all bids, in whole or in part, and include any Mortgage Loans in a later sale. Deliveries of Mortgage Loans will occur in at least two monthly settlements and the number of Mortgage Loans delivered will vary depending upon the number of Mortgage Loans the Participating Servicers have submitted for the payment of an FHA insurance claim. The Participating Servicers will not be able to submit claims on loans that are not included in the Mortgage Loan Portfolio set forth in the BIP. There can be no assurance that any Participating Servicer will deliver a minimum number of Mortgage Loans to HUD or that a minimum number of Mortgage Loans will be delivered to the Purchaser.

The SFLS 2016–1 Mortgage Loans are assigned to HUD pursuant to section 204(a)(1)(A) of the National Housing Act as amended under Title VI of the Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act, 1999. The sale of the Mortgage Loans is pursuant to section 204(g) of the National Housing Act.

Mortgage Loan Sale Procedure

HUD selected an open competitive whole-loan sale as the method to sell the Mortgage Loans for this specific sale transaction. For SFLS 2016–1, HUD has determined that this method of sale optimizes HUD's return on the sale of these Mortgage Loans, affords the greatest opportunity for all qualified bidders to bid on the Mortgage Loans, and provides the quickest and most efficient vehicle for HUD to dispose of the Mortgage Loans.

Bidder Ineligibility

In order to bid in SFLS 2016–1 as a qualified bidder, a prospective bidder must complete, execute and submit both a Confidentiality Agreement and a Qualification Statement acceptable to HUD and applicable to the loan pool being purchased. In the Qualification Statement, the prospective bidder must provide certain representations and warranties regarding (i) a prospective bidder, (ii) a prospective bidder's board of directors, (iii) a prospective bidder's direct parent, (iii) a prospective bidder's subsidiaries, and (iv) any related entity with which the prospective bidder shares a common officer, director,

subcontractor or sub-contractor who has access to Confidential Information as defined in the Confidentiality Agreement or is involved in the formation of a bid transaction (''Related Entities''), and (v) a prospective bidder's repurchase lenders. The prospective bidder is ineligible to bid on any of the Mortgage Loans included in SFLS if the prospective bidder, its Related Entities or its repurchase lenders, is any of the following, unless other exceptions apply as provided for the in Qualification Statement.

1. An individual or entity that is currently debarred, suspended, or excluded from doing business with HUD pursuant to the Governmentwide Suspension and Debarment regulations at 2 CFR parts 180 and 2424;

2. An individual or entity that is currently suspended, debarred or otherwise restricted by any department or agency of the federal government or of a state government from doing business with such department or agency;

3. An individual or entity that is currently debarred, suspended, or excluded from doing mortgage related business, including having a business license suspended, surrendered or revoked, by any federal, state or local government agency, division or department;

4. An entity that has had its right to act as a Government National Mortgage Association (''Ginnie Mae'') issuer terminated and its interest in mortgages backing Ginnie Mae mortgage-backed securities extinguished by Ginnie Mae;

5. An individual or entity that is in violation of its neighborhood stabilizing outcome obligations or post-sale reporting requirements under a Conveyance, Assignment and Assumption Agreement executed for a past sale;

6. An employee of HUD's Office of Housing, a member of such employee's household, or an entity owned or controlled by any such employee or member of such an employee's household with household to be inclusive of the employee's father, mother, stepfather, stepmother, brother, sister, stepbrother, stepsister, son, daughter, stepson, stepdaughter, grandparent, grandson, granddaughter, father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, first cousin, the spouse of any of the foregoing, and the employee's spouse;

7. A contractor, subcontractor and/or consultant or advisor (including any agent, employee, partner, director, or principal of any of the foregoing) who performed services for or on behalf of HUD in connection with the sale;

8. An individual or entity that knowingly acquired or will acquire prior to the sale date material non-public information, other than that information which is made available to Bidder by HUD pursuant to the terms of this Qualification Statement, about Mortgage Loans offered in the sale;

9. An individual or entity that knowingly uses the services, directly or indirectly, of any person or entity ineligible under 1 through 11 to assist in preparing any of its bids on the Mortgage Loans;

10. An individual or entity which knowingly employs or uses the services of an employee of HUD's Office of Housing (other than in such employee's official capacity); or

11. A Participating Servicer that contributed Mortgage Loans to a pool on which the Bidder is placing a bid.

The Qualification Statement has additional representations and warranties which the prospective bidder must make, including but not limited to the representation and warranty that the prospective bidder or its Related Entities are not and will not knowingly use the services, directly or indirectly, of any person or entity that is, any of the following (and to the extent that any such individual or entity would prevent Bidder from making the following representations, such individual or entity has been removed from participation in all activities related to this sale and has no ability to influence or control individuals involved in formation of a bid for this sale):

(1) An entity or individual is ineligible to bid on any included Mortgage Loan or on the pool containing such Mortgage Loan because it is an entity or individual that:

(a) serviced or held any Mortgage Loan at any time during the two-year period prior to the bid, or

(b) is any principal of any entity or individual described in the preceding sentence;

(c) any employee or subcontractor of such entity or individual during that two-year period; or

(d) any entity or individual that employs or uses the services of any other entity or individual described in this paragraph in preparing its bid on such Mortgage Loan.

Freedom of Information Act Requests

HUD reserves the right, in its sole and absolute discretion, to disclose information regarding SFLS 2016–1, including, but not limited to, the identity of any successful qualified bidder and its bid price or bid percentage for any pool of loans or individual loan, upon the closing of the sale of all the Mortgage Loans. Even if HUD elects not to publicly disclose any information relating to SFLS 2016–1, HUD will disclose any information that HUD is obligated to disclose pursuant to the Freedom of Information Act and all regulations promulgated thereunder.

Scope of Notice

This notice applies to SFLS 2016–1 and does not establish HUD's policy for the sale of other mortgage loans.

Dated: November 10, 2015.

Genger Charles,

General Deputy, Assistant Secretary for Housing.

[FR Doc. 2015–29486 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5838–N–08]

60-Day Notice of Proposed Information Collection: Public Housing Capital Fund Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 19, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. 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 FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives,

PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Public Housing Capital Fund Program.

OMB Approval Number: 2577–0157.

Type of Request: Revision of a currently approved collection.

Form Numbers: HUD Form 50075.1—Annual Statement/Performance and Evaluation Report and HUD–50075.2—Capital Fund Program Five-Year Action Plan, HUD–5084, HUD–5087, HUD–51000, HUD–51001, HUD–51002, HUD–51003, HUD–51004, HUD–51915, HUD–51915–A, HUD–51971–I–II, HUD–52396, HUD–52427, HUD–52482, HUD–52483–A, HUD–52484, HUD–52485, HUD–52651–A, HUD–52829, HUD–52830, HUD–52833, HUD–52845, HUD–52846, HUD–52847, HUD–52849, HUD–53001, HUD–53015, HUD–5370, HUD–5370EZ, HUD–5370C, HUD–5372, HUD–5378, HUD–5460, HUD–52828, 50071, 5370–C1, 5370–C2.

Description of the need for the information and proposed use: The Public Housing Capital Fund Program Final Rule (24 CFR 905) was published in the **Federal Register** October 24, 2013 (Docket No. 5236–F–02) and was effective on November 25, 2013. The new Capital Fund Rule de-coupled the capital funding annual performance and evaluation reports (HUD form 50775.1) and 5-Year Action Plan (HUD Form 50075.2) submissions that were formerly combined with the PHA Plan submissions. The HUD–50075.1 and HUD–50075.2 Capital Fund Annual Statement/Performance and Evaluation Report and 5-Year Action Plan forms and associated burden hours (10,070) are being removed from the approval for the PHA Plan under OMB no. 2577–0226 and added to the approval for the Capital Fund Program under OMB no. 2577–0157. The revision to PHA Plan information collection, OMB No. 2577–0226, is being submitted concurrently with this submission. HUD is in the process of moving to an electronic submission of the information collected with forms HUD–50075.1 and HUD–50075.2 under the Activity Planning Module of the Energy and Performance Information Center (EPIC) System. HUD began beta testing of the Activity Planning Module in EPIC in August of 2015. Once beta testing is complete, HUD will begin roll out of the submission of the HUD–50075.1 and HUD–50075.2 data to EPIC in lieu of using the paper forms for submission. The hours for the electronic collection of that information will then be moved from Capital Fund Information Collection, OMB No. 2577–0157 to the EPIC Information Collection—OMB No. 2577–0274.

Respondents: Members of Affected Public: State, Local or Local Government and Non-profit Organization.

Estimated Number of Respondents: 3,100.

Estimated Number of Responses: 79,044 annual responses.

Frequency of Response: 1.

Average Hours per Response: 3.49.

Total Estimated Burdens: 275,537 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 9, 2015.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2015–29467 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5835–N–24]

60-Day Notice of Proposed Information Collection: Manufactured Home Construction and Safety Standards Program

AGENCY: Office of the Assistant Secretary for Housing- Federal Housing—Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 19, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. 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 FURTHER INFORMATION CONTACT: Pamela Beck Danner, Administrator, Office of Manufactured Housing Programs, Department of Housing and Urban Development, 451 7th Street, SW., Room 9168, Washington, DC 20410; email *mhs@hud.gov* or telephone 202–708–6423. 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.

Copies of available documents submitted to OMB may be obtained from Ms. Danner.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Manufactured Home Construction and Safety Standards Program.

OMB Approval Number: 2502–0233.

Type of Request: Extension of currently approved collection.

Form Number: HUD–101, HUD–203, HUD–203B, HUD–301, HUD–302, HUD–303, and HUD–304.

Description of the need for the information and proposed use: Collection of this information will result in a better determination of reporting how Primary Inspection Agencies and manufacturers request certification labels, track payment, track production, refund monies, and report missing or damaged labels to the Department or its monitoring contractor.

Respondents: Business or other for-profit.

Estimated Number of Respondents: 176.

Estimated Number of Responses: 5,622.

Frequency of Response: On occasion.

Average Hours per Response: 6.5.

Total Estimated Burdens: 2,811.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 12, 2015.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing Associate Deputy Federal Housing Commissioner.

[FR Doc. 2015–29468 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5838–N–07]

60-Day Notice of Proposed Information Collection: Public Housing Agency (PHA) 5-Year and Annual Plan

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, PIH, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 19, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. 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 FURTHER INFORMATION CONTACT: Arlette Mussington, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street SW., (L'Enfant Plaza, Room 2206), Washington, DC 20410; telephone 202–402–4109, (this is not a toll-free number). Persons with hearing or speech impairments may access this number via TTY by calling the Federal Information Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Mussington.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Public Housing Agency (PHA) 5-Year and Annual Plan.

OMB Approval Number: 2577–0226.

Type of Request: Revision of currently approved collection.

Form Number(s): HUD–50075–5Y, HUD–50075–ST, HUD–50075–SM, HUD–50075–HCV, HUD–50075–HP, HUD–50077–CR, HUD–50077–SL, HUD–50077–CRT–SM, HUD–50077–ST–HCV–HP, HUD–50070, HUD–50071.

Description of the need for the information and proposed use: The Public Housing Agency (PHA) Plan was created by section 5A of the United States Housing Act of 1937 (42 U.S.C. 1437c-1). There are two different PHA Plans: the Five-Year Plan and the Annual Plan. The Five-Year Plan describes the agency's mission and long-range goals and objectives for achieving its mission over a five-year period, and their approach to managing programs and providing services for the upcoming year. The Annual PHA Plan is a comprehensive guide to PHA policies, programs, operations, and strategies for meeting local housing needs and goals.

The PHA Plans informs HUD, residents, and the public of the PHA's mission for serving the needs of low, very low-income, and extremely low-income families and its strategy for addressing those needs. This information helps provide accountability to the local community for how PHAs spend their funding and implement their policies. Also, PHA plans allow HUD to monitor the performance of programs and the performance of public housing agencies that administer them.

HUD's most recent action in October 2015 was to post a version of this collection which OMB approved as a full revision incorporating public comments in 2013, and with minor changes in late 2014. Public commenters urged HUD to return to earlier multiple versions of PHA Plan templates by specific PHA type instead of a ''One-Size Fits All'' form. With this current proposed information collection, HUD intends to further modify the HUD–50075–5Y, HUD–50075–ST, HUD–50075–SM, HUD–50075–HCV, HUD–50075–HP templates and HUD–50077 Civil Rights, PHA Plan, Related Regulations, and Consistency with State/local Consolidated Plan certifications in the following manner as needed without a major overhaul as was done for the 2013 approval: (1) Additional instructions will be provided to PHA's planning to convert all ACC units to Project-Based Assistance under RAD resulting in the removal of all ACC units from the PHAs public housing inventory. These PHA's will be required to provide a plan for disposition of remaining public housing property, (2)

Incorporating mandatory RAD information into the existing PHA Plan templates to improve, streamline, and provide clarity to the RAD significant amendment process, (3) Modify all forms as needed to reference or otherwise address the new requirements of the Affirmatively Furthering Fair Housing (AFFH) Rule published July 16, 2015, (4) Re-introduce as a submission requirement ''Challenged Elements,'' (5) Remove obsolete references to OMB circulars that were replaced by OMB's Uniform Administrative Requirements, Cost Principles, and Audit Requirements in 2 CFR 200, (6) Expand the Civil Rights certification to include equal access to all housing regardless of LGBT and marital status and prohibit inquiries made of applications or occupants concerning sexual orientation or gender identification and, (7) Replacing the 50077 form with customized versions to align with streamlined requirements of 24 CFR 903.

Finally, due to the de-coupling of Capital Fund Program activities from PHA Plan submissions, the HUD–50075.1 and HUD–50075.2 Capital Fund Annual Statement/Performance and Evaluation Report and 5-Year Action Plan forms and associated burden hours (10,070) will be removed from the approval for the PHA Plan under OMB no. 2577–0226 and added to the approval for the Capital Fund Program under OMB no. 2577–0157.

Respondents: Local, Regional and State Body Corporate Politic Public Housing Agencies (PHAs) Governments.

Estimated Number of Respondents: 4,053.

Estimated Number of Responses: 5,112 (Annual Plan: 1,059 and 5 Year Plan: 4,053).

Frequency of Response: Every five years for all PHAs, annually for all PHAs except HERA Qualified PHAs.

Average Hours per Response: 3.4 hrs. (An. Pl.—2,049.8 hrs. and 5 Yr. Pl.—15,401.4 hrs.)

Total Estimated Burdens: 17,451.2.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 9, 2015.

Merrie Nichols-Dixon,

Deputy Director, Office of Policy, Programs and Legislative Initiatives.

[FR Doc. 2015–29465 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5831–N–57]

30-Day Notice of Proposed Information Collection: Accountability in the Provision of HUD Assistance Applicant/Recipient Disclosure/Update Report—HUD 2880

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* December 18, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. 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.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on September 10, 2015 at 80 FR 54580.

A. Overview of Information Collection

Title of Information Collection: Accountability in the Provision of HUD Assistance ''Applicant/Recipient Disclosure/Update Report-HUD 2880''.

OMB Approval Number: 2510–0011.

Type of Request: Extension of a currently approved collection.

Form Number: HUD–2880.

Description of the need for the information and proposed use: Section 102 of the Department of Housing and Urban Development Reform Act of 1989 (HUD Reform Act) requires the Department to ensure greater accountability and integrity in the provision of assistance administered by the Department. One feature of the statute requires certain disclosures by applicants seeking assistance from HUD, assistance from states and units of local government, and other assistance to be used with respect to the activities to be carried out with the assistance. The disclosure includes the financial interests of persons in the activities, and the sources of funds to be made available for the activities, and the proposed uses of the funds.

Each applicant that submits an application for assistance, within the jurisdiction of the HUD, to a state or to a unit of general local government for a specific project or activity must disclose this information whenever the dollar threshold is met. This information must be kept updated during the application review process and while the assistance is being provided.

Members of affected public: Applicants for HUD competitively funded assistance.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The form, HUD 2880, must be submitted as part of an applicant's application for competitively funded assistance.

Number of respondents	Burden hours	Frequency of response	Total burden hours
16,900	2.0	1.2	40,560

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: 12 U.S.C. 1701z–1 Research and Demonstrations.

Dated: November 13, 2015.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2015–29477 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5832–N–11]

60-Day Notice of Proposed Information Collection: Renewable Energy Commitment Form

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 19, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. 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 FURTHER INFORMATION CONTACT: Crystal Bergemann, Senior Energy Analyst, Office of Economic Resilience, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Crystal Bergemann at *Crystal.A.Bergemann@hud.gov,* telephone 202–402–4592. 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.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Renewable Energy Commitment Form.

OMB Approval Number: 2506–0208.

Type of Request: Extension of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: Currently there is no vehicle available to allow program partners to make a public commitment toward the Administration's Federal Renewable Energy Target. For owners or managers of federally assisted housing (including Public Housing Authorities) to make a pledge, the must provide the amount of on-site renewable energy capacity they have already installed or intent to install by 2020. The information collected to make these organizations eligible for technical assistance funds, if available.

Respondents (*i.e.* affected public): Organizations 9owners or managers of federally assisted housing) that make a voluntary public commitment to the Administration's Federal Renewable Energy Target.

Estimated Number of Respondents: 50.

Estimated Number of Responses: 50.

Frequency of Response: Once per year.

Average Hours per Response: .5.

Total Estimated Burdens: 25 burden hours.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Total	50	1	1	.5	25	N/A	N/A

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of

information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 4, 2015.

Harriet Tregoning,

Principal Assistant Secretary, for Community Planning and Development.

[FR Doc. 2015–29463 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5841–N–04]

10-Day Extension to 60-Day Notice of Proposed Information Collection: Core Performance Reporting Requirements for Competitively-Funded Grants

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 10 additional days of public comment.

DATES: *Comments Due Date: November 30, 2015.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone number 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov.* Copies of the proposed forms and other information are available by contacting Ms. Pollard. 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 FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or by telephone at 202–402–3400. 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. Requests for copies of the proposed forms should be submitted to Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Core Performance Reporting for Competitively-Funded Grants.

OMB Approval Number: Pending.

Type of Request: Regular.

Type of Information Collection: New.

Form Numbers: HUD–PRL, HUD–CIRL, HUD–GF.

Description of the need for the information and proposed use:

This request is for the clearance of data collection and reporting requirements to enable the U.S. Department of Housing and Urban Development (HUD) Office of Strategic Planning and Management (OSPM) to better assess the effectiveness of competitively-funded grants included in this information collection request (ICR). The competitively–funded grant programs included in this ICR are: Community Development Block Grant Program for Indian Tribes and Alaska Native Villages (ICDBG), Family Self-Sufficiency Program (FSS), Housing Counseling (HC), Housing Opportunities for Persons with AIDS (HOPWA), JobsPlus Program (Jobs+), Juvenile Reentry Assistance Program (JRAP), Lead-Based Paint Hazard Control (LBPHC), Lead Hazard Reduction Demonstration (LHRD), Self-Help Homeownership Opportunity Program (SHOP), Supportive Services Demonstration Program (202), and Resident Opportunity and Self Sufficiency Service Coordinators Program (ROSS).

A key component of this proposed collection is the reporting of measureable outcomes. Additionally, the standardization of data collection and reporting requirements across the Department will increase data comparability and utilization. Consolidation of de-identified data drawn from pre-existing HUD systems and databases, as applicable, into a single repository will enhance the Department's comprehensive and comparative analysis of competitively-funded HUD programs. Data submission will be acceptable via Comma Separated Values (CSV), Extensible Markup Language (XML), and other file formats in addition to direct data entry into an online Web form.

The Department has several reporting models in place for competitive grant programs, including the eLogic Model. The reporting models provide information on a wide variety of outputs and outcomes and are based on unique data definitions and outcome measures in program-specific performance and progress reports. In Federal Fiscal Year 2013, nine program offices at HUD used six systems and 15 reporting tools to collect over 700 data elements in support of varied metrics to assess the performance of competitively-funded. The proposed data collection and reporting requirements described in this notice are designed to replace the use of the eLogic Model and other report forms and requirements.

The lack of standardized data collection and reporting requirements imposes an increased burden on grantees with multiple grant awards from HUD. The need for a comprehensive and standardized reporting approach is underscored by reviews conducted by external oversight agencies, including the Department's Office of Inspector General (OIG) and the Government Accountability Office (GAO). These oversight agencies have questioned the validity and comparability of data reported by the Department. To address these issues, the Department is using its statutory and regulatory authority to redesign and strengthen performance reporting for many of its competitive grant programs into a single comprehensive approach.

The Secretary's statutory and regulatory authority to administer housing and urban development programs include provisions allowing for the requirement of performance reporting from grantees. This legal authority is codified at 42 U.S.C. 3535(r). The individual privacy of service recipients is of the highest priority. The reporting repository established at HUD to receive data submission from grantees will not include any personally identifying information (PII). Additionally, if the data for a grant has 25 or fewer individuals served during a fiscal year as reported in the record-level reports, then the results for the demographic data elements for the 25 or fewer individuals will also be redacted or removed from the public-use data file and any publicly available analytical products in order to ensure the inability to identify any individual.

Eligible entities awarded grants by the Department are expected to implement the proposed recordkeeping and reporting requirements with available

grant funds. It is important to note that much of the data to be reported by grantees under this ICR is already required and reported to one or more program offices at HUD. Furthermore, generally only a subset of the universe of data elements presented will be submitted as data collection and reporting requirements are determined by the program office and include consideration of the type and level of service provided by the respective grant programs.

The reporting requirements in this proposal better organize the data already being collected, standardize outcomes and performance measures, and allow program offices at HUD to select which data elements and performance indicators are relevant for their respective programs. Documents detailing the data elements, performance indicators, and draft online data entry forms are available for review by request from Colette Pollard (*Colette.Pollard@hud.gov*). All information reported to HUD will be submitted electronically. Recipients or grantees may use existing management information systems provided those systems collect all of the required data elements and can be exported for submission to HUD. Recipients or grantees that sub-grant funds to other organizations will need to collect the required information from their sub-recipients or sub-grantees.

Information collected and reported will be used by recipients or grantees and the Department for the following purposes:

- To provide program and performance information to recipients, general public, Congress, and other stakeholders;
- To continuously improve the quality, effectiveness, and efficiency of grant-funded programs;
- To provide management information for use by the Department in program administration and oversight, including the monitoring of grant-specific participation, services, capital investments, and outcomes; and
- To better measure and analyze performance information to identify successful practices to be replicated and prevent or correct problematic practices and improve outcomes in compliance with the Government Performance and Results Act (GPRA) and the GPRA Modernization Act.

The data collection and reporting requirements will be phased in over a three-year period which includes a proof of concept pilot in FY16. The Department will provide technical assistance to recipients or grantees throughout the implementation.

Respondents (*i.e.* affected public): Organizations awarded competitively-funded grants as listed on page 2.

ANNUAL BURDEN ESTIMATE FOR THE REQUESTED REPORTING APPROACH, INITIAL YEAR OR PROOF OF CONCEPT PILOT PROJECT

Type of record	Number of respondents	Submission frequency	Hourly rate [1]	Average number of minutes	Estimated annual burden hours	Estimated annual burden dollars
Participant Record-level	63 grantees [2]	1	$14.19	20 Per Record	2,583	$36,653
Capital Investment Record-level	7 grantees [3]	1	14.19	15 Per Record	7	99
Grant Feedback	70 grantees	2	14.19	15	35	497
Total			14.19		2,625	37,249

[1] The hourly rate of $14.19 is the average wage for office and administrative support occupations as reported in the May 2014 *Occupational Employment and Wages* produced by the U.S. Department of Labor, Bureau of Labor Statistics.
[2] There are an estimated 7,749 individuals to be served by the 63 grantees.
[3] There are an estimated 28 project-level records for the 7 grantees.

ANNUAL BURDEN ESTIMATE FOR THE REQUESTED REPORTING APPROACH, SECOND AND SUBSEQUENT YEARS

Type of record	Number of respondents	Submission frequency	Hourly rate [1]	Average number of minutes	Estimated annual burden hours	Estimated annual burden dollars
Participant Record-level	2,850 grantees [2]	1	$14.19	20 Per Record	116,850	$1,658,102
Capital Investment Record-level	150 grantees [3]	1	14.19	15 Per Record	150	2,129
Grant Feedback	3,000 grantees	2	14.19	15	1,500	21,285
Total			14.19		118,500	1,681,516

[1] The hourly rate of $14.19 is the average wage for office and administrative support occupations as reported in the May 2014 *Occupational Employment and Wages* produced by the U.S. Department of Labor, Bureau of Labor Statistics.
[2] There are an estimated 351,000 individuals to be served by the 2,850 grantees.
[3] There are an estimated 600 project-level records for the 150 grantees.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comments in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 12, 2015.

Henry Hensley,

Acting Director, Office of Strategic Planning and Management.

[FR Doc. 2015–29484 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5696–N–17]

Guidance, Waivers, and Alternative Requirements for Grantees in Receipt of Community Development Block Grant Disaster Recovery Funds Under Public Law 113–2: ''Buyout'' and ''Acquisition'' Activities; Assistance to Agricultural Enterprises; and State of Colorado Waiver for Tourism Promotion

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This notice provides clarifying guidance for Community Development Block Grant disaster recovery (CDBG–DR) grantees in receipt of funds under the Disaster Relief Appropriations Act, 2013 (the Appropriations Act). It provides clarification regarding the requirements of ''buyout'' activities authorized in the Department's March 5, 2013, **Federal Register** notice and expands the eligibility criteria for buyout activities to include ''Disaster Risk Reduction Areas'' as defined by the grantee. It also modifies requirements of the March 5, 2013, notice on the prohibition of assistance to businesses that do not meet the Small Business Administration (SBA) definition of small businesses, permitting assistance also to eligible businesses engaged in ''farming operations,'' as determined by the U.S. Department of Agriculture (USDA). This notice also provides a waiver to the State of Colorado to expend additional CDBG–DR funds and to assist additional communities impacted by declared disasters in 2011, 2012, and 2013, through tourism promotion activities previously authorized in the Department's June 3, 2014, notice.

DATES: *Effective Date:* November 23, 2015.

FOR FURTHER INFORMATION CONTACT: Stanley Gimont, Director, Office of Block Grant Assistance, Department of Housing and Urban Development, 451 7th Street SW., Room 7286, Washington, DC 20410, telephone number 202–708–3587. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Facsimiled inquiries may be sent to Mr. Gimont at 202–401–2044. (Except for the ''800'' number, these telephone numbers are not toll-free.) Emailed inquiries may be sent to *disaster_recovery@hud.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background
II. Applicable Rules, Statutes, Waivers, and Alternative Requirements
III. Catalog of Federal Domestic Assistance
IV. Finding of No Significant Impact

I. Background

The Appropriations Act (Pub. L. 113–2, approved January 29, 2013) made available $16 billion in CDBG–DR funds for necessary expenses related to disaster relief, long-term recovery, restoration of infrastructure and housing, and economic revitalization in the most impacted and distressed areas, resulting from a major disaster declared pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974 (42 U.S.C. 5121 et. seq.) (Stafford Act) due to Hurricane Sandy and other eligible events in calendar years 2011, 2012, and 2013. On March 1, 2013, the President issued a sequestration order pursuant to section 251A of the Balanced Budget and Emergency Deficit Control Act, as amended (2 U.S.C. 901a), and reduced the amount of funding for CDBG–DR grants under the Appropriations Act to $15.18 billion. To date, a total of $15.18 billion has been allocated or set aside: $13 billion in response to Hurricane Sandy, $514 million in response to disasters occurring in 2011 or 2012, $655 million in response to 2013 disasters, and $1 billion for the National Disaster Resilience Competition.

This notice applies to grantees in receipt of allocations under the Appropriations Act, which are described within the **Federal Register** notices published by the Department on March 5, 2013 (78 FR 14329); April 19, 2013 (78 FR 23578); May 29, 2013 (78 FR 32262); August 2, 2013 (78 FR 46999); November 18, 2013 (78 FR 69104); December 16, 2013 (78 FR 76154); March 27, 2014 (79 FR 17173); June 3, 2014 (79 FR 31964); July 11, 2014 (79 FR 40133); October 7, 2014 (79 FR 60490); October 16, 2014 (79 FR 62182); January 8, 2015 (80 FR 1039); April 2, 2015 (80 FR 17772); May 11, 2015 (80 FR 26942); and August 25, 2015 (80 FR 51589) referred to collectively in this notice as the ''prior notices.'' The requirements of the prior notices continue to apply, except as modified by this notice.[1]

II. Applicable Rules (Including Clarifying Guidance), Statutes, Waivers, and Alternative Requirements

The Appropriations Act authorizes the Secretary to waive, or specify alternative requirements for, any provision of any statute or regulation that the Secretary administers in connection with HUD's obligation or use by the recipient of these funds (except for requirements related to fair housing, nondiscrimination, labor standards, and the environment). Waivers and alternative requirements are based upon a determination by the Secretary that good cause exists and that the waiver or alternative requirement is not inconsistent with the overall purposes of Title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301 *et seq.*) (HCD Act). Regulatory waiver authority is also provided by 24 CFR 5.110, 91.600, and 570.5.

For the waiver and alternative requirements described in this notice, the Secretary has determined that good cause exists and that the waiver and alternative requirements are not inconsistent with the overall purpose of the HCD Act. Grantees may request waivers and alternative requirements from the Department as needed to address specific needs related to their recovery activities. Under the requirements of the Appropriations Act, waivers must be published in the **Federal Register** no later than 5 days before the effective date of such waiver.

1. Acquisition of Real Property and Buyouts Outside of Floodplains

In response to a request from the State of Colorado, HUD is authorizing grantees in receipt of CDBG–DR funds under the Appropriations Act to acquire property for an amount equal to either the property's pre-disaster or post-disaster value (formerly referenced in the prior notices as pre- and post-flood values), for the buyout of properties in ''Disaster Risk Reduction Areas'' as defined by criteria established by the grantee, subject to the limitations of this notice.

The Department has previously authorized CDBG–DR grantees to carry out buyout programs in floodways or floodplains, by allowing grantees to offer to acquire properties in hazardous

[1] Links to the prior notices, the text of the Appropriations Act, and additional guidance prepared by the Department for CDBG–DR grants are available on the HUD Exchange Web site: *https://www.hudexchange.info/cdbg-dr/cdbg-dr-laws-regulations-and-federal-register-notices/*.

flood areas at pre-flood or post–flood value. The Secretary authorized this type of acquisition to: (1) Reduce the risk to homeowners from the effects of subsequent disasters; (2) assist in the recovery of low- and moderate-income households; and (3) protect taxpayer resources that might otherwise be needed after future disasters in the same area.

In previous notices, HUD referred to ''flood buyouts'' and recognized that grantees frequently used CDBG–DR funds to match funds for buyouts provided under section 404 of the Stafford Act, as amended. Section 404 empowers the Director of the Federal Emergency Management Agency (FEMA) to provide property acquisition and relocation assistance ''in providing hazard mitigation assistance under this section in connection with flooding . . . .'' Since flooding is by far the most prevalent and predictable source of widespread destruction in a Presidentially declared disaster, the Department did not address the potential need to include other types of hazards. Large scale disasters have the potential to create or exacerbate hazards in areas located outside of a floodplain or floodway. For example, the wildfires that swept through Colorado in 2013 destroyed vegetation in many areas, creating erosion and affecting soil stability in a manner that now places many homes at risk for mudslides in future disasters, although those homes are not located in a floodplain or floodway.

For the same reasons that buyouts in floodways and floodplains are permitted, HUD is amending its alternative requirement to expand the scope of authorized buyouts in the prior notices for grantees receiving CDBG–DR funds under the Appropriations Act. Accordingly, the definition of ''buyout'' in all prior notices is amended to mean ''acquisition of properties located in a floodway or floodplain that is intended to reduce risk from future flooding, or the acquisition of properties in 'Disaster Risk Reduction Areas' located outside of floodways and floodplains for the purpose of reducing risks from the hazard that was the basis of the Disaster Risk Reduction Area designation. 'Disaster Risk Reduction Areas' must be designated in accordance with the buyout requirements of applicable **Federal Register** Notices.''

Recognizing that States and units of general local government (UGLGs) are best positioned to determine what constitutes an unacceptable risk to their communities in exercising this additional authority, grantees will need to establish criteria to designate a '' Disaster Risk Reduction Area,'' subject to the following requirements: (1) The hazard must have been caused or exacerbated by the Presidentially declared disaster for which the grantee received its CDBG–DR allocation; (2) The hazard must be a predictable environmental threat to the safety and well-being of program beneficiaries, as evidenced by the best available data and science; and (3) The Disaster Risk Reduction Area must be clearly delineated so that HUD and the public may easily determine which properties are located within the Disaster Risk Reduction Area.

Once grantees have established criteria to designate a ''Disaster Risk Reduction Area,'' and designated a Disaster Risk Reduction Area in accordance with the established criteria, the grantee may conduct buyouts in the Disaster Risk Reduction Area only if the grantee's approved action plan contains a description of the buyouts to be conducted in the identified Disaster Risk Reduction Areas and the national objective that the buyouts will meet. Any buyouts conducted within the Disaster Risk Reduction Area will be subject to the requirements applicable to buyouts in the March 5, 2013, notice. These requirements include restrictions on redevelopment and the discretion to determine the appropriate valuation method (including the use of pre- or post-disaster fair market value (FMV)), so long as the valuation method is uniformly applied.

2. Clarification of ''Buyout'' and ''Real Property Acquisition'' Activities

CDBG–DR grantees under Public Law 113–2 that choose to undertake a buyout program have the discretion to determine the appropriate valuation method, including paying either pre-disaster or post-disaster FMV. In most cases, a program that provides *pre*-disaster FMV to buyout applicants provides compensation at an amount greater than the post-disaster FMV. When the purchase price exceeds the current FMV, any CDBG–DR funds in excess of FMV are considered assistance to the seller, thus making the seller a beneficiary of CDBG–DR assistance. If the seller receives assistance as part of the purchase price, this may have implications for duplication of benefits calculations or for demonstrating national objective criteria, as discussed below. However, a program that provides *post*-disaster FMV to buyout applicants merely provides the actual value of the property; thus, the seller is not considered a beneficiary of CDBG–DR assistance.

Regardless of purchase price, all buyout activities are a type of acquisition of real property (as permitted by section 105(a)(1) of the HCD Act). However, only acquisitions that meet the definition of a ''buyout'' are subject to the post-acquisition land use restrictions imposed by the applicable prior notices. The key factor in determining whether the acquisition is a buyout is whether the intent of the purchase is to reduce risk from future flooding or to reduce the risk from the hazard that lead to the property's Disaster Risk Reduction Area designation. The distinction between buyouts and other types of acquisitions is important, because grantees may only redevelop an acquired property if the property is not acquired through a buyout program (*i.e.,* the purpose of acquisition was something other than risk reduction). When acquisitions are not acquired through a buyout program, the purchase price must be consistent with applicable uniform cost principles (the pre-disaster FMV may not be used).

3. Clarification of Ownership and Maintenance Requirements for Property Acquired Through a Buyout Program

Any property acquired with CDBG–DR funds through a buyout program is subject to the requirement made applicable by the prior notices that property acquired through a buyout program be dedicated and maintained in perpetuity for a use that is compatible with open space, recreational, or wetlands management practices. In addition, no new structure may be erected on the property other than exceptions identified in the March 5, 2013, notice, and no subsequent application for Federal disaster assistance may be made for any purpose for the property. The acquiring entity may lease such property to adjacent property owners or other parties for compatible uses in return for a maintenance agreement. Although Federal policy encourages leasing rather than selling such property, the property may also be sold. In all cases, a deed restriction or covenant running with the property must require that the buyout property be dedicated and maintained for compatible uses in perpetuity.

4. Use of Low- and Moderate-Income Housing National Objective When Undertaking Buyout Activities

In order to demonstrate that a buyout meets the Low- and Moderate-Income (LMI) Housing National Objective (LMH), grantees must meet all requirements of the HCD Act and applicable regulatory criteria described below. Grantees are encouraged to

consult with HUD prior to undertaking a buyout program with the intent of using the LMH national objective.

Section 105(c)(3) of the HCD Act (42 U.S.C. 5305(c)(3)) provides that ''[a]ny assisted activity under this chapter that involves the acquisition or rehabilitation of property to provide housing shall be considered to benefit persons of low- and moderate-income only to the extent such housing will, upon completion, be occupied by such persons.'' In addition, the State CDBG regulations at 24 CFR 570.483(b)(3) and entitlement CDBG regulations at 24 CFR 570.208(a)(3) apply the LMH national objective to an eligible activity carried out for the purpose of providing or improving permanent residential structures that, upon completion, will be occupied by low- and moderate-income households. Therefore, a buyout program that merely pays homeowners to leave their existing homes does not result in an LMI household occupying a residential structure and thus cannot meet the requirements of the LMH national objective.

Buyout programs that assist LMI persons can be structured in one of the following ways: (1) The buyout program combines the acquisition of properties with another direct benefit, LMI housing activity, such as down payment assistance,[2] that results in occupancy and otherwise meets the applicable LMH housing national objective criteria in 24 CFR part 570 (*e.g.,* if the structure contains more than two dwelling units, at least 51 percent of the units must be occupied by LMI households); (2) The program meets the low- and moderate-income area benefit criteria to demonstrate national objective compliance, provided that the grantee can document that the properties acquired through buyouts will be used in a way that benefits all of the residents in a particular area where at least 51 percent of the residents are low- and moderate-income persons. When using the area benefit approach, grantees must define the service area based on the end use of the buyout properties; or (3) The program meets the criteria for the limited clientele national objective, including the prohibition on the use of the limited clientele national objective when an activity's benefits are available to all residents of the area. A buyout program could meet the national objective criteria for the limited clientele national objective if it restricts buyout program eligibility to exclusively low- and moderate-income persons, and the buyout provides an actual benefit to the low- and moderate-income sellers by providing pre-disaster valuation uniformly to those who participate in the program.

5. Clarification of Definition of Small Business for Agricultural Enterprises

The March 5, 2013, notice (78 FR 14329) instituted an alternative requirement to the provisions at 42 U.S.C. 5305(a), prohibiting grantees in receipt of funds under the Appropriations Act from assisting businesses, including privately owned utilities, that do not meet the definition of a small business as defined by SBA at 13 CFR part 121. The objective of this alternative requirement is to ensure that grantees target disaster recovery resources to the unmet needs of small businesses. HUD is now modifying these criteria to better enable assistance for agricultural businesses. Businesses and entities engaged in agricultural enterprises may now be assisted if they meet the alternative eligibility criteria employed by USDA assistance programs.

The SBA small business definition establishes a much lower income threshold for agricultural enterprises than for other businesses. The SBA criteria provides a gross income limit of $750,000 for most agricultural businesses, while the gross income limit for businesses in other sectors is $7.5 million or higher. These gross income limitations for agricultural enterprises may prevent CDBG–DR grantees from addressing unmet recovery needs of many agricultural businesses that would otherwise be considered small enterprises that meet the intent of HUD's requirements.

Legislation enacted in 1986 withdrew SBA's authority to provide disaster assistance loans to agricultural enterprises to ensure cooperation between USDA and SBA in the use of each agency's respective loan making authorities and to improve the delivery of disaster assistance to the agricultural segment of the country. SBA also decreased the gross income limits for the agricultural sector in its small business criteria, as described above, to further ensure that agricultural businesses would apply to USDA for other types of financial assistance. Consequently, HUD's use of the SBA definition in its March 5, 2013, notice may inadvertently limit small agricultural enterprises from accessing financial assistance through grantees' CDBG–DR programs under the Appropriations Act.

As HUD's intent to address the unmet recovery needs of small agricultural enterprises does not conflict with the goal of directing these businesses to USDA for other types of assistance, HUD is modifying its criteria for businesses engaged in agricultural enterprises to enable them to access CDBG–DR funds necessary for their recovery.

Accordingly, paragraph VI.D.41, of the March 5, 2013, notice is amended to read: ''To target assistance to small businesses, the Department is instituting an alternative requirement to the provisions at 42 U.S.C. 5305(a) to prohibit grantees from assisting businesses, including privately owned utilities, that do not meet the definition of a small business as defined by SBA at 13 CFR part 121. Grantees may also assist businesses that are engaged in ''farming operations,'' as defined at 7 CFR 1400.3, and that meet the USDA Farm Service Agency (FSA) criteria that are described at 7 CFR 1400.500 which are used by the FSA to determine eligibility for certain assistance programs.''

Grantees are also reminded that this modification may allow them to add new beneficiaries or programs described within their CDBG–DR action plans for disaster recovery. These changes would constitute a substantial amendment to the CDBG–DR action plan as described in the March 5, 2013, notice (78 FR 14329) at paragraph VI.A.3.a. If applicable, grantees must submit a Substantial Action Plan Amendment revising the description of their business assistance program to include potential beneficiaries, and this amendment will be subject to the citizen participation requirements of the March 5, 2013, notice at VI.A.3, which requires no less than 7 calendar days to solicit public comment.

6. Waiver To Permit Some Activities in Support of the Tourism Industry (State of Colorado Only)

In the **Federal Register** notice published on June 3, 2014 (79 FR 31964), the Department granted the State of Colorado a waiver of 42 U.S.C. 5305(a) to make eligible the use of up to $500,000 in CDBG–DR funds to support the State's tourism industry and to promote travel to the most impacted and distressed areas related to the 2013 floods. This notice replaces the previous waiver and authorizes the State to provide an additional $768,300 in

[2] The Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended, (URA) applies to the use of CDBG funds for down payment assistance. If down payment assistance is provided with CDBG funds awarded under the Appropriations Act (Pub. L. 113–2), URA requirements apply as modified by the March 5, 2013, notice (78 FR 14329). The use of other CDBG funds for down payment assistance is subject to the URA and regulatory requirements at 24 CFR 570.606. Other direct benefit LMI housing activities may also be subject to the URA.

CDBG–DR funds to support tourism promotion activities, increasing the amount covered by the waiver from $500,000 to $1,268,300. In addition, this revised waiver permits the State to support its tourism industry and promote travel to the most impacted and distressed counties that had a declared major disaster in 2011, 2012, or 2013, including those impacted by disasters other than flooding.

Using the funds provided under the initial waiver, the State established its first CDBG–DR Tourism Marketing Grant Program and received applications requesting a total of $787,927. Through this program, the State awarded eight grants totaling $500,000 in CDBG–DR funding to support a variety of activities such as advertising, marketing campaigns, promotion of community and spectator events, and Web site improvements in targeted areas that had experienced a reduction in tourism revenues following the 2013 floods in Colorado. This funding fell short of meeting the tourism promotion priorities identified through the initial round of State funding by $287,927. The State has also subsequently identified $480,373 in additional funding opportunities for the original applicants who were constrained by the initial grant size limitation, as well as for potential new applicants made eligible through the inclusion of areas impacted by disasters other than flooding.

In support of this request, the State has conducted an analysis of retail sales that indicates that the flooding and wildfire disasters continue to negatively affect local tourism revenues. Tourism is the primary economic contributor to the State of Colorado's economy and provides a valuable source of business revenue, taxes, and employment. According to analyses provided by the State, businesses supported by tourism, including hotels, lodges, restaurants, and grocery stores, are still experiencing weakened sales revenue. Tax revenue from these businesses benefits the State's economy and provides funding for other State activities and services. In addition, this industry employs many individuals who are of low- and moderate-income; thus, this population has been inordinately affected by the decrease in tourism revenue. Some of these jobs have been lost as a result of the disasters.

Because communities are diverting disposable tax revenue to physical recovery projects, funding for tourism marketing is scarce and communities face a worsening economic cycle from which the areas cannot recover without the injection of supplemental assistance. Therefore, the State has requested that an additional $768,300 of its total CDBG–DR award be made eligible for such tourism promotion activities. HUD continues to support the use of CDBG–DR funds in this scenario as a recovery tool in a damaged regional economy that depends on tourism for many of its jobs and tax revenue.

As the State of Colorado is proposing to use these additional funds for advertising and marketing activities that broadly support its tourism industry, rather than direct assistance to tourism-dependent businesses, and because long-term benefit from the proposed activities must be derived using indirect means, 42 U.S.C. 5305(a) is waived only to the extent necessary to make eligible an additional $768,300 to support tourism promotion activities. The State must award the additional $768,300 in CDBG–DR funds competitively through its existing CDBG–DR Tourism Marketing Grant Program to public or nonprofit entities that promote travel to or within a community or communities in general, provided the assisted activities are designed to support tourism to areas most impacted and distressed by a major disaster declared in 2011, 2012, or 2013.

As an additional condition of expanding this waiver, the State must demonstrate that funds will supplement and not replace State and local funding sources for this purpose. In its request for this waiver, the State indicated that entities selected for an award also pledged nearly a one-for-one match for their projects. The State may demonstrate that CDBG–DR funds will supplement, but not replace, local funding by requiring a match, including provision for in-kind contributions, similar to the existing competitive grant program offered by the Colorado Tourism Office. However, if the State does not require a match, the State must identify another means to adequately demonstrate that funds will supplement, but not supplant, State and local resources typically dedicated to promote tourism in these impacted areas.

The additional funds provided through this waiver for the State's CDBG–DR Tourism Marketing Grant Program are subject to all requirements in the notice published on June 3, 2014 (79 FR 31964), unless otherwise modified through this notice. The funds permitted under this waiver are subject to the same obligation and expenditure deadline applicable to all funds under the Appropriations Act. Therefore, this waiver remains in effect until 2 years following HUD's obligation of the funds permitted under this waiver.

The State is reminded that this expanded waiver will allow them to add new beneficiaries described within their CDBG–DR action plans for disaster recovery. These changes would constitute substantial amendments as described in the March 5, 2013 notice (78 FR 14329), at paragraph VI.A.3.a. If applicable, the State must submit a Substantial Action Plan Amendment revising its description of its CDBG–DR Tourism Marketing Grant Program to include potential beneficiaries, and this amendment will be subject to the citizen participation requirements of the March 5, 2013, notice at VI.A.3, which requires no less than 7 calendar days to solicit public comment.

III. Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number for the disaster recovery grants under this notice is 14.269.

IV. Finding of No Significant Impact

A Finding of No Significant Impact (FONSI) with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI is available for public inspection between 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Due to security measures at the HUD Headquarters building, an advance appointment to review the docket file must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number through TTY by calling the Federal Relay Service, toll-free, at 800–877–8339.

Dated: November 10, 2015.

Nani Coloretti,

Deputy Secretary.

[FR Doc. 2015–29487 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5832–N–12]

60-Day Notice of Proposed Information Collection: Indian Community Capital Initiative

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 19, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. 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 FURTHER INFORMATION CONTACT: Thann Young, Office of Rural Housing and Economic Development, Department of Housing and Urban Development, 451 7th Street SW., Room 7240, Washington, DC 20410; email Thann Young at *Thann.Young@hud.gov* or telephone 202–708–2290. 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. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Indian Community Capital Initiative.

OMB Approval Number: 2506—New.

Type of Request: New Collection.

Form Numbers: SF 424; HUD 424CB; HUD 424–CBW; SF–LLL; HUD 2880; HUD 2990; HUD 2991; HUD 2993; HUD 2994A; HUD 27061; and HUD 27300.

Description of the need for the information and proposed use: The Indian Community Capital Initiative (ICCI) is a collaborative effort among three federal agencies—the Department of Housing and Urban Development (HUD), the Department of the Treasury—Community Development Financial Institutions Fund (CDFI Fund), and the Department of Agriculture—Rural Development (USDA–RD). The ICCI's goal is to increase access to capital for business lending and economic development and entrepreneurship for Federally recognized Indian tribes.

Federally recognized Indian tribe means any tribal entity eligible to apply for funding and services from the Bureau of Indian Affairs by virtue of its status as an Indian tribe. The list of Federally recognized Indian tribes can be found in the notice published by the Department of the Interior on January 14, 2015 (Federal Register/Vol. 80, No. 9/Wednesday, January 14, 2015/Notices).

Respondents (*i.e.* affected public): Public.

Estimated Number of Respondents: 566.

Estimated Number of Responses: 566.

Frequency of Response: 1.

Average Hours per Response: 7211.

Total Estimated Burdens:

	Respondents	Annual responses	Total responses	Burden per response	Total annual hours	Burden cost per instrument
HUD–424CB	566	1	566	3.12	1,766	44,150
HUD–424CBW	566	1	566	3.12	1,766	44,150
HUD–2880	566	1	566	2.0	1,132	28,300
HUD–2990	566	1	566	0	0	0
HUD–2991	566	1	566	0	0	0
HUD–2993	566	1	566	0	0	0
HUD–2994A	566	1	566	.5	283	7,075
HUD–27061	566	1	566	1.0	566	14,150
HUD–27300	566	1	566	3.0	1,698	42,450
Total	5,094		5,094		7,211	180,275

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 4, 2015.

Harriet Tregoning,

Principal Deputy Assistant Secretary for Community Planning and Development.

[FR Doc. 2015–29461 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5886–N–01]

Annual Indexing of Basic Statutory Mortgage Limits for Multifamily Housing Programs

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In accordance with Section 206A of the National Housing Act, HUD has adjusted the Basic Statutory Mortgage Limits for Multifamily Housing Programs for Calendar Year 2015.

DATES: Effective date: January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Daniel J. Sullivan, Deputy Director, Office of Multifamily Development, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–8000, telephone (202) 402–6130 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The FHA Down Payment Simplification Act of 2002 (Pub. L. 107–326, approved December 4, 2002) amended the National Housing Act by adding a new Section 206A (12 U.S.C. 1712a). Under Section 206A, the following are affected:

I. Section 207(c)(3)(A) (12 U.S.C. 1713(c)(3)(A));

II. Section 213(b)(2)(A) (12 U.S.C. 1715e (b)(2)(A));

III. Section 220(d)(3)(B)(iii)(I) (12 U.S.C. 1715k (d)(3)(B)(iii)(I));

IV. Section 221(d)(4)(ii)(I) (12 U.S.C. 1715l(d)(4)(ii)(I));

V. Section 231(c)(2)(A) (12 U.S.C. 1715v(c)(2)(A)); and

VI. Section 234(e)(3)(A) (12 U.S.C. 1715y(e)(3)(A)).

The Dollar Amounts in these sections are the base per unit statutory limits for FHA's multifamily mortgage programs collectively referred to as the 'Dollar Amounts,' they are adjusted annually (commencing in 2004) on the effective date of the Consumer Financial Protection Bureau's adjustment of the $400 figure in the Home Ownership and Equity Protection Act of 1994 (HOEPA) (Pub. L. 103–325, approved September 23, 1994). The adjustment of the Dollar Amounts shall be calculated using the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) as applied by the Bureau of Consumer Financial Protection for purposes of the above-described HOEPA adjustment.

HUD has been notified of the percentage change in the CPI–U used for the HOEPA adjustment and the effective date of the HOEPA adjustment. The percentage change in the CPI–U is 2.0% and the effective date of the HOEPA adjustment is January 1, 2014. The Dollar Amounts have been adjusted correspondingly and have an effective date of January 1, 2015.

The adjusted Dollar Amounts for Calendar Year 2015 are shown below:

BASIC STATUTORY MORTGAGE LIMITS FOR CALENDAR YEAR 2015

Multifamily Loan Program

☐ Section 207—Multifamily Housing

☐ Section 207 pursuant to Section 223(f)—Purchase or Refinance Housing

☐ Section 220—Housing in Urban Renewal Areas

Bedrooms	Non-Elevator	Elevator
0	$50,164	$57,886
1	$55,569	$64,832
2	$66,376	$79,497
3	$81,813	$99,566
4+	$92,622	$112,581

☐☐ Section 213—Cooperatives

Bedrooms	Non-Elevator	Elevator
0	$54,364	$57,886
1	$62,683	$65,583
2	$75,598	$79,749
3	$96,766	$103,170
4+	$107,803	$113,251

☐☐ Section 234—Condominium Housing

Bedrooms	Non-Elevator	Elevator
0	$55,474	$58,378
1	$63,962	$66,923
2	$77,140	$81,377
3	$98,742	$105,276
4+	$110,002	$115,560

☐☐ Section 221(d)(4)—Moderate Income Housing

Bedrooms	Non-Elevator	Elevator
0	$49,924	$53,928
1	$56,671	$61,822
2	$68,501	$75,176
3	$85,980	$97,251
4+	$97,156	$106,754

☐☐ Section 231—Housing for the Elderly

Bedrooms	Non-Elevator	Elevator
0	$47,465	$53,928
1	$53,062	$61,822
2	$63,364	$75,176
3	$76,255	$97,251
4+	$89,650	$106,754

☐☐ Section 207—Manufactured Home Parks per Space—$23,030

Dated: November 9, 2015.

Edward L. Golding,

Principal Deputy Assistant Secretary for Housing.

[FR Doc. 2015–29469 Filed 11–17–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–FHC–2015–N217: FXFR1334088TWG0W4–123–FF08EACT00]

Trinity River Adaptive Management Working Group; Public Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a public meeting of the Trinity River Adaptive Management Working Group (TAMWG). The TAMWG is a Federal advisory committee that affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the Trinity Management Council (TMC). The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

DATES: *Public meeting:* TAMWG will meet from 9:30 a.m. to 4:30 p.m. Pacific Time on Thursday, December 10, 2015. *Deadlines:* For deadlines on submitting written material, please see ''Public Input'' under **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held at the Trinity River Restoration Program Office, 1313 South Main Street, Weaverville, CA 96093.

FOR FURTHER INFORMATION CONTACT: Joseph C. Polos, by mail at U.S. Fish and Wildlife Service, 1655 Heindon Road, Arcata, CA 95521; by telephone at 707–822–7201 or by email at *joe_polos@fws.gov* or Elizabeth W. Hadley, Redding Electric Utility, by mail at 777 Cypress Avenue, Redding, CA 96001; by telephone at 530–339–7308 or by email at *ehadley@reupower.com.* Individuals with a disability may request an accommodation by sending an email to either point of contact.

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App., we announce that the Trinity River Adaptive Management Working Group will hold a meeting.

Background

The TAMWG affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the TMC. The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

Meeting Agenda

- Designated Federal Officer (DFO) update;
- TMC Chair update;
- Executive Director and Trinity River Restoration Program (TRRP) staff update;
- Update on Coarse Sediment Lessons Learned Workshop;
- TMC efficiency subcommittee update;
- Public comment;
- Discussion of watershed restoration needs and role in meeting TRRP goals; and
- TRRP Goals, objectives, and definition of completion.

The final agenda will be posted on the Internet at *http://www.fws.gov/arcata.*

Public Input

If you wish to . . .	You must contact Elizabeth Hadley (**FOR FURTHER INFORMATION CONTACT**) no later than . . .
Submit written information or questions for the TAMWG to consider during the meeting	December 3, 2015.

Submitting Written Information or Questions

Interested members of the public may submit relevant information or questions for the TAMWG to consider during the meeting. Written statements must be received by the date listed in ''Public Input,'' so that the information may be available to the TAMWG for their consideration prior to this meeting. Written statements must be supplied to Elizabeth Hadley in one of the following formats: One hard copy with original signature, one electronic copy with original signature, and one electronic copy via email (acceptable file formats are Adobe Acrobat PDF, MS Word, PowerPoint, or rich text file).

Registered speakers who wish to expand on their oral statements, or those who wished to speak but could not be accommodated on the agenda, may submit written statements to Elizabeth Hadley up to 7 days after the meeting.

Meeting Minutes

Summary minutes of the meeting will be maintained by Elizabeth Hadley (see **FOR FURTHER INFORMATION CONTACT**). The minutes will be available for public inspection within 14 days after the meeting, and will be posted on the TAMWG Web site at *http://www.fws.gov/arcata.*

Dated: November 12, 2015.

Joseph C. Polos,

Supervisory Fish Biologist, Arcata Fish and Wildlife Office, Arcata, California.

[FR Doc. 2015–29411 Filed 11–17–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[FWS–R8–ES–2015–N184; FF08ESMF00–FXES11120800000–156]

Proposed Habitat Conservation Plan/Natural Community Conservation Plan for Western Butte County, California: Environmental Impact Statement

AGENCY: Fish and Wildlife Service, Interior; National Marine Fisheries Service, Commerce.

ACTION: Notice of availability; receipt of permit application, joint Draft Environmental Impact Statement/Environmental Impact Report, joint draft Habitat Conservation Plan/Natural Community Conservation Plan; request for comment.

SUMMARY: This notice advises the public that we, the U.S. Fish and Wildlife Service (FWS), have prepared a draft environmental impact statement and environmental impact report (DEIS/R) under the National Environmental Policy Act of 1967, as amended (NEPA), and its implementing regulations. The National Marine Fisheries Service (NMFS), U.S. Army Corps of Engineers (Corps), and U.S. Environmental Protection Agency (EPA) are cooperating agencies on the DEIS/R.

This notice also announces the receipt of applications for 50-year incidental take permits under the Endangered Species Act of 1973, as amended. The applicants prepared the Draft Butte Regional Conservation Plan (Draft Plan, or BRCP) pursuant to the Act and the California Natural Community Conservation Planning Act of 2002 (NCCPA). The permits are needed to authorize the incidental take of 39 covered species that could result from activities covered under the proposed Draft Plan. We also announce meetings and invite comments.

DATES: *Submitting Comments:* To ensure consideration, written comments must be received by February 16, 2016.

Public Meetings: Three public meetings will be held:

1. Monday, January 25, 2016; 6–8 p.m., Chico Masonic Center, 1110 W. East Ave., Chico, CA 95926.
2. Tuesday, January 26, 2016; 2–4 p.m., Oroville Southside Community Center, 2959 Lower Wyandotte Rd., Oroville, CA 95966.
3. Tuesday, January 26, 2016; 6–8 p.m., Gridley City Council Chambers, 685 Kentucky St., Gridley, CA 95948.

ADDRESSES: *Submitting Comments:* Please address written comments to one of the following individuals:

1. Mike Thomas, Chief, Conservation Planning Division; or Eric Tattersall, Deputy Assistant Field Supervisor, by mail/hand-delivery at U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W–2605, Sacramento, California 95825; or by facsimile to (916) 414–6713. You may telephone (916) 414–6600 to make an appointment during regular business hours to drop off comments at the Sacramento Fish and Wildlife Office.
2. Gretchen Umlauf, by mail/hand-delivery at National Oceanic and Atmospheric Administration, West Coast Region, National Marine Fisheries Service, 650 Capitol Mall, Suite 5–100, Sacramento, California 95814; or by facsimile to (916) 930–3629. You may telephone (916) 930–5646 to make an appointment during regular business hours to drop off comments at the National Marine Fisheries Service.

Please send comments related specifically to the California Environmental Quality Act (CEQA) process to the Jon Clark, Executive Director, Butte County Association of Governments, 2580 Sierra Sunrise Terrace, Suite 100, Chico, California 95928. You may also submit comments by facsimile to (530) 879–2444.

Reviewing Documents: You may obtain copies of the Draft Plan and DEIS/R from any of the individuals in **FOR FURTHER INFORMATION CONTACT**, or from the Sacramento Fish and Wildlife Office Web site at *http://www.fws.gov/sacramento.* Copies of these documents are also available for public inspection, by appointment, during regular business hours, at the Sacramento Fish and Wildlife Office. Additionally, hard-bound copies of the DEIS/R and Draft Plan are available for viewing, or for partial or complete duplication, at the following locations in Chico:

- Butte County Association of Governments, 2580 Sierra Sunrise Terrace, Suite 100;
- Biggs Branch Library, 464A B Street;
- Chico Branch Library, 1108 Sherman Avenue;
- Gridley Branch Library, 299 Spruce Street; and
- Oroville Branch Library, 1820 Mitchell Avenue.

FOR FURTHER INFORMATION CONTACT:

(1) Rick Kuyper, Endangered Species Division; Mike Thomas, Chief, Conservation Planning Division; or Eric Tattersall, Deputy Assistant Field Supervisor, at the Sacramento Fish and Wildlife Office address above or at (916) 414–6600 (telephone); or

(2) Gretchen Umlauf, National Marine Fisheries Service, at the address above or at (916) 930–5646 (telephone).

If you use a telecommunications device for the deaf, please call the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: This notice advises the public that we, the U.S. Fish and Wildlife Service (FWS), have prepared a draft environmental impact statement and environmental impact report (DEIS/R) under the National Environmental Policy Act of 1967, as amended (42 U.S.C. 4321 *et seq.;* NEPA), and its implementing regulations in the Code of Federal Regulations (CFR) at 40 CFR 1506.6. The National Marine Fisheries Service (NMFS), U.S. Army Corps of Engineers (Corps), and U.S. Environmental Protection Agency (EPA) are cooperating agencies on the DEIS/R.

This notice also announces the receipt of applications from the County of Butte, City of Oroville, City of Chico, City of Biggs, City of Gridley, Butte County Association of Governments (BCAG), California Department of Transportation (Caltrans), Western Canal Water District (WCWD), Biggs—West Gridley Water District, Butte Water District, and Richvale Irrigation District (applicants) for 50-year incidental take permits under the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.;* Act) from FWS and NMFS. The applicants prepared the Draft Butte Regional Conservation Plan (Draft Plan, or BRCP) pursuant to section 10(a)(1)(B) of the Act and the California Natural Community Conservation Planning Act of 2002 (NCCPA). A twelfth permit will also be considered for the implementing entity that will form prior to permit issuance. The implementing entity is described in the Draft Plan and Draft IA and will be composed of representatives from each of the applicants. The applicants are requesting the authorization of incidental take for 39 covered species that could result from activities covered under the proposed Draft Plan. We announce meetings and invite comments.

Introduction

The Draft Plan is a comprehensive, regional habitat conservation plan designed to provide long-term conservation and management of natural communities, sensitive species, and the habitats upon which those species depend, while accommodating other important land uses. The Draft Plan is being submitted as a habitat conservation plan pursuant to the Act, and a natural community conservation plan under the California Natural Community Conservation Planning Act (NCCPA).

FWS will serve as the administrative lead for all actions related to this **Federal Register** notice for the EIS component of the EIS/EIR and receipt of a section 10(a)(1)(B) permit for species under FWS's jurisdiction. NMFS will serve as the administrative lead for all actions related to this **Federal Register** notice for receipt of a section 10(a)(1)(B) permit for species under NMFS's jurisdiction. BCAG will serve as the State lead agency under the California Environmental Quality Act (CEQA) for the EIR component. BCAG, in accordance with the CEQA, is publishing a similar notice.

In addition to this notice of the draft EIR/EIS, EPA is publishing a notice announcing the draft EIS, as required under section 309 of the Clean Air Act (42 U.S.C. 7401 *et seq.*). The publication of EPA's notice is the official start of the minimum requirement for a public comment period for an EIS (see EPA's Role in the EIS Process).

Background Information

Section 9 of the Act (16 U.S.C. 1531–1544 *et seq.*) and Federal regulations (50 CFR part 17) prohibit the taking of fish and wildlife species listed as endangered or threatened under section 4 of the Act. Take of federally listed fish or wildlife is defined under the Act as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed species, or attempt to engage in such conduct. The term ''harass'' is defined in the regulations as to carry out actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3). The term ''harm'' is defined in the regulations as significant habitat modification or degradation that results in death or injury of listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). However, under specified circumstances, the Service may issue permits that allow the take of federally listed species, provided that the take that occurs is incidental to, but not the purpose of, an otherwise lawful activity.

Regulations governing permits for endangered and threatened species are at 50 CFR 17.22 and 17.32, respectively. Section 10(a)(1)(B) of the Act contains provisions for issuing such incidental take permits to non-Federal entities for the take of endangered and threatened species, provided the following criteria are met:

(1) The taking will be incidental;

(2) The applicants will, to the maximum extent practicable, minimize and mitigate the impact of such taking;

(3) The applicants will develop a proposed HCP and ensure that adequate funding for the HCP will be provided;

(4) The taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild; and

(5) The applicants will carry out any other measures that the Service may require as being necessary or appropriate for the purposes of the HCP.

Proposed Project

In 2007, the BRCP Planning Agreement was entered into and by and among the Local Agencies, BCAG, CDFG, the Service and NMFS. In 2010, Western Canal Water District, Biggs West Gridley Water District, Butte Water District, Richvale Irrigation District and Caltrans became signatories to the Planning Agreement. The Planning Agreement set out the initial scope of the program and defined the roles and responsibilities of the parties in the development of the BRCP. The Planning Agreement has helped guide the BRCP planning process and to define the initial scope of the effort. BCAG served

as the lead in coordination of the process and preparation of the BRCP.

The BRCP's conservation strategy proposes to provide a regional approach for the long-term conservation of covered species (see *Covered Species* below) and natural communities within the BRCP plan area while allowing for compatible future land use and development under county and city general plan updates and the regional transportation plans. The BRCP identifies and addresses the covered activities carried out by the permittees that may result in take of covered species within the BRCP plan area.

The proposed BRCP is consistent with and is intended to support compliance with other Federal and State wildlife and related laws and regulations, other local conservation planning efforts, and the city and county general plans. The BRCP was developed in coordination with the development of city and county general plans in the BRCP plan area, with feedback loops between the BRCP and general plan processes. These feedback loops identified opportunities and constraints and allowed for improvements in the general plans regarding the avoidance and minimization of impacts on biological resources and the development of open space and conservation elements that dovetail with the BRCP.

The proposed BRCP is designed to streamline and coordinate existing processes for review and permitting of public and private activities that potentially affect protected species. To meet this goal, the BRCP sets out a conservation strategy that includes measures intended to ensure that impacts on covered species and habitats related to covered activities are avoided, minimized, or mitigated, as appropriate. These covered activities encompass the range of existing and future activities that are associated with much of the regional economy (see Covered Activities, below). The proposed conservation strategy includes establishing a reserve system that would be composed of an estimated 89,600 acres of large, contiguous blocks of land that would be permanently preserved, monitored, and managed, and restoration of an estimated 1,121 acres of covered species' habitat. The conservation strategy would remain in rough step with impacts, and the reserve system would be assembled according to predefined milestones throughout the proposed 50-year permit term.

Plan Area

The BRCP plan area (or permit area) includes approximately 564,270 acres, including the western lowlands and foothills of Butte County. The BRCP Plan Area is bounded on the west by county boundaries with Tehama, Glenn, and Colusa Counties; bounded on the south by boundaries with Sutter and Yuba Counties; bounded on the north by the boundary with Tehama County; and bounded on the east by the upper extent of landscape dominated by oak woodland natural communities. Specifically, the eastern oak woodland boundary is defined by a line below which land cover types dominated by oak trees comprise more than one half of the land cover present, plus a small portion of the City of Chico that extends above the oak zone. The boundary of the BRCP plan area is based on political, ecological, and hydrologic factors.

Covered Activities

The proposed section 10 incidental take permit may allow take of wildlife covered species resulting from covered activities on non-Federal land in the proposed BRCP plan area. BCAG and local partners are requesting incidental take authorization for covered species that could be affected by activities identified in the BRCP. The activities within the BRCP plan area for which incidental take permit coverage is requested include construction and maintenance of facilities and infrastructure, both public and private, that are consistent with local general plans, and local, State, and Federal laws. The following is a summary of covered activities as proposed in the BRCP. Activities are grouped geographically (within urban permit areas, outside urban permit areas, and within the system of conservation lands established in the BRCP) and are further grouped into activities that result in permanent development, and activities involving maintenance of existing or new facilities that are expected to occur over time during the permit duration. This following list is not intended to be exhaustive; rather, it provides an overview of the types of activities that would be expected to occur.

1. Activities within Urban Permit Areas (UPAs) are areas within the BRCP plan area within which the cities and County anticipate urban development under their respective general plan updates.

a. Permanent Development: covered activities within UPAs as a result of new construction and improvements to existing facilities are covered, including the following types of activities: residential, commercial, public facilities, and industrial construction; recreational activity–related construction; transportation facilities construction; pipeline installation; utility services (above and below ground); waste and wastewater management activities; flood control and stormwater management activities; and in-water permanent development projects.

b. Recurring Maintenance: covered activities within UPAs include maintenance of existing and new facilities resulting in temporary impacts, including the following types of activities: recreational activities; transportation facilities maintenance; pipeline maintenance; utility services; waste and wastewater facilities management activities; flood control and stormwater management activities; vegetation management; bridge and drainage structure maintenance; in-water recurring maintenance activities; and irrigation and drainage canal activities (Western Canal Water District, Biggs West Gridley Water District, Butte Water District, and Richvale Irrigation District).

2. Activities Outside UPAs are areas of the County within the BRCP Plan Area and located outside of the UPAs. Covered activities include linear utilities, transportation construction and maintenance projects, and agricultural support services projects. Outside UPAs do not include areas that become part of BRCP conservation lands.

a. Permanent Development: covered activities of outside UPAs include new construction and improvements to existing facilities, including the following types of activities: waste management and wastewater facilities; rerouting of canals (Western Canal Water District, Biggs West Gridley Water District, Butte Water District, and Richvale Irrigation District); transportation facilities construction; BCAG Regional Transportation Plan and Caltrans projects; County rural bridge replacement projects; Butte County rural intersection improvement projects; Butte County rural roadway improvement projects; in-water permanent development projects; and agricultural services.

b. Recurring Maintenance covered activities of outside UPAs include maintenance of existing and new facilities, including the following types of activities: waste and wastewater management activities; irrigation and drainage canal activities (Western Canal Water District, Biggs West Gridley Water District, Butte Water District, and Richvale Irrigation District); transportation facilities maintenance; flood control and stormwater management activities; vegetation management; in-water maintenance activities; and bridge and drainage structure maintenance.

3. Conservation Lands include the system of conservation lands established under the BRCP. It includes conservation actions implemented by the BRCP on conservation lands, including the following types of activities: habitat management; habitat restoration and enhancement; habitat and species monitoring; directed studies; general maintenance of conservation lands and facilities; avoidance and minimization measures; and other species conservation measures.

Covered Species

Covered Species are those species addressed in the proposed BRCP for which conservation actions will be implemented and for which the Applicants will seek incidental take authorizations for a period of up to 50 years. Proposed covered species include threatened and endangered species listed under the Act, species listed under the California Endangered Species Act (CESA), as well as currently unlisted species that have the potential to become listed during the life of the BRCP. The BRCP currently includes 39 listed and non-listed wildlife and plant species.

The following federally listed threatened and endangered wildlife species are proposed to be covered by the BRCP (''NMFS'' indicates those species to be included only on the NMFS permit, and ''FWS'' indicates those species only to be included on the FWS permit): The threatened Central Valley steelhead (*Oncorhynchus mykiss*) (NMFS), endangered Sacramento River winter-run Chinook salmon (*Oncorhynchus tshawytscha*) (NMFS), threatened Central Valley spring-run Chinook salmon (*Oncorhynchus tshawytscha*) (NMFS), threatened green sturgeon (*Acipenser medirostris*) (NMFS), threatened Valley elderberry longhorn beetle (*Desmocerus californicus dimorphus*) (FWS), endangered vernal pool tadpole shrimp (*Lepidurus packardi*) (FWS), endangered conservancy fairy shrimp (*Branchinecta conservatio*) (FWS), threatened vernal pool fairy shrimp (*Branchinecta lynchi*) (FWS), and threatened giant garter snake (*Thamnophis gigas*) (FWS).

The following non-listed wildlife species are proposed to be covered by the BRCP (''NMFS'' indicates those species to be included on the NMFS permit and ''FWS'' indicates those species to be included on the FWS permit): tricolored blackbird (*Agelaius tricolor*) (FWS), yellow-breasted chat (*Icteria virens*) (FWS), bank swallow (*Riparia riparia*) (FWS), Western burrowing owl (*Athene cunicularia hypugaea*) (FWS), western yellow-billed cuckoo (*Coccyzus americanus occidentalis*) (FWS), greater sandhill crane (*Grus canadensis tabida*) (FWS), California black rail (*Laterallus jamaicensis coturniculus*) (FWS), American peregrine falcon (*Falco peregrinus anatum*) (FWS), Swainson's hawk (*Buteo swainsoni*) (FWS), white-tailed kite (*Elanus leucurus*) (FWS), bald eagle (*Haliaeetus leucocephalus*) (FWS), Blainville's horned lizard (*Phrynosoma blainvillii*) (FWS), Western pond turtle (*Actinemys marmorata*) (FWS), foothill yellow-legged frog (*Rana boylii*) (FWS), Western spadefoot toad (*Spea hammondii*) (FWS), and Central Valley fall/late fall-run Chinook salmon (*Oncorhynchus tshawytscha*) (NMFS).

Take of listed plant species is not prohibited on non-Federal land under the Act, and cannot be authorized under a section 10 permit. However, the applicants propose to include plant species in recognition of the conservation benefits provided for them under an HCP. For the purposes of the Plan, certain plant species are further included to meet regulatory obligations under section 7 of the Act and the CESA. All species included on an incidental take permit would receive assurances under FWS's ''No Surprises'' regulations found in 50 CFR 17.22(b)(5) and 17.32(b)(5). The following federally listed plant species are proposed to be included in the BRCP in recognition of the conservation benefits provided for them under the BRCP and the assurances permit holders would receive if they are included on FWS's permit: the threatened Hoover's spurge (*Chamaesyce hooveri*), endangered Butte County meadowfoam (*Limnanthes floccosa* ssp. *californica*), endangered hairy Orcutt grass (*Orcuttia pilosa*), threatened slender Orcutt grass (*Orcuttia tenuis*), and endangered Greene's tuctoria (*Tuctoria greenei*). The following unlisted plant species are also proposed to be included in the BRCP: Ferris' milkvetch (*Astragalus tener* var. *ferrisiae*), lesser saltscale (*Atriplex minuscula*), Ahart's dwarf rush (*Juncus leiospermus* var. *ahartii*), Red Bluff dwarf rush (*Juncus leiospermus* var. *leiospermus*), veiny monardella (*Monardella douglasii* ssp. *venosa*), Ahart's paronychia (*Paronychia ahartii*), California beaked-rush (*Rhynchospora californica*), Butte County checkerbloom (*Sidalcea robusta*), and Butte County golden clover (*Trifolium jokerstii*).

National Environmental Policy Act Compliance

FWS prepared the EIS, with NMFS, Corps, and EPA as cooperating agencies. The EIS is the Federal portion of the Draft EIS/R, to analyze the impacts of issuing incidental take permits based on the Draft Plan. BCAG facilitated the preparation of the EIR portion of the Draft EIS/R, in compliance with the CEQA, but all applicants share the CEQA lead agency role. The California Department of Fish and Wildlife is a CEQA Trustee and Responsible Agency. The Draft EIS/R was developed to inform the public of the proposed action, alternatives, and associated impacts; address public comments received during the scoping period for the Draft EIS/R; and disclose irreversible commitments of resources. The Draft EIS/R was developed to inform the public of the proposed action, alternatives, and associated impacts; address public comments received during the scoping period for the Draft EIS/R; and disclose irreversible commitments of resources.

The proposed permit issuance triggers the need for compliance with NEPA. FWS published a Notice of Intent (NOI) to prepare an EIS/R in the **Federal Register** on December 14, 2012 (77 FR 74500). The NOI announced a public scoping period during which time the public was invited to provide written comments and attend two public scoping meetings, which were held on January 9, 2012, in Oroville and Chico, California.

The Service is now providing notice of the availability of the Draft EIS/R, which evaluates the impacts of the Proposed Action described above (*i.e.,* issuance of the permits and implementation of the Draft Plan), as well as the No-Action Alternative, a Reduced Development/Reduced Fill Alternative, and a Greater Conservation Alternative, which are described below.

No-Action Alternative

Under the No-Action Alternative, FWS and NMFS would not issue incidental take permits to the Applicants, and the Draft Plan would not be implemented. Under this alternative, projects that may adversely affect federally listed species would require project-level consultation with FWS and NMFS pursuant to section 7 or section 10 of the Act. The applicants and others whose ongoing activities or future actions have the potential for incidental take of State-listed species in the plan area would apply for incidental take authorization under CESA through a Section 2081(b) permit. Under the No Action Alternative, there would be no comprehensive means to coordinate and standardize mitigation and compensation requirements of the Act and CESA within the Plan Area. This is

anticipated to result in a more costly, less equitable, less efficient project review process that would reap fewer conservation benefits. Conservation planning and implementation would not happen at a regional scale and, therefore, would not establish a large interconnected system of conservation lands to meet the needs of the species covered by the BRCP.

Reduced Development/Reduced Fill Alternative

Under the Reduced Development/Reduced Fill Alternative, the reduced development alternatives described in the applicants' general plan EIRs were combined to create a single reduced development/reduced fill footprint. Under the applicant's general plan alternatives, there would be either a reduction in the development footprint for the respective jurisdictions such that the development would be concentrated closer to urban centers or a reduction in the total dwelling units and commercial/industrial square footage such that less development would occur. Covered activities under this alternative would be similar to those described in the BRCP but would be limited to the reduced-development footprint and to a permit term of 30 years. The conservation strategy would be similar to that of the BRCP because it would apply similar natural community acreage limitations. This alternative would also reduce impacts on waters of the United States by reducing the potential impacts on jurisdictional waters, including wetlands, by reducing the amount of overall development anticipated to occur within the Plan Area and by applying the acreage limitations to jurisdictional waters as described in the BRCP. This also includes reduced dredge or fill of jurisdictional waters of the United States, including wetlands, by reducing or eliminating the types of covered activities identified in the BRCP associated with bridges and transportation projects. However, though the conservation measures (and any activities undertaken by the water districts or irrigation districts) would be the same as under the proposed action, there would be an overall reduced amount and extent of conserved lands under this alternative because less development would occur over a shorter time period.

Greater Conservation Alternative

The Greater Conservation Alternative would increase the target amount of certain natural community types to be conserved under the conservation strategy. This alternative would maintain the same Plan Area, covered species, covered activities, and conservation measures as the Proposed Action Alternative, but would modify the proposed conservation strategy to increase conservation of two land cover types: grasslands and rice. The increase in these land cover types, as compared to the Proposed Action, is expected to provide additional habitat for certain covered species (*e.g.,* Swainson's hawk, white-tailed kite, and giant garter snake). This alternative would increase grasslands conserved by 9,850 acres (an approximately 20 percent increase) and increase rice conservation by 35,310 acres (an approximately 90 percent increase) as compared to the proposed action. The Greater Conservation Alternative would result in approximately 51,955 and up to 78,140 total acres of grasslands and rice conservation, respectively.

EPA's Role in the EIS Process

The EPA is charged under section 309 of the Clean Air Act to review all Federal agencies' EISs and to comment on the adequacy and the acceptability of the environmental impacts of proposed actions in the EISs.

EPA also serves as the repository (EIS database) for EISs prepared by Federal agencies and provides notice of their availability in the **Federal Register**. The EIS database provides information about EISs prepared by Federal agencies, as well as EPA's comments concerning the EISs. All EISs are filed with EPA, which publishes a notice of availability on Fridays in the **Federal Register**.

For more information, see *http://www.epa.gov/compliance/nepa/eisdata.html.* You may search for EPA comments on EISs, along with EISs themselves, at *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

Public Comments

We request data, comments, new information, or suggestions from the public, other concerned governmental agencies, the scientific community, Tribes, industry, or any other interested party on this notice, the Draft EIS/R. and Draft Plan. We particularly seek comments on the following:

1. Biological information concerning the species;

2. Relevant data concerning the species;

3. Additional information concerning the range, distribution, population size, and population trends of the species;

4. Current or planned activities in the subject area and their possible impacts on the species;

5. The presence of archeological sites, buildings and structures, historic events, sacred and traditional areas, and other historic preservation concerns, which are required to be considered in project planning by the National Historic Preservation Act; and

6. Identification of any other environmental issues that should be considered with regard to the proposed development and permit action.

You may submit your comments and materials by one of the methods listed in the **ADDRESSES** section. Comments and materials we receive will be available for public inspection by appointment, during normal business hours (Monday through Friday, 8 a.m. to 4:30 p.m.) at the Service's Sacramento address (see **ADDRESSES**).

Public Availability of Comments

Before including your address, phone number, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—might be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Next Steps

This notice is provided under section 10(a) of the Act and FWS regulations for implementing the National Environmental Policy Act of 1969 (40 CFR 1506.6). We will evaluate the applications, associated documents, and comments submitted thereon to prepare a Final EIS/R. Permit decisions will be made no sooner than 30 days after the publication of the NOA of for the Final EIS/R and completion of the Record of Decision.

Authority

We publish this notice under the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321–4347 *et seq.;* NEPA), and its implementing regulations in the Code of Federal Regulations (CFR) at 40 CFR parts 1500–1508, as well as in compliance with section 10(c) of the Endangered Species Act (16 U.S.C. 1531–1544 *et seq.;* Act).

Dated: November 6, 2015.

Alexandra Pitts,

Deputy Regional Director, Pacific Southwest Region, U.S. Fish and Wildlife Service, Sacramento, California.

Dated: November 6, 2015.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–29447 Filed 11–17–15; 8:45 am]

BILLING CODE 4333–15–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Computer Cables, Chargers, Adapters, Peripheral Devices and Packaging Containing the Same, DN 3100;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Belkin International, Inc. on November 12, 2015. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain computer cables, chargers, adapters, peripheral devices and packaging containing the same. The complaint names as respondents Dongguan Pinte Electronic Co., Ltd. of China and Dongguan Shijie Fresh Electronic Products Factory of China. The complainant requests that the Commission issue a general exclusion order and a cease and desist order.

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3100'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures.[4]) Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[5]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Dated: November 12, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–29453 Filed 11–17–15; 8:45 am]

BILLING CODE 7020–02–P

[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

[5] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (15–105)]

Notice of Intent To Grant Exclusive License

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of intent to grant exclusive license.

SUMMARY: This notice is issued in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i). NASA hereby gives notice of its intent to grant an exclusive license in the United States to practice the invention described and claimed in Patent entitled ''Thermal Insulating Coating'', US Patent Number 6,939,610, Case Number MFS–31593–1 to PrimeBilec Investments, LLC, having its principal place of business in Austin, Texas. The patent rights in this invention have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. NASA has not yet made a determination to grant the requested license and may deny the requested license even if no objections are submitted within the comment period.

DATES: The prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, NASA receives written objections including evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7. Competing applications completed and received by NASA within fifteen (15) days of the date of this published notice will also be treated as objections to the grant of the contemplated exclusive license.

Objections submitted in response to this notice will not be made available to the public for inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

ADDRESSES: Objections relating to the prospective license may be submitted to Mr. James J. McGroary, Chief Patent Counsel, Marshall Space Flight Center, LS01, Huntsville, AL 35812, (256) 544–0013.

FOR FURTHER INFORMATION CONTACT: Mr. Sammy Nabors, Technology Transfer Office, Marshall Space Flight Center, ZP30, Huntsville, AL 35812, (256) 544–5226.

Information about other NASA inventions available for licensing can be found online at *http://technology.nasa.gov.*

Mark P. Dvorscak,

Agency Counsel for Intellectual Property.

[FR Doc. 2015–29422 Filed 11–17–15; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2016–003]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide agencies with mandatory instructions for what to do with records when agencies no longer need them for current Government business. The instructions authorize agencies to preserve records of continuing value in the National Archives of the United States and to destroy, after a specified period, records lacking administrative, legal, research, or other value. NARA publishes notice in the **Federal Register** for records schedules in which agencies propose to destroy records not previously authorized for disposal or to reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: NARA must receive requests for copies in writing by December 18, 2015. Once NARA appraises the records, we will send you a copy of the schedule you requested. We usually prepare appraisal memoranda that contain additional information concerning the records covered by a proposed schedule. You may also request these. If you do, we will also provide them once we have completed the appraisal. You have 30 days after we send you these requested documents in which to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting Records Management Services (ACNR) using one of the following means:

Mail: NARA (ACNR); 8601 Adelphi Road; College Park, MD 20740–6001.

Email: request.schedule@nara.gov.

FAX: 301–837–3698.

You must cite the control number, which appears in parentheses after the name of the agency that submitted the schedule, and a mailing address. If you would like an appraisal report, please include that in your request.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, by mail at Records Management Services (ACNR); National Archives and Records Administration; 8601 Adelphi Road; College Park, MD 20740–6001, by phone at 301–837–1799, or by email at *request.schedule@nara.gov.*

SUPPLEMENTARY INFORMATION: Each year, Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. These schedules provide for timely transfer into the National Archives of historically valuable records and authorize disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media-neutral unless otherwise specified. An item in a schedule is media-neutral when an agency may apply the disposition instructions to records regardless of the medium in which it has created or maintains the records. Items included in schedules submitted to NARA on or after December 17, 2007, are media-neutral unless the item is specifically limited to a specific medium. (See 36 CFR 1225.12(e).)

No agencies may destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value.

In addition to identifying the Federal agencies and any subdivisions

requesting disposition authority, lists the organizational unit(s) accumulating the records or lists that the schedule has agency-wide applicability (in the case of schedules that cover records that may be accumulated throughout an agency); provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction); and includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it also includes information about the records. You may request additional information about the disposition process at the addresses above.

Schedules Pending

1. Department of Agriculture, Farm Service Agency (DAA–0145–2015–0003, 2 items, 1 temporary item). County reports on foreign investment in U.S. farmland. Proposed for permanent retention are the central office reports.

2. Department of Agriculture, Farm Service Agency (DAA–0145–2015–0019, 7 items, 1 temporary item). Copies of aerial photographs of domestic farmland. Proposed for permanent retention are records related to aerial photography of domestic farmland, including original negative film, indexes, digital images, and film reports.

3. Department of the Interior, National Park Service (DAA–0079–2016–0001, 18 items, 4 temporary items). Records of the Valles Caldera National Trust, including routine and uncaptioned photographs, records on geothermal wells, and Web site content and management records. Proposed for permanent retention are organizational history files, board of trustees records, annual and other reports, executive director files, newsletters and news releases, still photographs, records relating to public meetings, publications, land use records, cartographic records, and blueprints.

4. Department of State, Bureau of Diplomatic Security (DAA–0059–2015–0009, 1 item, 1 temporary item). Records include copies of memorandums, internal instructions, and briefing materials.

5. Federal Communications Commission, Wireline Competition Bureau (DAA–0173–2016–0002, 1 item, 1 temporary item). Records include applications for equipment certification and registration.

6. Office of Personnel Management, Agency-wide (DAA–0478–2015–0003, 1 item, 1 temporary item). Records relating to insider threat program inquiry case files including complaints, investigations, and reports.

7. Peace Corps, Office of Strategic Partnerships (DAA–0490–2014–0003, 4 items, 2 temporary items). Records include routine administrative files and working papers. Proposed for permanent retention are partnership agreements and annual progress reports.

8. Securities and Exchange Commission, Division of Corporation Finance (DAA–0266–2016–0001, 1 item, 1 temporary item). Records related to the submission and processing of requests by businesses for confidential handling of certain proprietary business or financial information.

9. Securities and Exchange Commission, Office of the Chair (DAA–0266–2014–0011, 3 items, 1 temporary item). Copies of the Chair's correspondence. Proposed for permanent retention are records of the Chair including correspondence, subject files, itineraries, briefing books, speeches, and documentation of the strategies, decisions, and actions of the Chair.

10. Securities and Exchange Commission, Office of the General Counsel (DAA–0266–2015–0004, 6 items, 3 temporary items). Records include legal opinions, working files, and records of routine cases. Proposed for permanent retention are legal opinions provided to the Chair or the Commissioners, records of major cases, and records of Commission participation in reorganization proceedings under the Bankruptcy Act.

Dated: November 4, 2015.

Laurence Brewer,

Director, National Records Management Program.

[FR Doc. 2015–29436 Filed 11–17–15; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–609; NRC–2013–0235]

Northwest Medical Isotopes, LLC

AGENCY: Nuclear Regulatory Commission.

ACTION: Intent to conduct scoping process and prepare an environmental impact statement; public meeting and request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will conduct a scoping process to gather the information necessary to prepare an environmental impact statement (EIS) to evaluate the environmental impacts for construction, operation, and decommissioning of the proposed Northwest Medical Isotopes, LLC (NWMI) radioisotope production facility. The NRC is seeking stakeholder input on this action and has scheduled a public meeting.

DATES: Submit comments by January 4, 2016. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0235. 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.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Nancy Martinez, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2719; email: *Nancy.Martinez@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2013–0235 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2013–0235.
- 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 environmental report (ER) is available in ADAMS under Accession Nos. ML15086A265, ML15086A268, ML15086A269, ML15086A270, and ML15086A271, respectively.

- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2013–0235 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion

On November 7, 2014, NWMI filed with the NRC, pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), a portion (part one) of an application for a construction permit for a medical radioisotope production facility at the Discovery Ridge Research Park in Columbia, Missouri. By letter dated February 5, 2015 (ADAMS Accession No. ML15086A262), NWMI withdrew and resubmitted this portion of their construction permit application (ADAMS Accession No. ML15086A261) to include a discussion of connected actions in their ER in response to a letter from the NRC (ADAMS Accession No. ML14349A501). A separate notice of receipt and availability for part one of the application was published in the **Federal Register** on April 21, 2015 (80 FR 22227). A notice of acceptance for docketing for part one of the application was published in the **Federal Register** on June 8, 2015 (80 FR 32418).

By letter dated July 20, 2015 (ADAMS Accession No. ML15210A182), NMWI submitted part two of the construction permit application which includes the Integrated Safety Analysis Summary and the remaining sections of the construction permit application as required by 10 CFR 50.34(a). A separate notice of receipt and availability for part 2 of the application and a separate notice of acceptance for docketing of part 2 of the application will be published in the **Federal Register.**

An exemption from certain requirements of 10 CFR 2.101(a)(5) was granted by the Commission on October 7, 2013 (ADAMS Accession No. ML13238A333), in response to a letter from NWMI dated August 9, 2013 (ADAMS Accession No. ML13227A295), allowing for NWMI to submit its construction permit application in two parts.

III. Request for Comments

This notice informs the public of the NRC's intention to prepare an EIS related to the review of the construction permit application and to provide the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR 51.29.

The regulations in 36 CFR 800.8, ''Coordination with the National Environmental Policy Act,'' allows agencies to use their National Environmental Policy Act of 1969 (NEPA) process to fulfill the requirements of Section 106 of the National Historic Preservation Act (NHPA). Therefore, pursuant to 36 CFR 800.8(c), the NRC intends to use its process and documentation for the preparation of the EIS on the proposed action to comply with Section 106 of the NHPA in lieu of the procedures set forth at 36 CFR 800.3 through 36 CFR 800.6.

The NRC intends to gather the information necessary to prepare an EIS to evaluate the environmental impacts for construction, operation, and decommissioning of the proposed NWMI radioisotope production facility. The proposed construction will include space for 10 CFR part 70 operational activities. Possible alternatives to the proposed action (construction and operation of the proposed NWMI facility) include no action, alternative sites, and alternative technologies to produce radioisotopes. This notice is being published in accordance with NEPA and the NRC's regulations found at 10 CFR part 51.

The NRC will first conduct a scoping process for the EIS and, as soon as practicable thereafter, will prepare a draft EIS for public comment. Participation in the scoping process by members of the public and local, State, Tribal, and Federal government agencies is encouraged. The scoping process for the EIS will be used to accomplish the following:

a. Define the proposed action, which is to be the subject of the EIS;

b. Determine the scope of the EIS and identify the significant issues to be analyzed in depth;

c. Identify and eliminate from detailed study those issues that are peripheral or that are not significant;

d. Identify any environmental assessments and other ElSs that are being or will be prepared that are related to, but are not part of, the scope of the EIS being considered;

e. Identify other environmental review and consultation requirements related to the proposed action;

f. Indicate the relationship between the timing of the preparation of the environmental analyses and the Commission's tentative planning and decision-making schedule;

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation, and schedules for completing the EIS to the NRC and any cooperating agencies; and

h. Describe how the EIS will be prepared and include any contractor assistance to be used. The NRC invites the following entities to participate in scoping:

a. The applicant, NWMI;

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or that is authorized to develop and enforce relevant environmental standards;

c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards;

d. Any affected Indian tribe;

e. Any person who requests or has requested an opportunity to participate in the scoping process; and

f. Any person who has petitioned or intends to petition for leave to intervene.

IV. Public Meeting

In accordance with 10 CFR 51.26, the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to a proposed activity and to determine the

scope of issues to be addressed in an EIS. The NRC has decided to hold a public meeting for the NWMI environmental review on December 8, 2015. The meeting will begin with an open house from 5 p.m. until 6 p.m., followed by an NRC presentation and opportunity to hear public comments from 6 p.m. until 8 p.m., as necessary. The public meeting will be at the Holiday Inn Columbia-East, 915 Port Way, Columbia, MO 65201.

The meeting will be transcribed and will include: (1) An overview by the NRC staff of the NEPA environmental review process, the proposed scope of the EIS, and the proposed review schedule; and (2) the opportunity for interested government agencies, organizations, and individuals to submit comments or suggestions on the environmental issues or the proposed scope of the EIS. Additionally, the NRC staff will host informal discussions during the open house one hour prior to the start of each session at the same location. No formal comments on the proposed scope of the EIS will be accepted during the informal discussions. To be considered, comments must be provided either at the transcribed public meeting or in writing, as discussed in the **ADDRESSES** section of this notice.

Persons may register to attend or present oral comments at the meeting on the scope of the NEPA review by contacting the NRC Environmental Project Manager, Nancy Martinez, by telephone at 800–368–5642, ext. 2719, or by email at *Nancy.Martinez@nrc.gov,* no later than December 1, 2015. Members of the public may also register to speak at the meeting within 15 minutes of the start of the meeting. Individual oral comments may be limited by the time available, depending on the number of persons who register. Members of the public who have not registered may also have an opportunity to speak if time permits. Public comments will be considered in the scoping process for the EIS. Please contact Nancy Martinez no later than December 1, 2015, if accommodations or special equipment are needed to attend or present information at the public meeting so that the NRC staff can determine whether the request can be accommodated.

Participation in the scoping process for the EIS does not entitle participants to become parties to the proceeding to which the EIS relates. Matters related to participation in any hearing are outside the scope of matters to be discussed at this public meeting. The notice of acceptance for docketing of the application and a description of the hearing process will be published separately in the **Federal Register**.

Dated at Rockville, Maryland, this 12th day of November, 2015. For the Nuclear Regulatory Commission.

David J. Wrona,

Chief, Environmental Review and Guidance Update Branch, Division of License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–29425 Filed 11–17–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0033]

Information Collection: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** (FR) on October 26, 2015, regarding the submission to the Office of Management and Budget (OMB) of a request to renew an existing collection of information entitled, ''Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.'' This action is necessary to correct information about the number of respondents to this information collection.

DATES: The correction is effective November 18, 2015.

ADDRESSES: Submit comments directly to the OMB reviewer at: Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150–0214) NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–7315, email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Tremaine Donnell, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION: In the FR on October 26, 2015, in FR Doc. 2015–27063, on page 65254, in the third column, number 8, correct ''1,500 (300 NRC Licensees + 1,200 Agreement State Licensees)'' to read ''6,000 (300 NRC Licensees + 1,200 Agreement State Licensees + 4,500 individuals making a personal history disclosure as part of an application for an unescorted access authorization).''

Dated at Rockville, Maryland, this 12th day of November 2015.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–29353 Filed 11–17–15; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2016–19; Order No. 2812]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 19, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

On November 10, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, November 10, 2015 (Notice).

II. Notice of Commission Action

The Commission establishes Docket No. CP2016–19 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than November 19, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2016–19 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than November 19, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2015–29399 Filed 11–17–15; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2016–18; Order No. 2811]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 19, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

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

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I. Introduction

On November 10, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).[1]

To support its Notice, the Postal Service filed a copy of the Agreement, a redacted copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket No. CP2016–18 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than November 19, 2015. The public portions of the filing can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Curtis E. Kidd to serve as Public Representative in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2016–18 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Curtis E. Kidd is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than November 19, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

[1] Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, November 10, 2015 (Notice).

By the Commission.

Stacy L. Ruble,

Secretary.

[FR Doc. 2015–29398 Filed 11–17–15; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76430; File No. SR–FINRA–2015–029]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Order Instituting Proceedings To Determine Whether To Approve or Disapprove Proposed Rule Change To Adopt FINRA Rule 3210 (Accounts at Other Broker-Dealers and Financial Institutions), as Modified by Partial Amendment No. 1, in the Consolidated FINRA Rulebook

November 12, 2015.

I. Introduction

On July 31, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt a new, consolidated rule addressing accounts opened or established by associated persons of members at firms other than the firm with which they are associated.

The proposed rule change was published for comment in the **Federal Register** on August 14, 2015.[3] On September 22, 2015, FINRA extended the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to November 12, 2015. The Commission received four comment letters in response to the proposed rule change.[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Rel. No. 75655 (Aug. 10, 2015), 80 FR 48941 (Aug. 14, 2015) (File No. SR–FINRA–2015–029) (''Notice'').

[4] *See* Letters from Eric Arnold and Clifford Kirsch, Sutherland Asbill & Brennan LLP (for the Committee of Annuity Insurers), dated September 4, 2015 (''Sutherland Letter''); Michael J. Hogan, President and Chief Executive Officer, FOLIO*fn* Investments, Inc., dated September 4, 2015 (''FOLIO*fn* Letter''); Joseph C. Peiffer, President, Public Investors Arbitration Bar Association (''PIABA''), dated September 3, 2015 (''PIABA Letter''); and Kevin Zambrowicz, Associate General Counsel & Managing Director, and Stephen Vogt, Assistant Vice President & Assistant General Counsel, Securities Industry and Financial Markets

On November 10, 2015, FINRA responded to the comments and filed Partial Amendment No. 1 to the proposal.[5] The Commission is publishing this order to solicit comments on Partial Amendment No. 1 from interested persons and to institute proceedings pursuant to Exchange Act Section 19(b)(2)(B)[6] to determine whether to approve or disapprove the proposed rule change, as modified by Partial Amendment No. 1.

Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to the proposed rule change, nor does it mean that the Commission will ultimately disapprove the proposed rule change. Rather, as discussed below, the Commission seeks additional input on the proposed rule change, as modified by Partial Amendment No. 1, and issues presented by the proposal.

II. Description of the Proposed Rule Change[7]

As part of the process of developing a new consolidated rulebook (''Consolidated FINRA Rulebook''),[8] FINRA is proposing to adopt new FINRA Rule 3210 (Accounts at Other Broker-Dealers and Financial Institutions) in the Consolidated FINRA Rulebook, and to delete NASD Rule 3050, Incorporated New York Stock Exchange (''NYSE'') Rules 407 and 407A, and Incorporated NYSE Rule Interpretations 407/01 and 407/02.[9]

A. Current NASD Rule 3050

Current NASD Rule 3050 provides a means to inform member firms about transactions effected by their associated persons in accounts established outside the firm. This information gives members an opportunity to weigh the effect these accounts may have on the firm and its customers.[10] The rule imposes specified obligations on member firms and associated persons, including:

- *Obligations of Member Firms:* NASD Rule 3050(a) requires that a member (called an ''executing member'') that knowingly executes a transaction for the purchase or sale of a security for the account of a person associated with another member (called an ''employer member''), or for any account over which the associated person has discretionary authority, must use reasonable diligence to determine that the execution of the transaction will not adversely affect the interests of the employer member. NASD Rule 3050(b) requires that, when an executing member knows that a person associated with an employer member has or will have a financial interest in, or discretionary authority over, any existing or proposed account carried by the executing member, the executing member must:

(1) Notify the employer member in writing, prior to the execution of a transaction for the account, of the executing member's intention to open or maintain that account;

(2) upon written request by the employer member, transmit duplicate copies of confirmations, statements, or other information with respect to the account; and

(3) notify the person associated with the employer member of the executing member's intention to provide the notice and information required by (1) and (2), above.

- *Obligations of Associated Persons:* Associated persons who: (1) Open securities accounts or place securities orders through (a) a member firm other than their employer, or (b) other financial institution that is not a FINRA member, and (2) have a financial interest in, or discretionary authority over, such accounts or orders[11] must comply with the following:

(1) NASD Rule 3050(c) requires that a person associated with a member, prior to opening an account or placing an initial order for the purchase or sale of securities with another member, must notify both the employer member and the executing member, in writing, of his or her association with the other member. The rule also provides that if the account was established prior to the person's association with the employer member, the person must notify both members in writing promptly after becoming associated; and

(2) NASD Rule 3050(d) provides that if the associated person opens a securities account or places an order for the purchase or sale of securities with a broker-dealer that is registered pursuant to Exchange Act Section 15(b)(11) (a notice-registered broker-dealer), a domestic or foreign investment adviser, bank, or other financial institution (*i.e.,* firms that are not FINRA members), then he or she must: (i) Notify his or her employer member in writing, prior to the execution of any initial transactions, of the intention to open the account or place the order; and (ii) upon written request by the employer member, request in writing and assure that the notice-registered broker-dealer, investment adviser, bank, or other financial institution provides the employer member with duplicate copies of confirmations, statements, or other information concerning the account or order. NASD Rule 3050(d) also provides that if an account subject to Rule 3050(d) was established prior to the person's association with the member, the person must comply with the rule promptly after becoming associated.

In addition, NASD Rule 3050(f) provides that the requirements of Rule 3050 do not apply to transactions in unit investment trusts and variable contracts or redeemable securities of companies registered under the Investment Company Act of 1940 (''Investment Company Act''), or to accounts which are limited to transactions in such securities.

B. Current NYSE Rules 407 and 407A

The purpose of NYSE Rule 407 is similar to the purpose of FINRA Rule 3050—to provide member firms information about transactions effected by their associated persons in accounts established outside their firm. According to FINRA, the NYSE and NASD rules are similar with some variations, including:

- NYSE Rule 407(a) is similar to NASD Rule 3050(b), except that Rule 407(a) requires that an executing member receive an employer member's prior written consent before: (1) Opening a securities or commodities account, or (2) executing any transaction in which a member or employee associated with another member or member organization is directly or indirectly interested. The rule also requires that duplicate confirmations and account statements be sent promptly to the employer.
- NYSE Rule 407(b) is similar to NASD Rules 3050(c) and (d), except that Rule 407(b) generally requires that associated persons who: (1) Establish or maintain a securities or commodities account, or enter into a securities transaction at (a) another member firm, or (b) a domestic or foreign non-member

Association, dated September 3, 2015 (''SIFMA Letter'').

[5] *See* Letter from Patrice Gliniecki, Senior Vice President and Deputy General Counsel, FINRA, to the Commission, dated November 10, 2015 (''FINRA Response Letter''). The FINRA Response Letter and the text of Partial Amendment No. 1 are available on FINRA's Web site at *http://www.finra.org*, at the principal office of FINRA, and at the Commission's Public Reference Room.

[6] 15 U.S.C. 78s(b)(2)(B).

[7] The proposed rule change, as described in this Item II, is excerpted, in part, from the Notice, which was substantially prepared by FINRA. *See supra* note 3.

[8] The current FINRA rulebook consists of: (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE (''Incorporated NYSE Rules''). *See supra* note 3.

[9] For convenience, the Incorporated NYSE Rules are referred to as the ''NYSE Rules.''

[10] *See* Exchange Act Release No. 4924 (Aug. 21, 1953); *see also supra* note 3.

[11] *See* NASD Rule 3050(e).

broker-dealer, investment adviser, bank, or other financial institution,[12] and (2) have a financial interest in, or discretionary authority over, such accounts or transactions must obtain the employer firm's prior written consent. The rule also requires that persons having accounts or effecting transactions as covered by the rule must arrange for duplicate confirmations and statements (or their equivalents) to be sent to the employer firm. The rule further requires that all such accounts and transactions must periodically be reviewed by the employer member.

• NYSE Rule 407.12 is similar to NASD Rule 3050(f), except that Rule 407.12 excepts the specified transactions and accounts (*i.e.*, transactions in unit investment trusts and variable contracts or redeemable securities of companies registered under the Investment Company Act, or to accounts which are limited to transactions in such securities, or to monthly investment plan type accounts) only from the obligation to send duplicate confirmations and statements unless requested by the employer.

In addition, NYSE Rule 407A (Disclosure of All Member Accounts) requires members to promptly report to the NYSE any securities account (including accounts at a member or non-member broker-dealer, investment adviser, bank or other financial institution), in which the member has a financial interest or the power to make investment decisions. NYSE Rule 407A also requires a member having such an account to notify the financial institution that carries or services the account that it is a member of the NYSE. In addition, the rule requires that members report to the NYSE when any such securities account is closed. FINRA states that ''[t]hese reporting requirements were designed to provide the NYSE with current information about where floor members carry securities accounts.'' [13]

NYSE Rule Interpretation 407/01 addresses the process for determining whether the account of a spouse of an associated person should be subject to NYSE Rule 407.

NYSE Rule Interpretation 407/02 provides that NYSE Rule 407(b) applies when an associated person is also a majority stockholder of a non-public corporation that wishes to open a discretionary margin account at another member.

C. Proposed New FINRA Rule 3210 [14]

Proposed FINRA Rule 3210(a) would require an associated person to obtain his or her employer firm's prior written consent before opening or otherwise establishing an account in which securities transactions can be effected and in which the associated person has a beneficial interest at a member other than the employer member (*i.e.*, executing member), or at any other financial institution.[15] Proposed FINRA Rule 3210.02 would deem the associated person to have a beneficial interest in any account that is held by: (a) The spouse of the associated person; (b) a child of the associated person or of the associated person's spouse, provided that the child resides in the same household as or is financially dependent upon the associated person; (c) any other related individual over whose account the associated person has control; or (d) any other individual over whose account the associated person has control and to whose financial support the associated person materially contributes. Notably, the proposal would ''[eliminate] the language in the current rules that references accounts or transactions where the associated person has 'the power, directly or indirectly, to make investment decisions,' as set forth in NYSE Rule 407(b), and accounts where the associated person has 'discretionary authority,' as set forth in NASD Rule 3050(b).'' [16]

Proposed FINRA Rule 3210(b) would require an associated person to provide written notice to the executing member, or other financial institution, of his or her association with the employer member prior to opening or otherwise establishing an account subject to the rule.

Proposed FINRA Rule 3210(c) would require an executing member, upon written request by the employer member, to transmit duplicate copies of confirmations and statements, or the transactional data contained therein, with respect to an account subject to the rule.

Proposed FINRA Rule 3210.01 would require an associated person to obtain the written consent of the employer member, within 30 calendar days of becoming so associated, to maintain an account that was opened or otherwise established prior to the person's association with the employer member. The proposed rule also would require the associated person to notify in writing the executing member or other financial institution of his or her association with the employer member.

Proposed FINRA Rule 3210.03 states that proposed FINRA Rule 3210(c) (discussed above) would not apply to transactions in unit investment trusts, municipal fund securities as defined under MSRB Rule D–12, qualified tuition programs pursuant to Section 529 of the Internal Revenue Code, and variable contracts or redeemable securities of companies registered under the Investment Company Act, as amended, or to accounts that are limited to transactions in such securities, or to monthly investment plan type accounts.

Proposed FINRA Rule 3210.04 would require an employer member to consider the extent to which it will be able to obtain, upon written request, duplicate copies of confirmations and statements, or the transactional data contained therein, directly from the non-member financial institution in determining whether to provide its written consent to an associated person to open or maintain an account subject to the rule at a financial institution other than a member.

D. Partial Amendment No. 1

In its amendment, FINRA is proposing to amend proposed FINRA Rule 3210.03 to exclude from the requirements of FINRA Rule 3210 transactions in unit investment trusts, municipal fund securities as defined under MSRB Rule D–12, qualified tuition programs pursuant to Section 529 of the Internal Revenue Code, and variable contracts or redeemable securities of companies registered under the Investment Company Act, as amended, or to accounts that are limited to transactions in such securities, or to monthly investment plan type accounts.

This proposed amendment would establish a rebuttable presumption that an associated person has a beneficial interest in an account held by an individual listed in proposed Rule 3210.02(a)–(d). Specifically, the proposal would state that for purposes of Rule 3210, an associated person would be presumed (not deemed) to have a beneficial interest in any account that is held by an individual listed in Rule 3210.02(a)–(d). Further, the amendment to proposed Rule 3210.02(a) would require that in order for an

[12] NYSE Rule 407.13 states that, for purposes of the rule, the term ''other financial institution'' includes, but is not limited to, insurance companies, trust companies, credit unions, and investment companies.

[13] *See supra* note 3.

[14] The description in this section describes the proposed rules change prior to the proposed amendments, which are described below.

[15] Based on NYSE Rule 407.13 and NASD Rule 3050(d), proposed FINRA Rule 3210.05 provides that the terms ''other financial institution'' and ''financial institution other than a member'' include, but are not limited to, any broker-dealer that is registered pursuant to Exchange Act Section 15(b)(11), domestic or foreign non-member broker-dealer, investment adviser, bank, insurance company, trust company, credit union, and investment company.

[16] *See supra* note 3.

associated person to be presumed to have a beneficial interest in an account held by his or her spouse, the spouse must ''[reside] in the same household as the associated person.'' Moreover, amendment to proposed FINRA Rule 3210.02 would state that an associated person could overcome the presumption of beneficial interest in an account by ''[demonstrating], to the satisfaction of the employer member, that the associated person derives no economic benefit from the account.''

The text of the proposed rule change, as amended, is available, at the principal office of FINRA, on FINRA's Web site at *http://www.finra.org*, and at the Commission's Public Reference Room. In addition, you may also find a more detailed description of the original proposed rule change in the Notice.[17]

III. Summary of Comments

As noted above, the Commission received four comment letters on the proposed rule change. Two commenters generally expressed support for FINRA's proposal.[18] The other two commenters did not support the proposed rule.[19] All four commenters recommended amendments to the proposal. FINRA also responded to the comments.

A. Receipt of Duplicate Confirmations and Account Statements

One commenter stated that despite specifying that an employing firm is ''responsible for supervising its broker's trading activities,'' the proposal only requires an executing member to provide duplicate account documents (with respect to an account subject to the rule) upon written request by the employer member.[20] This commenter recommended that FINRA amend the proposal to require the employing firm to obtain these confirmations and statements from the executing firm so that the employing firm has sufficient information available for its supervisory personnel to monitor associated persons' outside trading activity.[21]

Similarly, this commenter stated its view that the proposed requirement for an employing firm to consider the extent to which it would be able to obtain duplicate account documents in determining whether to consent to an associated person opening or maintaining an account with a non-member financial institution would be ineffective.[22] This commenter recommended that FINRA amend the rule to require that duplicate copies of monthly statements and confirmations or the equivalent be available for the employing firm's review as a precondition to the opening of outside accounts.[23]

In its response, FINRA stated that the proposed requirement to transmit duplicate account documents ''upon written request'' by the employer member is intended to provide employer members reasonable flexibility to craft appropriate supervisory policies and procedures according to their business model and the risk profile of their activities.[24] Similarly, FINRA stated that with respect to accounts at non-member institutions the approach reflected in the proposal rule should permit employer members the flexibility they need to carry out their supervisory responsibilities under FINRA rules.[25] FINRA believes that specifying preconditions for such accounts would negate the flexibility the rule aims to achieve.[26]

Accordingly, FINRA declined to make the suggested changes.

B. Non-Member Accounts

One commenter stated its view that in trying to provide FINRA members greater flexibility in determining whether to consent to an associated person opening or maintaining an account at non-member financial institutions, the proposal focuses too much on only one element of the analysis (*i.e.*, duplicate statements).[27] This commenter believes that the proposal would be made easier to implement from a supervisory and operational standpoint if FINRA uses ''principles based'' language in Proposed FINRA Rule 3210.04.[28] Accordingly, the commenter recommended that FINRA amend the proposal to provide that if a firm decides to permit accounts of its associated persons to be opened and maintained at an outside institution, the firm must, at a minimum, determine that the account activity can be properly monitored pursuant to the requirements of Rule 3110(d).[29]

In its response, FINRA stated that the proposal is sufficient to imply, in light of the supervisory obligations that apply to all members, that members will consider whether activity in the account can be properly monitored when determining whether to provide their written consent to an associated person to open or maintain an account at a non-member financial institution.[30] In addition, FINRA reminded its members that the rule in no way lessens the breadth and scope of members' supervisory obligations.[31] Accordingly, FINRA declined to make the suggested changes.

C. Discretionary Accounts

One commenter recommended that FINRA maintain the requirement that brokers obtain prior written consent from their employing firm before opening discretionary accounts for customers at other firms.[32] The commenter believes that knowledge of the opening of these types of accounts allows employing members to take appropriate steps to supervise outside trading activity.[33]

In its response, FINRA stated that the proposal is designed to demarcate more clearly the respective scope of FINRA Rule 3210, which is meant to address monitoring of personal and related accounts, versus FINRA Rule 3280, which addresses private securities transactions.[34] Specifically, FINRA stated that to the extent associated persons make investment decisions or have discretionary authority in contexts that involve private securities transactions within the scope of FINRA Rule 3280, then such transactions are subject to that rule's provisions.[35] Accordingly, FINRA declined to make the suggested change.

D. Accessing Transactional Data

Two commenters expressed concern that the proposed rule change would limit the methods that an employer firm could use to receive and, consequently, access transactional data.[36] One commenter stated its view that by requiring transactional data to be ''transmitted'' to the employer firm, FINRA unintentionally restricts the various ways by which employer firms can have access to the transactional data.[37] Accordingly, this commenter recommended that FINRA amend the proposal to leave it up to the executing firm to decide, in considering its business model and technical sophistication, how to best make

[17] *See supra* note 3.
[18] *See* SIFMA Letter and FOLIO*fn* Letter.
[19] *See* PIABA Letter and Sutherland Letter.
[20] *See* PIABA Letter.
[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] *See* FINRA Response Letter.
[25] *Id.*
[26] *Id.*
[27] *See* SIFMA Letter.
[28] *Id.*
[29] *Id.*
[30] *See* FINRA Response Letter.
[31] *Id.*
[32] *See* PIABA Letter.
[33] *Id.*
[34] *See* FINRA Response Letter.
[35] *Id.*
[36] *See* FOLIOfn Letter and SIFMA Letter.
[37] *See* FOLIOfn Letter.

available the information.[38] Similarly, the other commenter recommended that FINRA amend the proposal to state that an employing member may satisfy its obligations under the proposal by receiving transactional data through automated means, such as electronic data feeds, in lieu of receiving hardcopy or imaged confirmations and statements.[39]

In its response, FINRA stated that it did not intend to specify any particular methodology as to transmission of the specified information.[40] FINRA also stated that it believes that the proposed rule change is sufficiently broad by its terms to permit members all reasonable flexibility as to the manner of obtaining and reviewing the specified information, whether by hard copy or electronic means.[41] Accordingly, FINRA declined to make the suggested changes.

E. Definition of ''Beneficial Interest''

Two commenters recommended that FINRA amend proposed Rule 3210.02 to revise the proposed definition of ''beneficial interest.'' [42] One commenter stated its view that presuming beneficial interest in any account held by the spouse of an associated person (and other familial relationships) is overly broad.[43] Instead, the commenter recommended that FINRA amend the proposed definition to apply only when and if an associated person has control over an account.[44]

Similarly, the other commenter stated its view that including all spousal accounts in the list of accounts in which an associated person is deemed to have a beneficial interest is overly broad and costly.[45] In particular, the commenter stated that it is not uncommon for spouses to maintain completely separate financial lives.[46] Accordingly, the commenter suggested that FINRA amend the definition of beneficial interest to apply to the spouse of the associated person, provided that the spouse resides in the same household as the associated person and that the associated person has control over such account.[47]

In its response, FINRA stated that it is aware of the potential difficulties that could arise with respect to spouse accounts as proposed in the original filing.[48] Accordingly, FINRA proposes in Partial Amendment No. 1 to amend to proposed Rule 3210.02 to: (1) State that for purposes of Rule 3210, an associated person would be presumed (not deemed) to have a beneficial interest in any account that is held by an individual listed in Rule 3210.02(a)–(d); (2) require that in order for an associated person to be presumed to have a beneficial interest in an account held by his or her spouse, the spouse must ''[reside] in the same household as the associated person;'' and (3) state that an associated person could overcome the presumption of beneficial interest in an account by ''[demonstrating], to the satisfaction of the employer member, that the associated person derives no economic benefit from the account.'' FINRA believes that these changes would address commenters' concerns regarding the potential issues that could be posed by different family circumstances.[49] In addition, FINRA believes that where a spouse resides with the associated person, it serves a legitimate purpose that there should be a presumption that the spouse's accounts are subject to the rule, regardless of whether the associated person exercises control.[50] However, FINRA also believes that the proposed rebuttable presumption would afford adequate flexibility for employer members to exclude accounts that pose little or no supervisory risk.[51]

F. Application of the Proposed Rule

1. Prospective Application

One commenter argued that proposed Rules 3210(a) (the consent requirement) and 3210(b) (the notice requirement) should not apply to accounts already opened by associated persons with executing members before the proposed rule's compliance date.[52] The commenter requested that FINRA confirm that these requirements would only apply to associated persons who open accounts after the compliance date.[53]

In response, FINRA clarified in Partial Amendment No. 1 that proposed Rules 3210(a) and 3210(b) would apply to accounts that an associated person opens or otherwise establishes on or after the proposed new rule's implementation date.[54] FINRA also stated, however, that if the associated person has an existing account prior to his or her association with an employer member, proposed FINRA Rule 3210.01 would apply, without regard to when the account was opened, whenever the associated person enters into a new association with a member.[55]

2. 30-Day Notice for Existing Accounts

One commenter argued that requiring an employing firm to consent to accounts established by an associated person prior to his or her association with the firm within 30-day (pursuant to proposed FINRA Rule 3210.01) might raise operational, supervisory, and related challenges.[56] Accordingly, the commenter recommended that FINRA amend the rule to require that within 30 calendar days of becoming so associated, the associated person shall notify in writing the executing member or other financial institution of his or her association with the employer member and seek written consent of the employer member to maintain the account.[57]

In its response, FINRA disagreed with the commenter and stated that it believes that employer members should be able to make a determination within the 30-day period.[58] Accordingly, FINRA declined to make the suggested change.

G. Exemptions for Certain Account Transactions

1. Exemption From Providing Transaction Data

One commenter recommended that FINRA amend proposed Rule 3210.03 to exempt transactions in all insurance contracts that are securities from the requirement that an executing member must provide the employing member with duplicate account confirmations and statements. The commenter argued that all insurance contracts that are securities are substantially similar to ''variable contracts'' that would be exempted under proposed Rule 3210.03, and therefore also pose limited risk with respect to the need to oversee associated persons accounts.[59]

In its response, FINRA stated that the original proposal added to the exemption products that are clearly identifiable and bear similarity to and are consistent with the rationale underlying the other products set forth in the rule.[60] FINRA also stated, however, that it is not prepared at this time to broadly except insurance

[38] *Id.*
[39] *See* SIFMA Letter.
[40] *See* FINRA Response Letter.
[41] *Id.*
[42] *See* FOLIOfn Letter and SIFMA Letter.
[43] *See* FOLIOfn Letter.
[44] *Id.*
[45] *See* SIFMA Letter.
[46] *Id.*
[47] *Id.*
[48] *See* FINRA Response Letter.
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] *See* Sutherland Letter.
[53] *Id.*
[54] *See* FINRA Response Letter.
[55] *Id.*
[56] *See* SIFMA Letter.
[57] *Id.*
[58] *See* FINRA Response Letter.
[59] *See* Sutherland Letter.
[60] *See* FINRA Response Letter.

products from the rule's requirements, but will consider whether further exceptions are appropriate based on the attributes of specific insurance products.[61] Accordingly, FINRA declined to make the suggested change.

2. Exemption From the Notice and Consent Requirements

Two commenters recommended that FINRA also exempt certain transactions (*i.e.,* transactions in unit investment trusts, municipal fund securities, 529 Plans, variable contracts, or mutual fund shares) from the requirement that an associated person must notify the executing member and obtain the prior written consent of the employer member before opening an account.[62] One of these commenters noted that current NASD Rule 3050 provides a complete exemption from all provisions of the rule for the exempted transactions and believes that adoption of the structure under NASD Rule 3050 would more closely track the policy determinations articulated under the proposed rule change and creates less regulatory burden on firms.[63] Similarly, the other commenter reasoned that: (1) Employees have no ability to engage in insider trading or other manipulative practices through these accounts or types of products; (2) firms will incur significant operational and supervisory costs associated with this new requirement without any appreciable investor protection benefits; and (3) not excluding these types of transactions and accounts from the entire rule will have a negative impact on firms' ability to design, implement, and maintain a reasonably designed, risk-based compliance system because firms will be required to direct limited compliance resources to processing notice requests for accounts and transactions that represent little, if any, risk of insider trading or other violative conduct.[64]

In its response, FINRA stated its goal that members not be burdened with information collection where the specified transactions and account types pose limited risk from the standpoint of the rule's supervisory purposes.[65] Accordingly, FINRA proposes in Partial Amendment No. 1 to amend Supplementary Material .03 to provide that the specified transactions and accounts shall not be subject to the requirements of proposed FINRA Rule 3210.[66]

[61] *Id.*

[62] *See* Sutherland Letter and SIFMA Letter.

[63] *See* Sutherland Letter.

[64] *See* SIFMA Letter.

[65] *See* FINRA Response Letter.

[66] *Id.*

H. Consistency With MSRB Rule G–28

One commenter recommended that, since both FINRA and the Municipal Securities Rulemaking Board (''MSRB'') have rules governing employee transactions, FINRA and the MSRB should work together to develop a uniform standard for the industry.[67]

In its response letter, FINRA stated that it believes that the comment is outside the scope of the proposed rule change.[68]

IV. Proceedings to Determine Whether to Approve or Disapprove SR–FINRA–2015–029 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Exchange Act Section 19(b)(2)(B) to determine whether the proposed rule change should be approved or disapproved.[69] Institution of proceedings appears appropriate at this time in view of the legal and policy issues raised by the proposal. As noted above, institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, the Commission seeks and encourages interested persons to comment on the issues presented by the proposed rule change and provide the Commission with arguments to support the Commission's analysis as to whether to approve or disapprove the proposal.

Pursuant to Exchange Act Section 19(b)(2)(B),[70] the Commission is providing notice of the grounds for disapproval under consideration. In particular, Exchange Act Section 15A(b)(6)[71] requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

The Commission believes FINRA's proposed rule change raises questions as to whether it is consistent with the requirements of Exchange Act Sections 15A(b)(6).

[67] *See* SIFMA Letter.

[68] *See* FINRA Response Letter.

[69] 15 U.S.C. 78s(b)(2). Exchange Act Section 19(b)(2)(B) provides that proceedings to determine whether to disapprove a proposed rule change must be concluded within 180 days of the date of publication of notice of the filing of the proposed rule change. The time for conclusion of the proceedings may be extended for up to an additional 60 days if the Commission finds good cause for such extension and publishes its reasons for so finding or if the self-regulatory organization consents to the extension.

[70] 15 U.S.C. 78s(b)(2)(B).

[71] 15 U.S.C. 78*o*–3(b)(6).

V. Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues raised by the proposed rule change, as modified by Partial Amendment No. 1. In particular, the Commission invites the written views of interested persons on whether the proposed rule change, as modified by Partial Amendment No. 1, is inconsistent with Section 15A(b)(6), or any other provision, of the Exchange Act, or the rules and regulations thereunder.

Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b-4, any request for an opportunity to make an oral presentation.[72]

Interested persons are invited to submit written data, views, and arguments by December 9, 2015 concerning whether the proposed rule change should be approved or disapproved. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by January 4, 2016. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2015–029 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2015–029. 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

[72] Exchange Act Section 19(b)(2), as amended by the Securities Acts Amendments of 1975, Pub. L. 94–29, 89 Stat. 97 (1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

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 principle office of FINRA. 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 publicly available. All submissions should refer to File Number SR–FINRA–2015–029 and should be submitted on or before December 9, 2015. If comments are received, any rebuttal comments should be submitted by January 4, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[73]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29394 Filed 11–17–15; 8:45 am]

BILLING CODE 8011–01–P

[73] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76428; File No. SR–NYSEMKT–2015–93]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Discontinue the NYSE MKT Realtime Reference Price Market Data Product Offering

November 12, 2015.

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 October 30, 2015, 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, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to discontinue the NYSE MKT Realtime Reference Price (''NYSE MKT RRP'') market data product offering. The text of 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

In 2009, the Securities and Exchange Commission (''Commission'') approved the NYSE MKT RRP market data product and certain fees for it.[4] The NYSE MKT RRP market data product provides, on a real-time basis, last sale prices in all securities that trade on the Exchange. Currently, there are no subscribers to the NYSE MKT RRP market data product. Therefore, the Exchange has determined to discontinue the NYSE MKT RRP market data product. The Exchange also proposes to update the Fee Schedule to remove reference to the NYSE MKT RRP in connection with this change.

The Exchange will announce the date that the NYSE MKT RRP will be decommissioned via an NYSE Market Data Notice.

[4] *See* Securities Exchange Act Release No. 61144 (December 10, 2009), 74 FR 67275 (December 18, 2009) (SR–NYSEMKT–2009–85).

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) [5] of the Act, in general, and furthers the objectives of Section 6(b)(5) [6] of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and it is not designed to permit unfair discrimination among customers, brokers, or dealers.

The Exchange believes that discontinuing NYSE MKT RRP and removing it from the Fee Schedule would remove impediments to and perfect a free and open market by streamlining the Exchange's market data product offerings to include those for which there has been more demand and would provide vendors and subscribers with a simpler and more standardized suite of market data products. The proposal to discontinue NYSE MKT RRP is applicable to all members, issuers and other persons and does not unfairly discriminate between customers, issuers, brokers or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to consumers of such data. It was believed that this authority would expand the amount of data available to users and consumers of such data and also spur innovation and competition for the provision of market data. The Commission concluded that Regulation NMS—by lessening regulation of the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[7]

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005) (File No. S7–10–04).

The Exchange believes that the discontinuation of a market data product for which there is little or no demand, as is the case with NYSE MKT RRP, is a direct example of efficiency because it acknowledges that investors and the public have indicated that they have little or no use for certain information and allows the Exchange to dedicate resources to developing products (including through innovations of existing products and entirely new products) that provide information for which there is more of an expressed need.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[8] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange notes that it operates in a highly competitive market in which other exchanges are free to offer similar products. Additionally, since there has been little or no demand for the NYSE MKT RRP product the Exchange's proposed discontinuance will not harm competition.

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 foregoing proposed rule 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 if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission,[9] 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]

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)[12] of the Act to determine whether the proposed rule change should be approved or disapproved.

A proposed rule change filed under Rule 19b–4(f)(6)[13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[14] 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 because it believes that immediate operation of this filing would not impact any users of NYSE MKT RRP. The Commission, noting that there are currently no subscribers to these data services, finds that it is consistent with the protection of investors and the public interest to waive the 30-day operative date and to permit the proposal to be operative upon filing.[15]

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–2015–93 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–2015–93. 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 will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* 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–2015–93 and should be submitted on or before December 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29392 Filed 11–17–15; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b)(8).

[9] The Exchange has fulfilled this requirement.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Commission will host the SEC Government-Business Forum on Small Business Capital Formation on Thursday, November 19, 2015, beginning at 9:00 a.m., in the auditorium of the Commission's headquarters at 100 F Street NE., Washington, DC. The forum will be open to the public and webcast on the

SEC's Web site. Doors will open at 8:15 a.m. Visitors will be subject to security checks.

The forum will include remarks by SEC Commissioners and panel discussions that Commissioners may attend. Panel topics will include exempt and registered offerings occurring after the passage of the JOBS Act.

Commissioner Stein, as duty officer, voted to consider the SEC Government-Business Forum on Small Business Capital Formation in open session, and determined that Commission business required consideration earlier than one week from today. No earlier notice of this Meeting was practicable.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information, please contact the Office of the Secretary at (202) 551–5400.

Dated: November 13, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–29502 Filed 11–16–15; 2:00 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold an Open Meeting on Wednesday, November 18, 2015 at 3:00 p.m., in the Auditorium, Room L–002.

The subject matter of the Open Meeting will be:

• The Commission will consider whether to propose amendments to Rule 3a1–1 and Regulation ATS and new Form ATS–N under the Securities Exchange Act of 1934 related to certain alternative trading systems.

Commissioner Stein, as duty officer, voted to consider the item listed for the Open Meeting in open session, and determined that Commission business required consideration earlier than one week from today. No earlier notice of this Meeting was practicable.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted, or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: November 13, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–29501 Filed 11–16–15; 2:00 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76431; File No. SR–NYSEArca–2015–104]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To Adopt a New Policy Relating to Trade Reports for Exchange Traded Products

November 12, 2015.

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 October 28, 2015, 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 the Substance of the Proposed Rule Change

The Exchange proposes a new policy relating to its treatment of trade reports for Exchange Traded Products that it determines to be inconsistent with the prevailing market. The text of 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 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

Trades in Exchange Traded Products (''ETP'') [4] occasionally occur at prices that deviate significantly from prevailing market prices and/or an investment fund's underlying value. These trades may be due to brief price dislocations caused, for example, by unusually large orders, momentary reductions in liquidity, or brief trading or pricing errors by individual market participants. The resulting trades may occasionally establish a high, a low or last sale price for a security that does not reflect price discovery in the fund holdings in a manner that is representative of ongoing trading in an ETP tracking the real-time value of the fund's underlying securities, and could impact statistics for the investment fund as computed by third parties in a way that is inappropriately reflective of very short-term market impact rather than ongoing fund performance, leading to investor confusion. For example, trading and quoting in a particular ETF holding a basket of stocks reflecting the S&P 500 index might track that index with de minimis tracking error every minute throughout all trading days for five years, then suddenly trade 1% higher than the S&P 500 index on the close one day due to a large order that was erroneously entered by a single broker-dealer as a ''Market'' order rather than a ''Market on Close'' order, hence trading through multiple price levels in

[4] For purposes of this filing, ETPs include Exchange Traded Funds (ETFs), Exchange Traded Notes (ETNs) and Exchange Traded Vehicles (ETVs). An ETF is an open-ended registered investment company under the Investment Company Act of 1940 that has received certain exemptive relief from the SEC to allow secondary market trading in the ETF shares. ETFs are generally index-based products, in that each ETF holds a portfolio of securities that is intended to provide investment results that, before fees and expenses, generally correspond to the price and yield performance of the underlying benchmark index. An ETV tracks the underlying performance of an asset or index, allowing investors exposure to underlying assets such as futures contracts, commodities and currencies without actually trading futures or taking physical delivery of the underlying asset. An ETV is traded intraday like an ETF. An ETV is an open-ended trust or partnership unit that is registered under the Securities Act of 1933. An ETN is a senior unsecured debt obligation designed to track the total return of an underlying index, benchmark or strategy, minus investor fees. ETNs are registered under the Securities Act of 1933 and are redeemable to the issuer. In 2014, NYSE Arca's listed ETPs had over $1.89 trillion in assets under management (AUM), representing over 90% of all U.S. listed Exchange Traded Products (ETPs). Additional information on ETPs is available on the Exchange's Web site at *https://www.nyse.com/products/etp-funds-etf.*

the book instantaneously rather than creating a disseminated imbalance that would attract normally-priced contra-sided interest in a closing auction. If this trade results in a daily last sale for the ETF that materially differs from the fund's NAV, an investor using a third-party Web site that utilizes trade data to compute tracking error statistics for the ETF could be misled into thinking that the ETF does not provide desired tracking performance to investors over time, when in fact the apparent poor tracking was due only to a single aberrant trade. While such events may occur randomly and on both sides of the market, because tracking error, for example, is measured as a mean squared deviation from NAV, both positive and negative divergence increase tracking error and therefore upside and downside deviations compound, rather than offset, over time.

The Exchange currently has a policy to address such instances of ''aberrant'' trades for equity securities generally.[5] The purpose of this proposed rule change is to adopt an additional policy to address instances of ''aberrant'' trades specific to ETPs traded on the Exchange.

With certain exceptions that are specific to the trading of ETPs, the proposed rule change is identical to the policy previously adopted by the Exchange.[6] The Exchange believes that the derivatively-priced nature of ETPs necessitates the use of a different, and generally broader, set of circumstances to determine that trades are ''aberrant.'' Unlike common stocks, the ''fair value'' and arbitrage pricing bands for an ETP are often known with a reasonably high degree of accuracy, since creation/redemption baskets reflecting actual fund holdings are disclosed daily and are available to be exchanged for new ETP shares, or to be received for redeeming ETP shares, on a daily basis, along with the dissemination of constituent information and intraday pricing information such as Intraday Optimized Portfolio Values (''IOPVs''). As a result, it is often the case that smaller dislocations in ETP trade prices than in stock prices are manifestly not reflective of the trading pattern in the security.

The Consolidated Tape Association (''CTA'') offers each Participant in the CTA Plan the discretion to append an indicator to a trade report to indicate that the market believes that the price of a trade executed on that market does not accurately reflect the prevailing market for the security (an ''Aberrant Report Indicator'').[7] During the course of monitoring by the Exchange or as a result of notification by another market, listed ETP issuer or market participant, the Exchange may become aware of ETP trade prices that do not accurately reflect the prevailing market for an ETP or an investment fund's underlying value. In such a case, the Exchange proposes to apply a new policy pursuant to which it:

(i) May determine to append an Aberrant Report Indicator to any trade report with respect to any ETP trade executed on the Exchange that the Exchange determines to be inconsistent with the prevailing market; and

(ii) Would encourage vendors and other data recipients not to use prices of trades to which the Exchange has appended the Aberrant Trade Indicator in any calculation of the high, low or last sale price of an ETP.

The Exchange would provide to data users an explanation of the parameters used in its aberrant trade policy and urge vendors to disclose the exclusion from high, low or last sale price data of any aberrant trades a vendor chooses to exclude from high, low or last sale price information it disseminates. Upon initial adoption of the Aberrant Report Indicator, the Exchange would also contact all of its listed ETP issuers to explain the aberrant trade policy and inform users of the information that trades appended with an Aberrant Report Indicator are still valid trades and not unwound as in the case of a clearly erroneous trade.[8] In addition, the Exchange would inform an NYSE Arca listed ETP issuer each time the Exchange appends an Aberrant Report Indicator to a trade in such issuer's listed ETP.

While the CTA disseminates its own calculations of high, low and last sale prices, vendors and other data recipients—and not the Exchange—frequently determine their own, different methodology by which they wish to calculate high, low and last sale prices. Therefore, the Exchange would provide to vendors and data recipients an explanation of the parameters used in its aberrant trade policy and the potential deleterious effects that can result from including in the calculations a trade to which the Aberrant Report Indicator has been appended.

In determining whether to append an Aberrant Report Indicator, the proposed Exchange policy would be as follows:

1. Absent exceptional circumstances, the Exchange will determine whether a trade price does not reflect the prevailing market for an ETP if the trade occurs at the greater of a minimum of 50 cents[9] or 50 basis points[10] away from a previous trade or valid ''Reference Price''. The Exchange believes that these are conservative values that are much larger than typical ETF arbitrage bounds, as evidenced for example by bid-ask spreads, and therefore should only be exceeded in cases where it may be appropriate to mark a given trade as aberrant, subject to the further conditions in (2) below. For example, the typical bid-ask spread in the iShares MSCI Emerging Markets ETF (''EEM'') and the Vanguard FTSE Emerging Markets ETF (''VWO''), which each hold many emerging-market stocks that may be lightly traded individually, are both only 3 basis points over the 45 trading days ending September 23, 2015, which included a particularly volatile period of trading.[11] As a result, and based on feedback from ETF issuers, beyond this level the Exchange believes that issuer performance measurements may be adversely impacted in a manner not reflective of long-term fund performance.

The ''Reference Price'' refers to (a) if the primary market for an ETP is open at the time of the trade, the national best bid or offer for the ETP, or (b) if the primary market for an ETP is not open at the time of the trade, the first executable quote or print for the ETP on the primary market after execution of the trade in question. However, if the circumstances suggest that a different Reference Price would be more appropriate, the Exchange will use the different Reference Price. For instance,

[5] *See* Securities Exchange Act Release No. 59937 (May 18, 2009), 74 FR 25291 (May 27, 2009) (SR–NYSEArca–2009–24). The NYSE Arca policy is substantially similar to policies adopted by other markets. *See* Securities Exchange Act Release Nos. 59064 (December 5, 2008), 73 FR 76082 (December 15, 2008) (SR–NYSE–2008–91); and 59151 (December 23, 2008), 74 FR 158 (January 2, 2009) (SR–NASDAQ–2008–100).

[6] *Id.*

[7] The CTA recommends that data recipients should exclude the price of any trade to which the Aberrant Report Indicator has been appended from any calculation of the high, low or last sale prices for the security.

[8] This proposed rule change would not impact a listed ETP issuer's ability to seek cancellation of a transaction on the basis that it was ''clearly erroneous'' under Rule 7.10 (Clearly Erroneous Executions). In the event that a listed ETP issuer files for a transaction to be ''clearly erroneous,'' and the transaction is not cancelled, the Exchange reserves discretion to append an Aberrant Trade Indicator to the trade report to indicate that the market believes that the trade price in a trade executed on that market does not accurately reflect the prevailing market and/or value for an ETP.

[9] As proposed, the 50 cent threshold would be applicable when the trade price or Reference Price is $100 or below.

[10] As proposed, the 50 basis point threshold would be applicable when the trade price or Reference Price is more than $100.

[11] *http://www.etf.com/EEM* and *http://www.etf.com/VWO,* each accessed September 24, 2015.

if the national best bid and offer for an ETP are so wide apart as to fail to reflect the market for an ETP, the Exchange might use as the Reference Price a trade price or best bid or offer that was available prior to the trade in question.

2. If the conditions in (1) above are met, the Exchange will determine whether to append an Aberrant Report Indicator upon consideration of all factors related to a trade, including the following: [12]

- Index changes, reconstitutions and rebalances;
- News released in the market where the ETP's assets are primarily invested;
- Changes in availability of ETP creations and/or redemptions;
- Executions in other derivative instruments tracking the same underlying indices;
- ETP issuer credit risk changes;
- Whether the trade price represents a 52-week high or low for the ETP;
- Whether the trade price reflects a share-split, reorganization or other corporate action;
- System malfunctions or disruptions;
- Validity of consolidated tape trades and quotes;
- General market volatility of market conditions;
- Historical volume and volatility for the ETP;
- Material news released pertaining to the ETP;
- Whether trading in the ETP was recently halted/resumed;
- Trading bands, collars or circuit breakers;
- A request from the ETP issuer, provided with documentation of a factual basis for believing that an execution is representative of market impact or trading issues outside of the issuer's control, rather than true price discovery; and
- Executions otherwise inconsistent with the trading pattern in the ETP.

The Exchange would consider each of these factors with a view towards maintaining a fair and orderly market and the integrity of reported trade data. If the Exchange determines to append the Aberrant Report Indicator to a trade which represented the last sale of that ETP on the Exchange during a trading session, the Exchange may also determine to remove that trade's designation as the last sale. The Exchange may do so either on the day of the trade or at a later date, so as to provide reasonable time for the Exchange to conduct due diligence regarding the trade, including the consideration of input from markets and other market participants.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[13] in general, and furthers the objectives of Section 6(b)(5),[14] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

In particular, the Aberrant Report Indicator is consistent with the protection of investors and the public interest in that the Exchange will seek to ensure a proper understanding of the Aberrant Report Indicator among securities market participants by: (i) Urging vendors to disclose the exclusion from high, low or last sale price data of any aberrant trades excluded from high, low or last sale price information they disseminate and to provide to data users an explanation of the parameters used in the Exchange's aberrant trade policy; (ii) informing the affected listed ETP issuer each time the Exchange appends the Aberrant Report Indicator to a trade in an NYSE Arca listed ETP; and (iii) reminding the users of the information that these are still valid trades in that they were executed and not unwound as in the case of a clearly erroneous trade.

The Exchange believes its proposal to append an Aberrant Report Indicator to certain trades is a reasonable means to alert investors and other market participants that the Exchange believes that the trade price of an ETP executed on its market does not accurately reflect the prevailing market for the ETP.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to adopt a new policy that is similar to an existing policy to alert investors and other market participants that the Exchange believes that the trade price of an ETP executed on its market does not accurately reflect the prevailing market for the ETP.

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

Within 45 days of the date of publication of this notice in the **Federal Register** or such longer time 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:

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–2015–104 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–NYSEArca–2015–104. 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

[12] A majority of the factors listed are identical to factors the Exchange considers in determining whether or not to append an Aberrant Report Indicator to trades in equity securities under the current policy. The Exchange has listed additional factors that it will consider in determining whether or not to append an Aberrant Report Indicator because these factors are specific to trading in ETPs, such as Index change, reconstitutions and rebalances, changes in availability of ETP creations and/or redemptions.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

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–2015–104 and should be submitted on or before December 9, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29395 Filed 11–17–15; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76429; File No. SR–NYSEARCA–2015–109]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Discontinue the NYSE Arca Realtime Reference Price Market Data Product Offering

November 12, 2015.

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 October 30, 2015, 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, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to discontinue the NYSE Arca Realtime Reference Price (''NYSE Arca RRP'') market data product offering. The text of 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

In 2008, the Securities and Exchange Commission (''Commission'') approved the NYSE Arca RRP market data product and certain fees for it.[4] The NYSE Arca RRP market data product provides, on a real-time basis, last sale prices in all securities that trade on the Exchange. Currently, there are no subscribers to the NYSE Arca RRP market data product. Therefore, the Exchange has determined to discontinue the NYSE Arca RRP market data product. The Exchange also proposes to update the Fee Schedule to remove reference to the NYSE Arca RRP in connection with this change.

The Exchange will announce the date that the NYSE Arca RRP will be decommissioned via an NYSE Market Data Notice.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b)[5] of the Act, in general, and furthers the objectives of Section 6(b)(5)[6] of the Act, in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and it is not designed to permit unfair discrimination among customers, brokers, or dealers.

The Exchange believes that discontinuing NYSE Arca RRP and removing it from the Fee Schedule would remove impediments to and perfect a free and open market by streamlining the Exchange's market data product offerings to include those for which there has been more demand and would provide vendors and subscribers with a simpler and more standardized suite of market data products. The proposal to discontinue NYSE Arca RRP is applicable to all members, issuers and other persons and does not unfairly discriminate between customers, issuers, brokers or dealers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to consumers of such data. It was believed that this authority would expand the amount of data available to users and consumers of such data and also spur innovation and competition for the provision of market data. The Commission concluded that Regulation NMS—by lessening regulation of the market in proprietary data—would itself further the Act's goals of facilitating efficiency and competition:

> [E]fficiency is promoted when broker-dealers who do not need the data beyond the prices, sizes, market center identifications of the NBBO and consolidated last sale information are not required to receive (and pay for) such data. The Commission also believes that efficiency is promoted when broker-dealers may choose to receive (and pay for) additional market data based on their own internal analysis of the need for such data.[7]

The Exchange believes that the discontinuation of a market data product for which there is little or no demand, as is the case with NYSE Arca RRP, is a direct example of efficiency because it acknowledges that investors

[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. 58444 (August 29, 2008), 73 FR 51872 (September 5, 2008) (SR–NYSEArca–2008–96).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005) (File No. S7–10–04).

and the public have indicated that they have little or no use for certain information and allows the Exchange to dedicate resources to developing products (including through innovations of existing products and entirely new products) that provide information for which there is more of an expressed need.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[8] the Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange notes that it operates in a highly competitive market in which other exchanges are free to offer similar products. Additionally, since there has been little or no demand for the NYSE Arca RRP product the Exchange's proposed discontinuance will not harm competition.

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 foregoing proposed rule 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 if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission,[9] 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]

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) [12] of the Act to determine whether the proposed rule change should be approved or disapproved.

A proposed rule change filed under Rule 19b–4(f)(6) [13] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[14] 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 because it believes that immediate operation of this filing would not impact any users of NYSE Arca RRP. The Commission, noting that there are currently no subscribers to these data services, finds that it is consistent with the protection of investors and the public interest to waive the 30-day operative date and to permit the proposal to be operative upon filing.[15]

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–2015–109 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–NYSEARCA–2015–109. 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 will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* 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–2015–109 and should be submitted on or before December 9,2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–29393 Filed 11–17–15; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78f(b)(8).

[9] The Exchange has fulfilled this requirement.

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 240.19b–4(f)(6).

[14] 17 CFR 240.19b–4(f)(6)(iii).

[15] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9348]

In the Matter of the Designation of Maghomed Maghomedzakirovich Abdurakhmanov, Also Known as Abu Banat, Also Known as Abu al Banat, as a Specially Designated Global Terrorist Pursuant to Section 1(b) of Executive Order 13224, as Amended

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the individual known as Maghomed Maghomedzakirovich Abdurakhmanov also known as Abu Banat also known as Abu al Banat, committed, or poses a significant risk of committing, acts of

terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that ''prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously,'' I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: October 29, 2015.

John F. Kerry,

Secretary of State.

[FR Doc. 2015–29446 Filed 11–17–15; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–15–64]

Petition for Exemption; Summary of Petition Received; HUVRData, LLC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before December 8, 2015.

ADDRESSES: Send comments identified by docket number FAA–2014–0942 using any of the following methods:

- *Federal eRulemaking 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: 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 *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT: David May (202) 267–4653, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on November 13, 2015.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2014–0942

Petitioner: HUVRData, LLC

Section(s) of 14 CFR Affected: 14 CFR 91.119(c)

Description of Relief Sought: Requesting to allow UAS flights higher than 400 feet above ground level (AGL) as long as the Operator remains within 50 feet of the structure and obtains advanced approval from the FAA prior to any operation involving a structure over 400AGL. The purpose is to conduct aerial imaging for (1) wind farm survey; (2) solar farm survey; (3) inspection of industrial infrastructure including electrical towers, flare stacks and pipelines; and (4) precision agriculture using the AscTec Falcon 8.

[FR Doc. 2015–29419 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty-First Meeting: RTCA Special Committee (225) Rechargeable Lithium Battery and Battery Systems

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of Twenty-First RTCA Special Committee 225 Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Twenty-First RTCA Special Committee 225 meeting.

DATES: The meeting will be held December 8th–10th from 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at NBAA, 1200 G Street NW., Suite 1100, Washington, DC 20005, Tel: (202) 330–0662.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Jennifer Iversen, Program Director, RTCA, Inc., *jiversen@rtca.org*, (202) 330–0662.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA Special Committee 225. The agenda will include the following:

Tuesday, December 8, 2015

1. Introductions and administrative items (including DFO & RTCA Statement) (5 min)
2. Review agenda (1 min)
3. Review and approve summary from the last Plenary (5 min)
4. Review DO–311A recovery plan & establish date for next plenary (10 min)
5. Adjourn to working group
   a. Tasks to accomplish
   i. Allocate requirements/tests based on categories
   ii. Continue reviewing reformatted document
   iii. Define section 2.2 requirements for testing
6. Review Plenary action items (1 min)

Wednesday, December 9, 2015

1. Review agenda, other actions (1 min)
2. Adjourn to working group
3. Review Plenary action items (1 min)

Thursday, December 10, 2015

1. Review agenda, other actions (5 min)
2. Review DO–311A recovery plan (5 min)

3. Establish Agenda for next Plenary (5 min)
4. Adjourn to working group
5. Working Group Report (5 min)
6. Review Plenary action items (1 min)
7. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 10, 2015.

Latasha Robinson,

Management & Program Analyst, Next Generation, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2015–29386 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Third Meeting: RTCA Special Committee (234) Portable Electronic Devices (PEDs) and EUROCAE WG–99 Plenary #6

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of Third RTCA Special Committee 234 Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Third RTCA Special Committee 234 meeting.

DATES: The meeting will be held January 20–22 from 08:30 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC, 20036, Tel: (202) 330–0680.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Karan Hofmann, Program Director, RTCA, Inc., *khofmann@rtca.org,* (202) 330–0680.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA Special Committee 234. The agenda will include the following:

Wednesday, January 20, 2015

1. Welcome and Administrative Remarks
2. Introductions
3. Agenda Review
4. Meeting-Minutes Review
5. Status Report of Task-Group Leaders (TG #1–#4)
   a. TG–1—General Background, Regulations, App, etc
   b. TG–2—Front Door Guidance
   c. TG–3—Back Door Guidance
   d. TG–4—Continuous Airworthiness
6. Review of Completeness of previous WG–99/SC–234 tasks
7. Integration of outcome into Revised ED–130 and new RTCA document structure
8. DO–307 Update
9. Review of program schedule
10. Any other Business
11. Date and Place of Next Meeting
12. Adjourn

Thursday, January 21, 2015

1. Continuation of Plenary or Working Group Session

Friday, January 22, 2015

1. Continuation of Plenary or Working Group Session

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 10, 2015.

Latasha Robinson,

Management & Program Analyst, Next Generation, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2015–29388 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Thirty-Seventh Meeting: RTCA Special Committee (224) Airport Security Access Control Systems

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of Thirty-Seventh RTCA Special Committee 224 meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Thirty-Seventh RTCA Special Committee 224 meeting.

DATES: The meeting will be held December 11th from 10:00 a.m.–3:00 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC 20036, Tel: (202) 330–0680.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Karan Hofmann, Program Director, RTCA, Inc., *khofmann@rtca.org,* (202) 330–0680.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA Special Committee 224. The agenda will include the following:

Friday, December 11, 2015

1. Welcome/Introductions/Administrative Remarks
2. Review/Approve Previous Meeting Summary
3. Report from the TSA
4. Report on Safe Skies on Document Distribution
5. Report on TSA Security Construction Guidelines progress
6. Review of DO–230G Sections
7. Action Items for Next Meeting
8. Time and Place of Next Meeting
9. Any Other Business
10. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 10, 2015.

Latasha Robinson,

Management & Program Analyst, Next Generation, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2015–29389 Filed 11–17–15; 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, and funding capital development for up to 15 current joint-use or former military airports seeking first time designation or redesignation to participate in the MAP.

DATES: Applications must be received on or before January 19, 2016.

ADDRESSES: Submit an original and two copies 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/resources/forms/* along with all supporting and justifying documentation required by this notice. Applicant should specifically request to be considered for designation or redesignation to participate in the fiscal year 2016 MAP. Submission 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. Kendall Ball (*Kendall.Ball@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) 267–7436.

SUPPLEMENTARY INFORMATION:

General Description of the Program

The MAP allows the Secretary to designate current joint-use or former military airports to receive grants from the Airport Improvement Program (AIP). The Secretary is authorized to designate an airport (other than an airport designated before August 24, 1994) only if:

(1) The airport is a former military installation closed or realigned under 10 U.S.C. 2687 (announcement of closures of large Department of Defense installations after September 30, 1977), or under Section 201 or 2905 of the Defense Authorization Amendments and Base Closure and Realignment Acts; or

(2) the airport is a military installation with both military and civil aircraft operations.

The Secretary shall consider for designation only those current joint-use or former military airports, at least partly converted to civilian airports as part of the national air transportation system, that will reduce delays at airports with more than 20,000 hours of annual delays in commercial passenger aircraft takeoffs and landings, or will enhance airport and air traffic control system capacity in metropolitan areas, or reduce current and projected flight delays (49 U.S.C. 47118(c)).

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 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.

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 nine slots available for designation or redesignation in FY 2016. Of the nine slots available there is one GA slot available in FY 2016.

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 of an additional term not to exceed five years. Those airports must meet current eligibility requirements in 49 U.S.C. 47118(a) at the beginning of each grant period and have MAP eligible projects. The FAA will evaluate applications for redesignation primarily in terms of warranted projects fundable only under the MAP as these candidates 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, 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 each fiscal year to construct, improve, and 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 that include hangars, cargo facilities, fuel farms, automobile surface parking, and utility work.

Designation Considerations

In making designations of new candidate airports, the Secretary of Transportation may only designate an airport (other than an airport so designated before August 24, 1994) if it meets the following general requirements:

(1) The airport is a former military installation closed or realigned under:

(A) Section 2687 of title 10;

(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, have the greatest need of funding to convert to, or to incorporate, 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 charter 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 MAP will make the airport a viable civil 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.

Standard Form 424:

Sponsors may obtain this fillable form at: *http://www.faa.gov/airports/resources/forms/*

Applicants should fill this form out 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''.
- In 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 should 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 review and approvals must indicate that the operator or owner of the airport has good title, 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 Capital Improvement Plan (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 should 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 should 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 ALP's 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 civil 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 level 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 9, 2015.

Elliott Black,

Director, Office of Airport Planning and Programming.

[FR Doc. 2015–29385 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Forty-Second Meeting: RTCA Special Committee (206) Aeronautical Information and Meteorological Data Link Services

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: Notice of Forty-Second RTCA Special Committee 206 Meeting.

SUMMARY: The FAA is issuing this notice to advise the public of the Forty-Second RTCA Special Committee 206 meeting.

DATES: The meeting will be held December 7th–11th from 8:30 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC 20036, Tel: (202) 330–0680.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org* or Karan Hofmann, Program Director, RTCA, Inc., *khofmann@rtca.org,* (202) 330–0680.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of RTCA Special Committee 206. The agenda will include the following:

Monday, December 7, 2015

1. Opening Plenary

a. Opening remarks: DFO, RTCA, Chairman, and Hosts

b. Attendees' introductions

c. Review and approval of meeting agenda

d. Approval of previous meeting minutes (Chicago, IL)

e. Action item review

f. Final TOR Changes

g. Sub-Groups' reports (SG1/6: MASPS, SG4: EDR, & SG7: Winds)

h. Industry presentations

i. Aircraft Access to SWIM (AAtS) Technology Transfer Package report, Robert Klein, FAA ANG–B2

2. Sub-Groups Meetings

Tuesday–Thursday, December 8–10, 2015

1. Sub-Groups Meetings

Friday, December 11, 2015

1. Closing Plenary

a. Sub-Groups' reports

b. Future meetings plans and dates

c. Industry coordination

d. SC–206 action item review

e. Other business

2. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Plenary information will be provided upon request. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 10, 2015.

Latasha Robinson,

Management & Program Analyst, Next Generation, Enterprise Support Services Division, Federal Aviation Administration.

[FR Doc. 2015–29387 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Public Teleconference

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee Teleconference.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of a teleconference of the Commercial Space Transportation Advisory Committee (COMSTAC). The Teleconference will take place on Thursday, December 10, 2015, starting at 3:00 p.m. Eastern Standard Time and will last approximately one hour. The agenda and call-in number will be posted at least one week in advance at *http://www.faa.gov/go/ast.*

The proposed agenda for this teleconference is to review findings and recommendations on FAA AST possible engagement with European Space Agency to foster U. S. commercial participation in the refinement and attainment of the lunar village concept.

Interested members of the public may submit relevant written statements for the COMSTAC members to consider under the advisory process. Statements may concern the issues and agenda items mentioned above and/or additional issues that may be relevant for the U.S. commercial space transportation industry. Interested parties wishing to submit written statements should contact Larry Scott, COMSTAC Designated Federal Officer, (the Contact Person listed below) in writing (mail or email) by December 3, 2015, so that the information can be made available to COMSTAC members for their review and consideration before the December 10 teleconference. Written statements should be supplied in the following formats: One hard copy with original signature and/or one electronic copy via email.

An agenda will be posted on the FAA Web site at *www.faa.gov/go/ast.*

Individuals who plan to participate and need special assistance should inform the Contact Persons listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Larry Scott, telephone (202) 267–7982; email *larry.scott@faa.gov,* FAA Office of Commercial Space Transportation (AST–3), 800 Independence Avenue SW., Room 331, Washington, DC 20591.

Complete information regarding COMSTAC is available on the FAA Web

site at: *http://www.faa.gov/about/office_org/headquarters_offices/ast/advisory_committee/.*

Issued in Washington, DC, November 12, 2015

George C. Nield,

Associate Administrator for Commercial Space Transportation.

[FR Doc. 2015–29493 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[Docket No. FTA–2015–0029]

Supplemental Notice and Response to Comments on National Transit Database

AGENCY: Federal Transit Administration, DOT.

ACTION: Request for Comments

SUMMARY: This notice responds to comments on a proposed expansion of the Federal Transit Administration's (FTA) National Transit Database (NTD); requests comments on additional proposed reporting; and requests comments on updating the NTD's approval to collect information under the Paperwork Reduction Act.

DATES: Comments are due by January 19, 2016. FTA will consider late comments to the extent practicable.

ADDRESSES: Please identify your submission by Docket Number (FTA–2015–0029) through one of the following methods:

- *Federal eRulemaking Portal:* Submit electronic comments and other data to *http://www.regulations.gov*.
- *U.S. Mail:* Send comments to Docket Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Room W12–140, 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 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations, U.S. Department of Transportation, at (202) 493–2251.

Instructions: You must include the agency name (Federal Transit Administration) and Docket Number (FTA–2015–0029) for this notice, at the beginning of your comments. If sent by mail, submit two copies of your comments. Due to security procedures in effect since October 2001, mail received through the U.S. Postal Service may be subject to delays. Parties submitting comments should consider using an express mail firm to ensure their prompt filing of any submissions not filed electronically or by hand. If you wish to receive confirmation that FTA received your comments, you must include a self-addressed stamped postcard. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. You may review U.S. DOT's complete Privacy Act Statement published in the **Federal Register** on April 11, 2000, at 65 FR 19477–8 or *http://DocketsInfo.dot.gov*.

Electronic Access and Filing: This document and all comments received may be viewed online through the Federal eRulemaking portal at *http://www.regulations.gov*. Electronic submission and retrieval help and guidelines are available on the Web site. It is available 24 hours each day, 365 days a year. Please follow the instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at *https://www.federalregister.gov*.

FOR FURTHER INFORMATION CONTACT: Maggie Schilling, National Transit Database Deputy Program Manager, FTA Office of Budget and Policy, (202) 366–2054 or *margaret.schilling@dot.gov*.

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A. Background

On August 19, 2014, FTA published a **Federal Register** notice (initial notice) (Docket No. FTA–2014–0006, 79 FR 49146) for comment on proposed revisions to the NTD Reporting Manual. The notice described various proposed changes to the NTD annual module, including a revised capital asset inventory reporting module for urban reporters, which is the subject of this supplemental notice.

The proposed changes to the NTD Reporting Manual stem from amendments to Federal transit law made by the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141, July 6, 2012), which require recipients of Chapter 53 funds to report to the NTD any information relating to a transit asset inventory or condition assessment conducted by the recipient. 59 U.S.C. 5335(c). Currently, the NTD collects asset inventory information on revenue vehicles and summary counts for other asset categories, such as maintenance facilities and fixed guideway. There are some assets, such as signal or communications systems, for which NTD collects no data. In the initial notice, FTA proposed to collect additional asset inventory data to meet the asset inventory and condition reporting requirements at 49 U.S.C. 5335(c).

In the initial notice, FTA proposed that the NTD Asset Inventory Module collect the following data through a recipient's submission of electronic forms:

- Agency Identification. Collects organizational and contact information.
- Administrative and Maintenance Facilities. Collects information on administrative and maintenance facilities used to supply transit service, including facility name, street address, square footage, year built or substantially reconstructed, primary transit mode supported, and estimated replacement cost.
- Passenger and Parking Facilities. Collects information on passenger and passenger parking facilities used in the provision of transit service, including facility name, street address, square footage and number of parking spaces, year built or substantially reconstructed, primary mode, and estimated replacement cost.
- Rail Fixed Guideway. Collects data on linear guideway assets and power and signal equipment, including the length of specific types of guideway and corresponding equipment, reported as network totals by mode and operating agreement. The data includes quantity, expected service years, date of construction or major rehabilitation (within a ten year window), and estimated replacement cost.
- Track. Collects data on track assets, including length and total number of track special work, reported as network totals by rail mode and operating agreement. The data includes expected service years and date of construction or major rehabilitation.
- Service Vehicles. Collects data on service vehicles that support transit service delivery, maintain revenue vehicles, and perform administrative activities. The data includes quantity, expected service life, year of manufacture, and estimated replacement cost.

In the initial notice, FTA proposed that it would begin implementing the proposed reporting requirements beginning with the 2015 NTD reporting cycle (beginning September 2015). FTA proposed granting a waiver for the 2015 NTD reporting cycle and granting waivers on a case-by-case basis for the 2016 NTD reporting cycle.

B. Response to Comments on Expansion of Capital Asset Reporting for Urban Reporters

The comment period for the initial notice closed on October 20, 2014. FTA received 75 comments to its initial notice. This notice includes FTA's responses to eighteen (18) comments related to the NTD Asset Inventory Module. FTA responded previously to the remaining fifty-seven (57) comments in the **Federal Register** notice: Revised NTD Reporting Manual and Response to Comments (80 FR 18699, Apr. 7, 2015). Following is a summary of the comments from the initial notice related to the NTD Asset Inventory Module.

Comment: Six (6) commenters raised a concern over implementing the proposed inventory module prior to the publication of a final Transit Asset Management rule implementing 49 U.S.C. 5326. One commenter stated that ''the proposed expansion of NTD reporting to include asset inventory data is premature. Because the Secretary of Transportation has yet to define ''state of good repair'' or to establish the official performance measure for that condition, relevant asset information cannot be identified at this time.'' Commenters recommended postponing the implementation of the module until after the publication of a final rule. While one (1) commenter did not specifically request postponing the implementation of the module, the commenter expressed concern that this module may conflict with additional requirements of the transit asset management rulemaking.

Response: FTA will implement proposed revisions to the NTD Asset Inventory Module concurrent with effective date of final TAM rule. The reader should be aware, however, that FTA's proposed changes to the NTD Asset Inventory Module in the initial notice were based, primarily, on the authority at 49 U.S.C. 4335(c) that recipients report asset inventory and condition assessment information to the NTD. The proposed changes in the initial notice were not dependant on FTA first defining the term ''state of good repair'' or issuing a final TAM rule. The requirements of the new TAM program, while related to NTD reporting, are separate. The new TAM program requires each recipient of FTA grant funds to develop a Transit Asset Management Plan that includes an inventory of its capital assets and condition assessment of those assets. 49 U.S.C. 5326(a)(2) and (b)(2). The TAM program also includes new requirements for the annual reporting of the condition of a recipient's public transportation system and a recipient's progress towards meeting performance targets. 49 U.S.C. 5326(b) and (c)(3).

Comment: Five (5) commenters expressed that the proposed asset inventory would be too burdensome to implement and that it would be both difficult and costly to put their data into the requested format. One (1) commenter expressed concern that providing the requested replacement cost information for stations would require ''costly engineering studies.'' One (1) commenter stated that it would take effort, but they would be able to provide the data requested within the proposed timeline.

Response: FTA is committed to implementing reasonable data reporting requirements, while also meeting the requirements in the law for reporting asset condition information. FTA believes that the proposed changes to the NTD Asset Inventory Module in the initial notice would strike the appropriate balance in minimizing reporting burden while still allowing for meaningful data analysis on the national capital needs of the transit industry. While FTA recognizes that the proposed changes would result in an increase over the current reporting requirements, the highest burden would exist in the first year of start-up reporting. Once an asset has been entered into the inventory module, the information would be pre-populated for each subsequent year. Reporters only would be responsible for providing annual updates to new or retired asset inventory items in subsequent years.

FTA is also sensitive to commenters' concerns that providing the most accurate replacement cost information may require an engineering study of a facility. FTA further recognizes that accurate replacement cost information may be especially difficult to obtain for historic systems and those systems with a large facility inventory. After additional consideration, FTA has decided to remove the proposed replacement cost reporting requirement to reduce the burden on reporting agencies.

Comment: Five (5) commenters requested a longer implementation timeline or requested that requirements be phased in over time. Two (2) commenters specifically requested that the 2015 implementation phase be eliminated with initial implementation pushed out to 2016.

Response: FTA will implement proposed revisions to the NTD Asset Inventory Module concurrent with effective date of a final TAM rule. However, recipients will have the option to begin reporting the asset inventory data proposed in the initial notice in reporting year 2016 and up until the effective date of a final TAM rule, after which FTA may consider requests for a one-year extension.

Comment: Two (2) commenters stated that the NTD was not the appropriate place to collect asset inventory information. One (1) commenter disagreed with FTA's interpretation of MAP–21 and suggested that maintaining an asset inventory through NTD is redundant and unnecessary and recommended that FTA continue to use sampling to obtain the inventory data needed to estimate the backlog through the Transit Economic Requirements Model (TERM).

Response: MAP–21 amended 49 U.S.C. 5335 (c) (National Transit Database) to require the reporting of ''any information relating to a transit asset inventory or condition assessment conducted by the recipient.'' Accordingly, FTA believes that the NTD is the appropriate place to report this information, and FTA believes that consolidating various reporting requirements together in the NTD would minimize the reporting burden on the industry.

Comment: Three (3) commenters requested technical or layout changes to the module. Two (2) commenters requested an adjustment to the layout of the data collection form, specifically, requesting the addition of cells that would allow them to enter their own vehicle ID information. Additionally, one commenter requested a bulk upload feature be added to the NTD.

Response: FTA will add a 'notes' column to the vehicle inventory module that will allow reporters to enter additional identifying information for vehicles. This information would only be included for the ease of the reporter and would not be used for official identification purposes by FTA.

FTA is in the process of developing a 'bulk upload' feature for the NTD that would allow reporters to enter information into a specified excel spreadsheet format for upload into the NTD. FTA will continue to refine the layout and functionality of the asset inventory module in response to user feedback and testing.

Comment: Four (4) commenters raised concerns regarding asset inventories for

assets owned or maintained by a third party. One commenter stated that third party assets should be differentiated from agency-owned assets. Another commenter expressed concerns about the ability to obtain asset inventory information from third party contractors that may not use those assets exclusively for transit service. Additionally, some commenters stated that private companies have expressed concerns over losing their competitive edge by sharing this data. Another commenter suggested that FTA should only request information on assets which are owned or leased by an agency, as agencies often do not keep records on assets owned or maintained by other entities.

Response: FTA is sensitive to the additional burden of obtaining detailed information on assets owned and operated by a third party, especially any information that may compromise competition amongst private parties providing transit services. Therefore, FTA does not intend to require replacement cost information for third party-owned vehicles. Reporters still would be required to report additional vehicle inventory information on these vehicles.

FTA does not intend to collect detailed asset inventory on a non-dedicated fleet. Reporting requirements for a non-dedicated fleet would remain the same as historic NTD reporting requirements. Reporters may reference these requirements in the NTD Reporting Manual located on the NTD Web site: *www.ntdprogram.gov.* Reporters would be expected to provide information on a ''representative vehicle'' for non-dedicated fleets. Replacement cost information would not be collected for any other asset types. FTA will update the proposed form and reporting manual to clearly reflect these requirements.

Comment: Three (3) commenters stated that FTA should keep asset inventory reporting requirements at a high level. One (1) commenter suggested that the October 2012 TAM Guide should be used as the representative consensus view. Another commenter expressed concern that the NTD requirements ''dismiss the results of FTA's Asset Inventory Module Pilot Program'' and requested clarification on the intent behind collecting this level of detail.

Response: FTA is sensitive to the request to keep the asset inventory data requirements at a high level in order to minimize the burden on reporting agencies. The proposed asset inventory data requirements were informed by FTA's TAM Guide. The TAM Guide is FTA's primary source of guidance on transit asset management. The TAM Guide combines previous research, case studies and lessons learned from other FTA State of Good Repair initiatives, the existing state of the practice in asset management from other fields, and the international asset management standard efforts by the International Standards Organization.

The proposed asset inventory requirements would implement the statutory requirement for inclusion in the NTD of any information related to a transit asset inventory and condition assessment conducted by grant recipients. 49 U.S.C. 5335(c). FTA believes that the proposed asset inventory module balances the requirement for this data with current industry practices and recommendations. FTA believes that the requested level of detail is at the appropriate level for a meaningful analysis of the transit industry's capital liabilities as well as the state of good repair backlog. The data collected through these modules would improve the outputs of TERM and allow for a more detailed discussion of the conditions and performance of the Nation's transit systems in the C&P Report.

Comment: One (1) commenter cautioned that standardized data across all modes may not be appropriate, specifically stating that ferry boats are not equipped with an odometer and therefore cannot provide an odometer reading as requested.

Response: FTA understands that not all transit vehicles are equipped with an odometer or hubometer. For the purpose of reporting in this form, the mileage for a mode that is not equipped with this type of equipment could be reported as an annual estimate using a defensible methodology. FTA will update the manual to clearly reflect this change.

Comment: One (1) commenter requested clarity on whether or not there will be a requirement to report on ''support'' vehicles.

Response: Form A–60 in the proposed NTD Asset Inventory Module tracks non-revenue service vehicles. This would be the appropriate place for a reporter to include information on support vehicles such as police cars, vehicles driven by service supervisors or maintenance personnel, etc.

Comment: One commenter requested flexibility in setting a minimum threshold for asset inclusion. Specifically, they felt that items less than $10K should not be included.

Response: FTA developed the proposed inventory categories and reporting requirements to keep information at a high level and does not anticipate that the proposed inventory categories would include assets that are valued below $10,000.

Comment: One (1) commenter expressed concern that square footage requirements may not correlate to replacement costs and may be difficult to obtain from legacy system records. They recommended removing the square footage requirement.

Response: While FTA recognizes that square footage alone may not directly correlate with the replacement cost of a facility in all cases, it believes that the connection between facility square footage and replacement cost is strong enough to justify the collection of this information. Moreover, FTA is no longer proposing to collect estimated replacement cost information directly, in the interests of minimizing reporting burden. As such, collecting square footage is the least-burdensome way for FTA to have any basis of estimating replacement cost, and by extension, of estimating the state of good repair backlog.

Comment: One (1) commenter suggested changes to the fixed guideway and track forms including: Limiting the classifications for guideway; consolidating the power substation building and equipment into one category; and ''using the term 'interlocking plant' along with grade crossings to describe special work and eliminate the other categories.''

Response: FTA believes that limiting the data as the commenter recommends would not properly account for the variety of operating climates and infrastructure represented in the NTD. At this time, FTA believes the proposed categories would allow for a meaningful analysis without presenting an undue reporting burden.

Comment: One (1) commenter identified an issue with the ownership structure of their passenger stations and the proposed asset inventory reporting instructions. Many of their stations are owned by the cities where the stations are located and the proposed changes in the initial notice suggests that the cities would be required to report these stations or else they would go unreported.

Response: FTA intends to request a transit agency to provide basic inventory information for all stations used in the provision of service. Station location information would be reported for all stations, However, size and financial information would be required only if the transit agency has full or partial capital responsibility for the station.

Comment: Two (2) commenters noted that the proposed categories do not mirror the F–20 (use of capital funds) form and suggested that these categories should remain consistent.

Response: FTA acknowledges that the proposed categories in the initial notice are different than those in the F–20 form. The F–20 form is intended to align with the standard cost categories used by FTA to report the expenditure of grant monies. The proposed inventory was organized according to the four capital asset categories identified in MAP–21: Equipment, rolling stock, infrastructure, and facilities; and is intended to meet MAP–21 requirements and capture information on capital assets to inform state of good repair needs and trends across the industry. FTA does not believe that the two forms need to be organized in the same manner.

C. Additional Proposed Changes to Capital Asset Inventory Data

1. Urban Reporters

In its initial notice, FTA proposed that the NTD Asset Inventory Module collect the following facility-related data through a recipient's submission of electronic forms:

- Administrative and Maintenance Facilities. Information on administrative and maintenance facilities used to supply transit service, including facility name, street address, square footage, year built or substantially reconstructed, primary transit mode supported, and estimated replacement cost.
- Passenger and Parking Facilities. Collects information on passenger and passenger parking facilities used in the provision of transit service, including facility name, street address, square footage and number of parking spaces, year built or substantially reconstructed, primary mode, and replacement cost.

In addition to the information listed above, through this notice, FTA is proposing to require that an urban recipient also report on the condition of its facilities using the TERM 1 (poor) to 5 (excellent) scale. As indicated in FTA's response to comments, it will not collect replacement cost data as initially proposed. FTA seeks comment on its proposal to require reporting of facility condition data. The proposed forms can be viewed at *http://www.ntdprogram.gov/ntdprogram/assetInventory.htm.*

2. Capital Asset Reporting for 5310 and 5311 Recipients

Through this notice, FTA is proposing reduced asset inventory reporting requirements for providers that exclusively receive 5310 or 5311 funds. The proposed vehicle inventory form for 5310 recipients mirrors the current rural vehicle inventory module. Reporters would be required to provide information on their vehicle type, length, seating capacity, year of manufacture and funding source. The proposed forms can be viewed at *http://www.ntdprogram.gov/ntdprogram/assetInventory.htm.*

Recipients of 5311 funds would continue to report vehicle inventory data for their subrecipients as they have in the past; however, FTA proposes that 5311 recipients provide additional detail on their facilities. The proposed facility inventory requirements for 5311 recipients mirror those proposed for urban reporters above (see description above). Reporters would be required to provide expanded information on administrative and maintenance facilities used to supply transit service. For each facility, the facility name, street address, square footage, year built or substantially reconstructed, primary transit mode supported, and asset condition rating (ranked on a 5-point scale in keeping with the Transit Economic Requirements Model).

To the extent that 5311 recipients have passenger and parking facilities, they would also be responsible for providing information for each facility, including: The facility's name, street address, square footage and number of parking spaces, year built or substantially reconstructed, primary mode, and asset condition rating.

To simplify reporting, the system would retain data from the previous year's report. Only new assets, retired assets, and refurbished assets would need to be reported after the first year. Condition assessments for all facilities, including administrative and maintenance buildings as well as passenger stations and parking structures, would be updated at least once every three years.

FTA seeks comments on its proposed reporting requirements for recipients of 5310 and 5311 funds.

3. Proposed Performance Measures and Targets Data

Pursuant to the requirements of 49 U.S.C. 5326(c), FTA intends to collect performance metrics and targets in the NTD. Subsequent to publication of a final TAM rule, FTA is proposing that all recipients would be required to report annually on their targets and progress for the following:

- Equipment-Service Vehicles. The proposed performance measure for non-revenue, support and maintenance vehicles is the percentage of vehicles that have met or exceeded their useful life benchmark (ULB). To determine the ULB, a Transit Provider may either use the default ULB established by FTA or a ULB, established by the Transit Provider in consideration of local conditions and usage and approved by FTA. The NTD system would calculate annual performance based on the manufacturer's age information that is entered into the vehicle inventory. FTA does not currently collect the age of manufacture for service vehicles. FTA is proposing that this information be collected as part of the expanded capital asset inventory. Reporters would be required to provide one target for the percentage of classification of non-revenue vehicle that have met or exceeded their useful life benchmark for each service vehicle category.
- Rolling Stock. The proposed performance measure for rolling stock is the percentage of revenue vehicles within a particular asset class that have either met or exceeded their useful life benchmark (ULB). To determine the ULB, a recipient may either use the default ULB established by FTA or a ULB established by the recipient in consideration of local conditions and usage and approved by FTA. FTA currently collects the year of manufacture for revenue vehicles. FTA is proposing that recipients report one target and useful life benchmark for each revenue vehicle classification. The NTD system would calculate annual performance based on the date of manufacture information entered into the vehicle inventory.
- Rail-fixed Guideway Infrastructure (track, signals, and systems). The proposed performance measure for rail-fixed guideway infrastructure is the percentage of track segments, signals, and systems with performance restrictions. FTA is proposing that recipients report a target and performance of this metric for each mode. FTA will provide additional technical assistance and guidance on how to measure a performance restriction.
- Facilities. The proposed performance measure for facilities is the percentage of all facilities rated below condition 3 on the condition scale used by FTA's Transit Economic Requirements Model (TERM). FTA is proposing that the condition rating for each facility be reported through the capital asset reporting. The system would automatically calculate performance based on these reports. Reporters would also be required to provide an annual target for each facility type. FTA will provide additional technical assistance and guidance on to

measure a facility condition rating on the TERM scale.

FTA seeks comment on its proposal to require recipients to report the above performance-related information. The Transit Asset Management Notice of Proposed Rulemaking was published in the **Federal Register** on September 30, 2015. 80 FR 58912. The comment period closes on November 30, 2015. FTA encourages readers to submit comments on the NPRM, including the proposed performance measures, to docket # FTA–2014–0020 at *www.regulations.gov.*

C. Paperwork Reduction Act

Anticipated Burden

A Paperwork Reduction Act justification of these changes has been submitted for review. FTA estimates that the initial year burden nationally will be 18,636 hours for urban reporters and 13,097 hours for state and rural reporters or 31,733 hours in total. This represents a 10.5% increase to the total NTD in the first year. The burden in subsequent years is estimated at 9,318 hours for urban reporters and 6,549 for state and rural reporters or a total of 15,867 hours representing a 5.2% increase to the total NTD.

Estimated Annual Burden on Respondents (new module): 15,867 hrs.

Estimated Total Annual Burden (Total NTD): 318,267 hrs.

Frequency: Reporting Annually.

Therese W. McMillan,

Acting Administrator.

[FR Doc. 2015–29384 Filed 11–17–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Environmental Impact Statement for the Green Line to the Airport Project, Sacramento County, California

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of intent to prepare an Environmental Impact Statement (EIS).

SUMMARY: The Federal Transit Administration (FTA) and Sacramento Regional Transit District (RT) issue this Notice of Intent (NOI) to advise other agencies and the public that it will prepare an Environmental Impact Statement (EIS) for the proposed Green Line to the Airport Project in Sacramento County, California. The EIS will be prepared as a joint document that includes an Environmental Impact Report (EIR) prepared pursuant to the California Environmental Quality Act (CEQA). The project consists of an extension of the existing Green Line light rail service from the existing terminus of the Green Line at Township 9 (at North 7th Street and Richards Boulevard near Downtown Sacramento) to the Sacramento International Airport. The proposed project would provide new transit service and related infrastructure in the City of Sacramento, serving communities such as the River District and the South and North Natomas communities, as well as linking these areas better to the larger Sacramento region. The EIS will evaluate alternatives to the proposed action, including the No Build Alternative and possible minimum operable segments.

The EIS will be prepared in accordance with regulations implementing the National Environmental Policy Act (NEPA) regulations (40 CFR parts 1500 through 1508), 23 U.S.C. 139, and FTA's regulations and guidance implementing NEPA under 23 CFR 771. FTA will serve as the federal lead agency and RT will serve as a joint lead agency per NEPA. RT is also the local lead agency under CEQA. The U.S Army Corps of Engineers (USACE) will be a cooperating agency pursuant to 40 CFR 1501.6.

The purpose of this notice is to alert interested parties regarding the intent to prepare the EIS/EIR, to provide information on the nature of the proposed action and possible alternatives, to invite participation in the EIS process including providing comments on the scope of the Draft EIS; and to announce that public scoping meetings will be conducted.

DATES: Written comments on the scope of the Draft EIR/EIS including the project's purpose and need, the alternatives to be considered, the impacts to be evaluated, and the methodologies to be used in the evaluations should be sent to RT on or before Friday, January 15, 2016. See **ADDRESSES** below. Public scoping meetings to accept comments on the scope of the EIS/EIR will be held on the following dates:

- Tuesday, December 1, 2015; beginning at 6 p.m. at the Natomas Park Elementary School at 4700 Crest Drive, Sacramento, CA 95835.
- Wednesday, December 2, 2015; beginning at 6 p.m. at the Library Galleria, Downtown Sacramento Public Library at 828 I Street, Sacramento, CA 95814.
- Thursday, December 3, 2015; beginning at 6 p.m. at South Natomas Community Center at 2921 Truxel Road, Sacramento, CA 95833.

The locations are accessible to persons with disabilities. Any individual who requires a language interpreter or signing services or other special accommodations, to participate in the scoping meetings should contact Gladys Cornell at (916) 442–1168 or *gcornell@aimconsultingco.com* at least 48 hours before the scoping meeting.

Scoping materials will be available at the meetings and on the RT Web site (*http://www.sacrt.com/dna*). Representatives of Native American tribal governments and of all federal, state, regional and local agencies that may have an interest in any aspect of the project will be invited to be participating or cooperating agencies, as appropriate.

ADDRESSES: Comments will be accepted at the public scoping meetings or they may be sent to Jeff Damon, Project Manager, at RT, 1400 29th Street, Sacramento, CA 95816.

FOR FURTHER INFORMATION CONTACT: Jeff Damon at the address above or Lucinda Eagle, Community Planner, Region IX Office, Federal Transit Administration at 201 Mission Street, Suite 1650, San Francisco, CA 94015, phone (415) 744–2590, or via email at *lucinda.eagle@dot.gov*.

SUPPLEMENTARY INFORMATION:

Scoping

Scoping is the process of determining the scope, focus, and content of an EIS. The FTA and RT invite all interested individuals and organizations, agencies, and Native American groups to provide comments on the scope of the Draft EIS including the project's purpose and need, the alternatives under consideration, the environmental impacts to be evaluated, and the evaluation approach.

Purpose and Need for the Proposed Project

The purpose of the project is to improve transit linkages and coverage to communities and activity centers within the study area, alleviate roadway congestion by providing a robust transit network that offers an alternative to automobile travel, and provide a safe, convenient, and affordable alternative for traveling between Downtown Sacramento, South and North Natomas, and the Sacramento International Airport. In addition, the project would provide a connection directly to the region's major intermodal facility at the Sacramento Valley Station, where bus, light rail, and Amtrak commuter rail

services provide access to a much larger region.

The need for the project is based on recent and projected future population and employment growth in the study area, including new developments proposed as a result of the lifting of a building moratorium by the Federal Emergency Management Agency (FEMA) in March 2015. The building moratorium in Natomas went into effect in 2008 to ensure the advancement of levee improvement to provide flood protection in the Natomas area. The region is showing significant signs of economic recovery and job growth is leading housing growth. The proposed project alignment is entirely within Center and Corridor Communities, and is forecast to be among the primary growth areas in the region. Based on Sacramento Area Council of Governments forecasts, the population in the area is expected to grow by 811,000 people, an increase of about 36 percent, between 2012 and 2036. The growth projections include approximately 439,000 new employees from 2012 to 2036, as compared to the 361,000 new employees forecasted in the last plan from 2008 to 2035. By 2036, the land use forecast projects that 30 percent of new housing and 35 percent of new employees will be located in Center and Corridor Communities. New activity centers in the study area include North Natomas, Greenbriar, Metro Air Park, and redevelopment of the Sleep Train Arena complex. In addition, the southern portion of the study area includes the Railyards development project, the largest redevelopment of a brownfields site west of the Mississippi River that will include new housing, business, and entertainment destinations, as well as a regional hospital complex.

The projected development, population and employment growth, and new activity centers increase demand for additional transportation infrastructure capacity. The only connection currently serving the study area, between Downtown Sacramento and the airport, is Interstate 5 (I–5). The California Department of Transportation reports that existing levels of service along the segment of I–5 in the vicinity of the proposed project operates at level of service F, a forced or breakdown flow of traffic with stop and go traffic. Increases in traffic congestion are projected in the study area in the absence of significant new investments in alternative transportation. Increases in traffic volumes will worsen conditions on the I–5 corridor, which connects the Natomas area to Downtown Sacramento via an existing American River bridge crossing carrying local, regional, and interstate vehicle traffic. Congestion on the bridge and its connecting roadways (Garden Highway and Richards Boulevard) results in undesirable travel delays including delays for buses and emergency vehicles. Increases in traffic volumes in the study area are expected to stimulate increased demand for transit services, which in the study area are currently limited to local RT bus routes and one Yolobus route that serves Sacramento International Airport.

Study Area Description

The project study area is located in Sacramento County, California, and includes portions of North and South Natomas. The corridor study area extends approximately 11.3-miles between Township 9 (at North 7th Street and Richards Boulevard near Downtown Sacramento) and Sacramento International Airport. The study area surrounding the Township 9 station is within the River District, a historically industrial area that is being redeveloped as a mixed-use community. The American River Parkway is located north of the River District. The Parkway includes recreation areas and natural land cover. South Natomas, between the American River Parkway and I–80, is primarily single- and multi-family residential with supporting neighborhood commercial and institutional uses. North Natomas, between the I–80 and State Route 99 crossings, is a recently developed area containing new single-family residential neighborhoods, several multi-family residential complexes, and larger commercial, industrial, and institutional land uses. North Natomas also includes the large Sleep Train Arena complex, which is expected to be redeveloped in the near future. Two proposed development sites—Greenbriar and Metro Air Park—are located between North Natomas and Sacramento International Airport.

Alternatives Considered

Between 2001 and 2003, RT conducted the Downtown-Natomas-Airport Alternatives Analysis (AA) to evaluate the costs, benefits, and impacts of a range of transportation alternatives to address mobility and transportation connectivity between Downtown Sacramento and the Sacramento International Airport. The AA report considered a wide range of transit technology and alignment alternatives for the corridor. Transit technology options included bus rapid transit and light rail, and the alignment options included Truxel Road to the Airport, I–5 between Downtown and I–80 and Truxel Road between I–80 and the Airport, and I–5 to Airport. On December 12, 2001, a Notice of Intent was issued in the **Federal Register** of the Downtown-Natomas-Airport Light Rail Transit The Board adopted a Locally Preferred Alternative (LPA) in 2003. However, no EIS or Record of Decision was prepared due to lack of federal funding and participation in the project. The LPA is included in the RT Transit Action Plan, the City of Sacramento General Plan, and the Sacramento Area Council of Governments Metropolitan Transportation Plan/Sustainable Communities Plan. Following the AA, a Program EIR was prepared for the Downtown-Natomas-Airport Light Rail Transit project in accordance with CEQA and was certified in 2008.

The Draft EIS/EIR will analyze reasonable alternatives uncovered during scoping. The alternatives being evaluated include:

No-Build Alternative: The No-Build Alternative represents conditions that would be reasonably expected to occur in the foreseeable future if the proposed build alternative were not implemented. The No-Build Alternative includes existing conditions, services, and facilities plus all possible service improvements and committed transit improvements in the proposed project corridor.

Locally Preferred Alternative: The LPA is an approximately 11.3-mile light rail transit project between Township 9 and Sacramento International Airport. The LPA includes refinements to the alignment since the LPA was adopted by the Board in 2003. This alternative consists of features typical of light rail transit, including but not limited to stations, tracks, overhead catenary, traction power substations, signaling and safety features, park-and-ride facilities, and maintenance and storage facilities. The alignment follows Richards Boulevard and Sequoia Pacific Boulevard through the River District. It crosses the American River to Truxel Road and includes a section of dedicated right-of-way adjacent to the roadway in North Natomas. The alignment turns westerly, crossing Highway 99 and traversing planned transit-oriented developments at Greenbriar and Metro Air Park before terminating at the Sacramento International Airport. Due to the associated increases in the size of RT's light rail vehicle fleet, the project also includes an expansion of RT's existing light rail maintenance facility (on Academy Way in North Sacramento) in combination with a new maintenance

facility near Sacramento International Airport.

The LPA includes a new bridge over the American River which will accommodate transit, bicycles, and pedestrians, and include connections to the American River Parkway on the north and south sides of the river. A design option of the bridge includes a wider bridge cross section to accommodate automobiles.

In addition to the alternatives described above, the Draft EIS will examine alignment design options to respond to new opportunities and conditions at the Sleep Train Arena site and at the Sacramento International Airport. Also, depending on funding availability from various federal and local sources, construction to Sacramento International Airport may require one or more phases. Phased implementation of the Green Line project or minimum operable segments will be considered as part of the Draft EIS.

Probable Effects

The purpose of the EIS is to study, in a public setting, the potential effects and benefits on the physical, human, and natural environment of implementing the proposed action. The permanent or long-term effects to be investigated during this study include effects to public parks and recreation lands (Section 4(f) Evaluation), traffic and transportation, land use and socioeconomic, visual character and aesthetics, noise and vibration, historical and archaeological resources, community effects, and natural resources. Temporary effects during construction may include effects to transportation and traffic, air quality, water quality, noise and vibration, natural resources, and encounters with hazardous materials and contaminated soils. Measures to avoid, minimize, and mitigate adverse impacts will also be identified and evaluated.

The analysis during the environmental review process will be undertaken in conformity with Federal environmental laws, regulations, and executive orders applicable to the proposed project. These requirements include, but are not limited to, the regulations of the Council on Environmental Quality implementing NEPA (40 CFR parts 1500 through 1508), FTA's NEPA implementing regulations and procedures (23 CFR part 771 and 23 U.S.C. 139), the air quality transportation conformity regulation of the U.S. Environmental Protection Agency (EPA) (40 CFR part 93), guidelines for disposal of dredged or fill material in section 404(b)(1) guidelines of EPA (40 CFR part 230), Executive Orders 13609and 11988 on floodplains, 11990 on wetlands, and 12898 on environmental justice, and regulations implementing section 106 of the National Historic Preservation Act (36 CFR part 800), section 7 of the Endangered Species Act (50 CFR part 402), and section 4(f) of the Department of Transportation Act (23 CFR 774).

FTA's Public and Agency Involvement Procedures

Regulations implementing NEPA and FTA guidance call for public involvement in the environmental review process. In accordance with these regulations and guidance, FTA and RT will: (1) Extend an invitation to other federal and non-federal agencies and Native American tribes that may have an interest in the proposed project to become participating agencies (any interested agency that does not receive an invitation can notify any of the contact persons listed earlier in this NOI); (2) provide an opportunity for involvement by participating agencies and the public to help define the purpose and need for a proposed project, as well as the range of alternatives for consideration in the EIS/EIR; and (3) establish a plan for coordinating public and agency participation in, and comment on, the environmental review process.

With the publication of this NOI, the scoping process and the public comment period for the project begins allowing the public to offer input on the scope of the EIS/EIR until Friday, January 15, 2016. Public comments will be received through those methods explained earlier in this NOI and will be incorporated into a Scoping Summary Report. The Scoping Summary Report will detail the scope of the EIS/EIR and the potential environmental effects that will be considered during the study period. After the completion of the Draft EIS/EIR, a public and agency review period will allow for input on the Draft EIS/EIR and these comments will be incorporated into the Final EIS/EIR for this project. In accordance with Section 1319 of the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–114), *Accelerated Decision-making in Environmental Reviews,* FTA may consider the use of errata sheets attached to the Draft EIS/EIR in place of a in place of a traditional Final EIS/EIR and/or development a single environmental decision document that consists of a Final EIS/EIR and a Record of Decision (ROD), if certain conditions exist following the conclusion of the public and agency review period for the project's Draft EIS/EIR.

Leslie T. Rogers,

Regional Administrator, Regional IX, Federal Transit Administration.

[FR Doc. 2015–29418 Filed 11–17–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0109]

National Emergency Medical Services Advisory Council (NEMSAC) and Federal Interagency Committee on Emergency Medical Services (FICEMS); Notice of Federal Advisory Committee Meeting

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT)

ACTION: Meeting Notice—National Emergency Medical Services Advisory Council and Federal Interagency Committee on Emergency Medical Services

SUMMARY: The NHTSA announces meetings of NEMSAC and FICEMS to be held consecutively in the Metropolitan Washington, DC, area. This notice announces the date, time, and location of the meetings, which will be open to the public, as well as opportunities for public input to the NEMSAC and FICEMS. The purpose of NEMSAC, a nationally recognized council of emergency medical services representatives and consumers, is to advise and consult with DOT and the FICEMS on matters relating to emergency medical services (EMS). The purpose of FICEMS is to ensure coordination among Federal agencies supporting EMS and 9–1–1 systems.

DATES: The NEMSAC meeting will be held on December 1, 2015 from 9 a.m. to 12:30 p.m. EST, and on December 1, 2015 from 9 a.m. to 11:30 a.m. EST. A public comment period will take place on December 1, 2015 between 12:15 p.m. and 12:30 p.m. EST and December 2, 2015 between 10:45 a.m. and 11 a.m. EST. NEMSAC committees will meet in the same location on Tuesday, December 1, 2015 from 2 p.m. to 5 p.m. EST. Written comments for the NEMSAC from the public must be received no later than November 25, 2015.

The FICEMS meeting will be held on December 2, 2015 from 12:30 p.m. to 3:30 p.m. EST. A public comment period will take place on December 2,

2015 between approximately 3 p.m. and 3:30 p.m. EST. Written comments for FICEMS from the public must be received no later than November 25, 2015.

ADDRESSES: The meetings will be held at the Thomas ''Tip'' O'Neill Building, 200 C Street SW. (Corner of 3rd Street and C, SW.—large glass building on the southeast corner), Washington, DC 20201. Lower Level—Willow Conference Room. Attendees should plan to arrive 20 minutes early to accommodate security screening.

FOR FURTHER INFORMATION CONTACT: Gamunu Wijetunge, U.S. Department of Transportation, Office of Emergency Medical Services, 1200 New Jersey Avenue SE., NTI–140, Washington, DC 20590, *Gamunu.Wijetunge@dot.gov* or 202–493–2793.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.). The NEMSAC is authorized under Section 31108 of the Moving Ahead with Progress in the 21st Century Act of 2012. The FICEMS is authorized under Section 10202 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU).

Tentative Agenda of the National EMS Advisory Council Meeting

The tentative NEMSAC agenda includes the following:

Tuesday, December 1, 2015 (9 a.m. to 12:30 p.m. EST)

(1) Opening Remarks
(2) Federal Liaison Update–Reports and Updates from the Departments of Transportation, Homeland Security, and Health & Human Services
(3) Disclosure of Conflicts of Interests by Members
(4) Overview of New NEMSAC Committees:
  a. Funding and Reimbursement
  b. Innovative Practices of EMS Workforce
  c. Data Integration and Technology
  d. Patient Care, Quality Improvement and General Safety
  e. Provider and Community Education
  f. Ad Hoc Committee on Recognition of EMS Personnel Licensure Interstate Compact (REPLICA)
(5) Public Comment Period (12:15 p.m. to 12:30 p.m. EST)
(6) Recess for Day–12:30 p.m. EST
NEMSAC Committees Breakout Sessions from 2 p.m.–5 p.m. (on-site and open to the public)

Wednesday, December 2, 2015 (9 a.m. to 11:30 a.m. EST)

(1) Reconvene and Approval of July 30–31, 2015 Meeting Minutes (9 a.m.–9:30 a.m. EST)
(2) Presentation on ''Fatigue in EMS'' Project–NHTSA (9:10 a.m.–9:30 a.m. EST)
(3) NEMSAC Committee Reports/Updates/Discussion (9:30 a.m.–10:45 a.m. EST)
(4) Public Comment Period (10:45 a.m. to 11 a.m. EST)
(5) Next Steps and Adjourn (11 a.m.–11:30 a.m. EST)

Tentative Agenda of the Federal Interagency Committee on EMS Meeting

Wednesday, December 2, 2015 (12:30 p.m. to 3:30 p.m. EST)

(1) Welcome, Introductions and Opening Remarks from Ed Gabriel, Chair
(2) Review and Approval of Executive Summary of August 12, 2015 Meeting
(3) NEMSAC Report (John Sinclair, NEMSAC Chair)
(4) Technical Working Group (TWG) Committee Reports
  a. Strategic Planning Implementation Update
  b. EMS Data Standardization and Exchange
  c. Preparedness
  d. Evidence-based Practice and Quality
  e. Workforce and Veterans Credentialing
  f. Safety
(5) Update from EMS for Children: Performance Measures, Pediatric Emergency Care Applied Research Network (PECARN), and Funding Opportunities (EMS for Children Staff)
(6) Other FICEMS Business
(7) Public Comment Period (approximately 3 p.m. EST)
(8) Election of 2016 FICEMS Chair and Vice-Chair
(9) Next Steps and Adjourn

Registration Information: These meetings will be open to the public; however, pre-registration is requested. Individuals wishing to attend must register online no later than November 27, 2015. For NEMSAC please register at: *https://www.SignUp4.net/public/ap.aspx?EID=NEMS13E.* For FICEMS please register at: *https://www.SignUp4.net/public/ap.aspx?EID=FICE11E.* For assistance with registration, please contact Gamunu Wijetunge at *Gamunu.Wijetunge@dot.gov* or 202–493–2793. There will not be a teleconference option for these meetings.

Public Comment: Members of the public are encouraged to comment directly to the NEMSAC and FICEMS during designated public comment periods. In order to allow as many people as possible to speak, speakers are requested to limit their remarks to 5 minutes. Written comments from members of the public will be distributed to NEMSAC or FICEMS members at the meeting and should reach the NHTSA Office of EMS no later than November 27, 2015. Written comments may be submitted by either one of the following methods: (1) You may submit comments by email: *nemsac@dot.gov* or *ficems@dot.gov* or (2) you may submit comments by fax: (202) 366–7149.

A final agenda as well as meeting materials will be available to the public online through *www.EMS.gov* on or before November 27, 2015.

Issued on: November 12, 2015.

Jeffrey P. Michael,

Associate Administrator for Research and Program Development.

[FR Doc. 2015–29421 Filed 11–17–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

FEDERAL RESERVE SYSTEM

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Joint Comment Request

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of information collection.

SUMMARY: In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), the OCC, the Board, and the FDIC (collectively, the agencies) may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number. On July 29, 2015, the agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), published a notice in the **Federal Register** (80 FR 45274) and requested public comment for 60 days on a proposal to extend, with revision, the Foreign Branch Report of Condition

(FFIEC 030 and FFIEC 030S), which is a currently approved information collection for each agency. The comment period for this notice expired on September 28, 2015. The agencies did not receive any comments addressing the proposed changes and are now submitting a request to OMB for review and approval of the extension, with revision, of the FFIEC 030 and FFIEC 030S.

DATES: Comments must be submitted on or before December 18, 2015.

ADDRESSES: Interested parties are invited to submit written comments to any or all of the agencies. All comments, which should refer to the OMB control number, will be shared among the agencies.

OCC: Because paper mail in the Washington, DC, area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0099, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Board: You may submit comments, identified by FFIEC 030 or FFIEC 030S, by any of the following methods:

- *Agency Web site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at: *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: regs.comments@federalreserve.gov.* Include reporting form number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Robert DeV. Frierson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551.

All public comments are available from the Board's Web site at *www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9:00 a.m. and 5:00 p.m. on weekdays.

FDIC: You may submit comments, which should refer to ''Foreign Branch Report of Condition, 3064–0011,'' by any of the following methods:

- *Agency Web site: http://www.fdic.gov/regulations/laws/federal/propose.html.* Follow the instructions for submitting comments on the FDIC's Web site.
- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: comments@FDIC.gov.* Include ''FFIEC 030 and FFIEC 030S'' in the subject line of the message.
- *Mail:* Gary A. Kuiper, Counsel, Attn: Comments, Room MB–3016, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received will be posted without change to *http://www.fdic.gov/regulations/laws/federal/propose.html* including any personal information provided. Comments may be inspected at the FDIC Public Information Center, Room E–1002, 3501 Fairfax Drive, Arlington, VA 22226, between 9:00 a.m. and 5:00 p.m. on business days.

Additionally, commenters may send a copy of their comments to the OMB desk officer for the agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503; by fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the revisions discussed in this notice, please contact any of the agency clearance officers whose names appear below. In addition, copies of the report forms can be obtained at the FFIEC's Web site (*http://www.ffiec.gov/ffiec_report_forms.htm*).

OCC: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Mark Tokarski, Federal Reserve Board Acting Clearance Officer, (202) 452–3829, Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may call (202) 263–4869.

FDIC: Gary A. Kuiper, Counsel, (202) 898–3877, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION: Proposal to request approval from OMB of the extension for three years, with revision, of the following currently approved collection of information:

Report Title: Foreign Branch Report of Condition.

Form Numbers: FFIEC 030 and FFIEC 030S.

Frequency of Response: Annually, and quarterly for significant branches.

Affected Public: Business or other for profit.

OCC

OMB Number: 1557–0099.

Estimated Number of Respondents: 199 annual branch respondents (FFIEC 030), 57 quarterly branch respondents (FFIEC 030), 30 annual branch respondents (FFIEC 030S).

Estimated Average Time per Response: 3.4 burden hours (FFIEC 030), 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 1,467 burden hours.

Board

OMB Number: 7100–0071.

Estimated Number of Respondents: 14 annual branch respondents (FFIEC 030), 24 quarterly branch respondents (FFIEC 030), 11 annual branch respondents (FFIEC 030S).

Estimated Average Time per Response: 3.4 burden hours (FFIEC 030), 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 380 burden hours.

FDIC

OMB Number: 3064–0011.

Estimated Number of Respondents: 8 annual branch respondents (FFIEC 030),

1 quarterly branch respondent (FFIEC 030), 8 annual branch respondents (FFIEC 030S).

Estimated Average Time per Response: 3.4 burden hours (FFIEC 030), 0.5 burden hours (FFIEC 030S).

Estimated Total Annual Burden: 45 burden hours.

General Description of Reports

This information collection is mandatory: 12 U.S.C. 602 (Board); 12 U.S.C. 161 and 602 (OCC); and 12 U.S.C. 1828 (FDIC). This information collection is given confidential treatment under 5 U.S.C. 552(b)(4) and (8).

Abstract

The FFIEC 030 contains asset and liability information for foreign branches of insured U.S. banks and insured U.S. savings associations (U.S. institutions) and is required for regulatory and supervisory purposes. The information is used to analyze the foreign operations of U.S. institutions. All foreign branches of U.S. institutions regardless of charter type file this report as provided in the instructions to the FFIEC 030 and FFIEC 030S.

An institution must file a separate report for each foreign branch, but in some cases may consolidate filings for multiple foreign branches in the same country. A branch with either total assets of at least $2 billion or commitments to purchase foreign currencies and U.S. dollar exchange of at least $5 billion as of the end of a calendar quarter is considered a ''significant branch'' and is required to report quarterly on the FFIEC 030. A foreign branch that does not meet either of the criteria to file quarterly, but has total assets in excess of $250 million, must file the entire FFIEC 030 report on an annual basis as of each December 31.

A foreign branch that does not meet the criteria to file the FFIEC 030 report, but has total assets of $50 million or more (but less than or equal to $250 million), must file the Abbreviated Foreign Branch Report of Condition (FFIEC 030S) on an annual basis as of each December 31. A foreign branch with total assets of less than $50 million is exempt from filing the FFIEC 030 and 030S reports.

Current Actions

On July 29, 2015, the agencies published a notice in the **Federal Register** (80 FR 45274) and requested comment on a proposal to revise the officer declaration requirement that applies to the FFIEC 030 and FFIEC 030S, reduce the information provided if the consolidation option is elected, and add a field on the cover page for an institution to indicate whether the branch meets the criteria for annual or quarterly filing. These revisions would become effective for the December 31, 2015, report date. The comment period for this notice expired on September 28, 2015. The agencies did not receive any comments addressing the proposed changes and are now submitting to OMB a request for review and approval of the extension, with revision, of the FFIEC 030 and FFIEC 030S.

Request for Comment

Public comment is requested on all aspects of this joint notice. Comments are invited on:

a. Whether the information collection is necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

b. The accuracy of the agencies' estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide the requested information.

Comments submitted in response to this notice will be shared among the agencies. All comments will become a matter of public record.

Dated: November 4, 2015.

Stuart Feldstein,

Director, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency.

Board of Governors of the Federal Reserve System, November 12, 2015.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 2nd day of November, 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–29410 Filed 11–17–15; 8:45 am]

BILLING CODE 4810–33–P 6210–01–P 6714–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of a Specially Designated National and Blocked Person Pursuant to Executive Order 13566

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is removing the name of one individual whose property and interests in property have been unblocked pursuant to Executive Order 13566 of February 25, 2011, ''Blocking Property and Prohibiting Certain Transactions Related to Libya.''

DATES: OFAC's actions described in this notice are effective November 13, 2015.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Assistant Director for Sanctions Compliance & Evaluation, tel.: 202/622–2490, Assistant Director for Licensing, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The SDN List and additional information concerning OFAC sanctions programs are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Action

On November 13, 2015, OFAC unblocked the property and interests in property of the following individual pursuant to E.O. 13566, ''Blocking Property and Prohibiting Certain Transactions Related to Libya.'' All property and interests in property of the individual that are in the United States or the possession or control of United States persons are now unblocked, and the individual's name and other identifying information has been removed from the SDN List.

Individual

1. 'ABD–AL–SALAM, Humayd (a.k.a. A.A. ABDUSSALAM, Ahmid; a.k.a. 'ABD–AL–SALAM, Hmeid; a.k.a. ABDUL HADI ABDUL SALAM, Ahmid Abdussalam; a.k.a. ABDUSSALAM, Abdulhadi; a.k.a. ABDUSSALAM, Ahmid; a.k.a. ''ABDULHADI''; a.k.a. ''HUMAYD''); DOB 30

Dec 1965; Passport 55555 (Libya) (individual) [LIBYA2].

Dated: November 13, 2015.

Andrea Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2015–29432 Filed 11–17–15; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Order 13687

AGENCY: Office of Foreign Assets Control, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is publishing the names of 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.''

DATES: OFAC's actions described in this notice are effective November 13, 2015.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: 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*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Actions

On November 13, 2015, OFAC blocked the property and interests in property of the following four individuals and one entity pursuant to E.O. 13687, ''Imposing Additional Sanctions With Respect To North Korea'':

Individuals

1. KIM, Sok Chol, Burma; DOB 08 May 1955; nationality Korea, North; Passport 472310082; North Korean Ambassador to Burma (individual) [DPRK2].
2. KIM, Kwang Hyok, Burma; DOB 20 Apr 1970; nationality Korea, North; Passport 654210025 (Korea, North); Korean Mining Development Trading Corporation Representative in Burma (individual) [DPRK2] (Linked To: KOREA MINING DEVELOPMENT TRADING CORPORATION).
3. RI, Chong Chol (a.k.a. RI, Jong Chol); DOB 12 Apr 1970; Passport 199110092 (Korea, North) expires 17 Mar 2014; alt. Passport 472220503 (Korea, North) expires 06 Jun 2018; alt. Passport 654220197 (Korea, North) expires 07 May 2019 (individual) [DPRK2] (Linked To: KOREA MINING DEVELOPMENT TRADING CORPORATION).
4. HWANG, Su Man (a.k.a. HWANG, Kyong Nam); DOB 06 Apr 1955; nationality Korea, North; Passport 472220033 (Korea, North) (individual) [DPRK2] (Linked To: KOREA MINING DEVELOPMENT TRADING CORPORATION).

Entity

1. EKO DEVELOPMENT AND INVESTMENT COMPANY (a.k.a. EKO DEVELOPMENT & INVESTMENT FOOD COMPANY; a.k.a. EKO IMPORT AND EXPORT COMPANY), 35 St. Abd al-Aziz al-Sud, al-Manial, Cairo, Egypt [DPRK2].

Dated: November 13, 2015.

Andrea Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2015–29431 Filed 11–17–15; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Order 13581

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 two entities whose property and interests in property are blocked pursuant to Executive Order 13581 of July 24, 2011, ''Blocking Property of Transnational Criminal Organizations.''

DATES: OFAC's actions described in this notice were effective on November 12, 2015.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Policy, tel.: 202–622–2746, 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 Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Actions

On November 12, 2015, the Director of OFAC, in consultation with the Attorney General and the Secretary of State, blocked the property and interests in property of the following two entities pursuant to the Order:

1. ALTAF KHANANI MONEY LAUNDERING ORGANIZATION, Australia; Canada; Pakistan; United Arab Emirates; United Kingdom; United States [TCO].
2. AL ZAROONI EXCHANGE (a.k.a. ALZROONI EXCHANGE; a.k.a. M/S. AL ZAROONI EXCHANGE), P.O. Box 116348, Dubai, United Arab Emirates; Near Florida Hotel, Building of Abdul Rahim Mohd. Ismail Badri, Al Sabkha Street, Naif Road, Deira, Dubai, United Arab Emirates; Sikhat Al Khail Road, Dubai, United Arab Emirates; Web site *www.alzarooniexchange.ae*, C.R. No. 91715; Dubai Chamber of Commerce Membership No. 70103; RTN 823410101; License 535436 [TCO].

Dated: November 12, 2015.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2015–29383 Filed 11–17–15; 8:45 am]

BILLING CODE 4810–AL–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

48 CFR Chapter 3

Health and Human Services Acquisition Regulations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

48 CFR Chapter 3

RIN 0991–AB86

Health and Human Services Acquisition Regulations

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (HHS) is issuing a final rule to amend its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation (HHSAR), to update its regulation to current FAR requirements; to remove information from the HHSAR that consists of material that is internal, administrative, and procedural in nature; to add or revise definitions; to correct certain terminology; and to delete outdated material or material duplicative of the FAR.

DATES: Effective December 18, 2015.

FOR FURTHER INFORMATION CONTACT: Deborah Griffin, Procurement Analyst, Department of Health and Human Services, Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, *deborah.griffin@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

HHS published a proposed rule in the **Federal Register** at 80 FR 11266 on March 2, 2015, to conform to current statutory and FAR requirements. This final rule changes the HHSAR to conform to these new requirements and to align the requirements with the current FAR. In addition, the procedural materials that were deemed internal or non-regulatory in nature are moved to internal procedures for department-wide application.

II. Discussion and Analysis

HHS reviewed the comments in the development of this final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Summary of Significant Changes to the Proposed Rule

HHSAR 311.71, Public Accommodations and Commercial Facilities, and the relevant clause at 352.211–1, Public Accommodations and Commercial Facilities, are renamed and revised to clarify public accommodation and the use of commercial facilities.

HHSAR 302.101, Definitions, is revised to clarify the definition of ''agency head or head of the agency'' as the Secretary of HHS or specified designee. This allows for the delegation to the appropriate acquisition official within HHS.

HHSAR 303.704, Policy, is clarified to specify the HCA as the designee for voiding and rescinding contracts; however, coordination is required with the SPE.

HHSAR 306.202, Establishing or maintaining alternative sources, is revised to clarify that the ''agency head'' as specified in FAR 6.202(a) is the SPE rather than the Competition Advocate.

HHSAR 306.302–7, Public interest, is deleted. The information is considered duplicative of the FAR.

HHSAR 309.403, Definitions, is revised to delete the definition of ''acquiring agency's head or designee.''

HHSAR 317.108, Congressional notification, is revised to clarify that the SPE shall give the approval of the notification required by FAR 17.108(a) and that the HCA shall finalize and sign the congressional notification letter and provide it to the appropriate House and Senate committees.

HHSAR 317.204, Contracts, is revised to clarify that a request to exceed the 5-year limitation specified in FAR 17.204(e) must follow the guidance in FAR 1.7.

HHSAR 324.70, Health Insurance Portability and Accountability Act of 1996, is revised to clarify the references to controlling law.

In addition, several editorial changes were made to the rule.

B. Analysis of Public Comments

HHSAR 315.305, Proposal Evaluation

The respondent states that the coverage in HHSAR 315.305, concerning advisors who are brought in to assist in proposal evaluation has a different set of restrictions and requirements than are found in Part 337, Service Contracting-General, citing those found in FAR 37.203, Policy. The provisions of HHSAR 315.305 specifically address those circumstances when HHS must use a statutorily mandated contractor selection process of Peer Review. As such, the respondent is correct that the primary focus of this HHSAR section deals with potential conflicts which must be avoided in source selection. HHS does not believe that any change to the coverage is necessary. FAR 15.305, Proposal Evaluation, already contains a cross reference to FAR part 37, Service Contracting.

319.270–1, Mentor Protégé Program Solicitation Provision and Contract Clause

The respondent notes that the HHS Mentor Protégé Program is currently suspended and requests that the suspension be lifted or, alternatively, the section be removed from the HHSAR. HHS has retained the HHSAR coverage as currently written with intent to reinstate the program at a later date.

352.204–70(c)(5), Prevention and Public Health Fund-Reporting Requirements

The respondent believes the language in the clause at 352.204–70(c)(5), Prevention and Public Health Fund-Reporting Requirements, is duplicative and should be deleted and replaced with the requirement to report subcontract information in the Federal Funding Accountability and Transparency Act Subaward Reporting System. The requirement in the HHSAR is specific to Prevention and Public Health Fund funding, and the reporting requirement is contained within the structure of the program. Therefore, the language in the proposed rule is retained.

352.211–1, Public Accommodations and Commercial Facilities

The respondent supports HHS' inclusion of HHSAR coverage to provide accessible meeting locations. However, HHS believes further clarification is necessary for public accommodation and commercial facilities. Therefore, the language in HHSAR 311.71, Public Accommodations and Commercial Facilities and the related clause at 352.211–1, Public Accommodations and Commercial Facilities, is revised.

352.237–74, Non-Discrimination in Service Delivery

The clause at 352.237–74, Non-Discrimination in Service Delivery, specifies that the contractor may not discriminate on several bases to include sex, gender, religion, and others as are often found in such clauses and relate to specific non-discrimination Federal laws. Several respondents provided comments that are mostly identical and suggested two modifications. The first is to expand the enumerated areas of prohibited discrimination to include genetics, politics, and veteran status among others. It then suggests ''that nothing in this clause limits the ability of a recipient to target assistance to certain populations as defined in the award.'' Thus the respondents ask that HHS go beyond the current requirements of Federal law in prohibiting other possible forms of

discrimination and then asks that the benefits distributed NOT be subject to this restriction in that certain benefits are, by design, targeted to go to certain defined groups. Another comment also ''reiterates that prohibiting contractors from discrimination while delivering taxpayer-funded services in no way violates religious liberty protections.'' No change is being made to the coverage. HHS intends to comply with all applicable Federal legislation regarding this subject.

352.270–5a, Notice to Offerors of Requirement for Compliance With the Public Health Service Policy on Humane Care and Use of Laboratory Animals, and 352.270–5b, Care of Live Vertebrate Animals

The respondent asks for further consideration to repeal using animals in research. No change is being made to the coverage. HHS intends to comply with all applicable federal legislation regarding this subject.

352.270–9, Non-Discrimination for Conscience

Several respondents commented on the clause at 352.270–9, Non-Discrimination for Conscience. Most of the comments are identical. Each notes that their concern is with the statute, not the regulation implementing it. They further ask that the law be ''robustly operationalized.'' HHS intends to enforce section 7631(d) of the Leadership Act. Therefore, no change is being made to the coverage.

352.270–12, Needle Exchange

The respondent commented on the clause at 352.270–12, Needle Exchange, which prevents Federal funds from being used for safe needle exchange. The respondent believes that safe needle exchanges at HHS locations make logical sense. HHS intends to comply with all applicable Federal legislation regarding this subject. Therefore, no change is being made to the coverage.

352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research

Several respondents commented on the clause at 352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research. All but one of the comments were identical. The remaining comment was more expansive. This clause prohibits the use of Federal funds for abortion, creating embryos for the purpose of harvesting cells from them (commonly referred to as ''stem cell research''), and the cloning of humans.

The respondents want the rule changed as to abortion to permit abortion in the case of incest, rape, and life endangerment ''pursuant to prevailing law.'' HHS intends to comply with all applicable Federal legislation regarding this subject. Therefore, no change is being made to the coverage.

III. Executive Orders 12866 and 13563

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

This is not a significant regulatory action and, therefore, is not subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

A final regulatory flexibility analysis has been prepared consistent with 5 U.S.C. 604.

1. Statement of the Need for, and the Objectives of, the Rule

The Department of Health and Human Services (HHS) is revising its Federal Acquisition Regulation (FAR) Supplement, the HHS Acquisition Regulation (HHSAR), to update its regulation to current FAR requirements; to remove information from the HHSAR that consists of material that is internal administrative and procedural in nature; to add or revise definitions; to correct certain terminology; and to delete outdated material or material duplicative of the FAR.

2. Statement of the Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis, a Statement of the Assessment of the Agency of Such Issues, and a Statement of any Changes Made to the Rule as a Result of Such Comments

No issues were raised by the public in response to the initial regulatory flexibility analysis.

3. The Response of the Agency to Any Comments Filed by the Chief Counsel for Advocacy of the Small Business Administration in Response to the Rule, and a Detailed Statement of any Change Made in the Final Rule as a Result of the Comments

No issues were raised by the Chief Counsel for Advocacy of the Small Business Administration in response to the rule.

4. Description of and an Estimate of the Number of Small Entities to Which This Rule Will Apply

HHS awarded approximately 95,836 contract actions in FY 2014; over 44 percent (42,467) of those actions were for small businesses acting as prime contractors; therefore, it is estimated that the rule will apply to over 42,000 small business entities.

5. Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Rule

There are no new reporting, recordkeeping, or other compliance requirements in the final rule. The reporting and recordkeeping requirements are the same as those prior to the proposed rule.

6. Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes

The final rule does not revise or place any new requirements on small business entities. Therefore, this final rule should have no significant economic impact on a substantial number of small business entities.

V. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. Chapter 35) applies. The rule contains information collection requirements. OMB has cleared these information collection requirements under OMB Control Numbers 0990–0430, 0990–0431, 0990–0432, 0990–0433, 0990–0434, and 0990–0436.

List of Subjects in 48 CFR Parts 301 Through 370

Government procurement.

Dated: October 29, 2015.

Angela Billups,

Associate Deputy Assistant Secretary—Acquisition.

For the reasons stated in the preamble, HHS is revising 48 CFR chapter 3 to read as follows:

Title 48—Federal Acquisition Regulations System

CHAPTER 3—HEALTH AND HUMAN SERVICES

SUBCHAPTER A—GENERAL

PART 301—HHS ACQUISITION REGULATION SYSTEM
PART 302—DEFINITIONS OF WORDS AND TERMS
PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST
PART 304—ADMINISTRATIVE MATTERS

SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING

PART 305—PUBLICIZING CONTRACT ACTIONS
PART 306—COMPETITION REQUIREMENTS
PART 307—ACQUISITION PLANNING
PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES
PART 309—CONTRACTOR QUALIFICATIONS
PART 310—MARKET RESEARCH
PART 311—DESCRIBING AGENCY NEEDS
PART 312—ACQUISITION OF COMMERCIAL ITEMS

SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

PART 313—SIMPLIFIED ACQUISITION PROCEDURES
PART 314—SEALED BIDDING
PART 315—CONTRACTING BY NEGOTIATION
PART 316—TYPES OF CONTRACTS
PART 317—SPECIAL CONTRACTING METHODS

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

PART 319—SMALL BUSINESS PROGRAMS
PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS
PART 323—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG–FREE WORKPLACE
PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION
PART 326—OTHER SOCIOECONOMIC PROGRAMS

SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

PART 327—PATENTS, DATA, AND COPYRIGHTS
PART 328—RESERVED
PART 330—COST ACCOUNTING STANDARDS
PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES
PART 332—CONTRACT FINANCING
PART 333—PROTESTS, DISPUTES, AND APPEALS

SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

PART 334—MAJOR SYSTEM ACQUISITION
PART 335—RESEARCH AND DEVELOPMENT CONTRACTING
PART 336—CONSTRUCTION AND ARCHITECT–ENGINEER CONTRACTS
PART 337—SERVICE CONTRACTING—GENERAL
PART 339—ACQUISITION OF INFORMATION TECHNOLOGY

SUBCHAPTER G—CONTRACT MANAGEMENT

PART 342—CONTRACT ADMINISTRATION

SUBCHAPTER H—CLAUSES AND FORMS

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES
PART 353—FORMS

SUBCHAPTERS I—L [RESERVED]

SUBCHAPTER M—HHS SUPPLEMENTATIONS

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

SUBCHAPTER A—GENERAL

PART 301—HHS ACQUISITION REGULATION SYSTEM

Subpart 301.1 Purpose, Authority, and Issuance

Sec.
301.101 Purpose.
301.103 Authority.
301.106 Office of Management and Budget approval under the Paperwork Reduction Act.

Subpart 301.2—[Reserved]

Subpart 301.4—Deviations from the FAR

301.401 Deviations.

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

301.602 Contracting officers.
301.602–3 Ratification of unauthorized commitments.
301.603 Selection, appointment, and termination of appointment of contracting officers.
301.603–1 General.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 301.1—Purpose, Authority, and Issuance

301.101 Purpose.

(a) The Department of Health and Human Services (HHS) Acquisition Regulation (HHSAR) establishes uniform HHS acquisition policies and procedures that implement and supplement the Federal Acquisition Regulation (FAR).

(b)(1) The HHSAR contains HHS policies that govern the acquisition process or otherwise control acquisition relationships between HHS' contracting activities and contractors. The HHSAR contains—

(i) Requirements of law;

(ii) HHS-wide policies;

(iii) Deviations from FAR requirements; and

(iv) Policies that have a significant effect beyond the internal procedures of HHS or a significant cost or administrative impact on contractors or offerors.

(2) Relevant internal procedures, guidance, and information not meeting the criteria in paragraph (b)(1) of this section are issued by HHS in other announcements, internal procedures, guidance, or information.

301.103 Authority.

(b) The Assistant Secretary for Financial Resources (ASFR) prescribes the HHSAR under the authority of 5 U.S.C. 301 and section 205(c) of the Federal Property and Administrative Services Act of 1949, as amended (40 U.S.C. 121(c)(2)), as delegated by the Secretary).

(c) The HHSAR is issued in the Code of Federal Regulations (CFR) as chapter 3 of title 48, Department of Health and Human Services Acquisition Regulation. It may be referenced as ''48 CFR chapter 3.''

301.106 Office of Management and Budget approval under the Paperwork Reduction Act.

(a) The Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) imposes a requirement on Federal agencies to obtain approval from the Office of Management and Budget (OMB) before collecting the same information from 10 or more members of the public.

(b) The following OMB control numbers apply to the information collection and recordkeeping requirements contained in this chapter:

HHSAR Segment	OMB Control No.
311.7102	0990–0434
311.7202(b)	0990–0434
311.7300	0990–0436
337.103(d)(3)	0990–0430
337.103(d)(4)	0990–0433
370.301	0990–0431
370.401	0990–0432
352.211–1	0990–0434
352.211–2	0990–0434
352.211–3	0990–0436
352.227–11	0990–0419
352.227–14	0990–0419
352.227–71	0990–0430

HHSAR Segment	OMB Control No.
352.237–72	0990–0433
352.237–73	0990–0431
352.270–4a	0990–0431
352.270–4b	0990–0431
352.270–10	0990–0431
352.270–11	0990–0432
352.270–5a	0990–0432
352.270–5b	0990–0432

Subpart 301.2—[Reserved]

Subpart 301.4—Deviations from the FAR

301.401 Deviations.

Contracting officers are not permitted to deviate from the FAR or HHSAR without seeking proper approval. With full acknowledgement of FAR 1.102(d) regarding innovative approaches, any deviation to FAR or the HHSAR requires approval by the Senior Procurement Executive (SPE).

Subpart 301.6—Career Development, Contracting Authority, and Responsibilities

301.602 Contracting officers.

301.602–3 Ratification of unauthorized commitments.

(b) *Policy.* (1) The Government is not bound by agreements with, or contractual commitments made to, prospective contractors by individuals who do not have delegated contracting authority. Unauthorized commitments do not follow the appropriate process for the expenditure of Government funds. Consequently, the Government may not be able to ratify certain actions, putting a contractor at risk for taking direction from a Federal official other than the contracting officer. See FAR 1.602–1. Government employees responsible for unauthorized commitments are subject to disciplinary action. Contractors perform at their own risk when accepting direction from unauthorized officials. Failure to follow statutory and regulatory processes for the expenditure of Government funds is a very serious matter.

(2) The head of the contracting activity (HCA) is the official authorized to ratify an unauthorized commitment. No other re-delegations are authorized.

(c) *Limitations.* (5) The HCA shall coordinate the request for ratification with the Office of General Counsel, General Law Division and submit a copy to the SPE.

301.603 Selection, appointment, and termination of appointment of contracting officers.

301.603–1 General.

(a) The Agency head has delegated broad authority to the Chief Acquisition Officer, who in turn has further delegated this authority to the SPE. The SPE has further delegated specific acquisition authority to the Operating and Staff Division heads and the HCAs. The HCA (non-delegable) shall select, appoint, and terminate the appointment of contracting officers.

(b) To ensure proper control of redelegated acquisition authorities, HCAs shall maintain a file containing successive delegations of HCA authority through the contracting officer level.

PART 302—DEFINITIONS OF WORDS AND TERMS

Subpart 302.1—Definitions

Sec.
302.101 Definitions.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 302.1—Definitions

302.101 Definitions.

(a) *Agency head or head of the agency,* unless otherwise stated, means the Secretary of Health and Human Services or specified designee.

(b) *Contracting Officer's Representative (COR)* is a Federal employee designated in writing by a contracting officer to act as the contracting officer's representative in monitoring and administering specified aspects of contractor performance *after* award of a contract or order. In accordance with local procedures, operating divisions (OPDIVs) or staff divisions (STAFFDIVs) may designate CORs for firm fixed-price contracts or orders. COR's responsibilities may include verifying that:

(1) The contractor's performance meets the standards set forth in the contract or order;

(2) The contractor meets the contract or order's technical requirements by the specified delivery date(s) or within the period of performance; and

(3) The contractor performs within cost ceiling stated in the contract or order. CORs must meet the training and certification requirements specified in 301.604.

(c) *Head of the Contracting Activity (HCA)* is an official having overall responsibility for managing a contracting activity, *i.e.* the organization within an OPDIV or STAFFDIV or other HHS organization which has been delegated broad authority regarding the conduct of acquisition functions.

PART 303—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Subpart 303.1—Safeguards

Sec.
303.101 Standards of conduct.
303.101–3 Agency regulations.
303.104–7 Violations or possible violations of the Procurement Integrity Act.

Subpart 303.2—Contractor Gratuities to Government Personnel

303.203 Reporting suspected violations of the Gratuities clause.

Subpart 303.6—Contracts with Government Employees or Organizations Owned or Controlled by Them

303.602 Exceptions.

Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions

303.808–70 Solicitation provision and contract clause.

Subpart 303.10—Contractor Code of Business Ethics and Conduct

303.1003 Requirements.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 303.1—Safeguards

303.101 Standards of conduct.

303.101–3 Agency regulations.

(a)(3) The HHS Standards of Conduct are prescribed in 45 CFR part 73.

303.104–7 Violations or possible violations of the Procurement Integrity Act.

(a)(1) The contracting officer shall submit to the head of the contracting activity (HCA) for review and concurrence the determination (along with supporting documentation) that a reported violation or possible violation of the statutory prohibitions has no impact on the pending award or selection of a contractor for award.

(2) The contracting officer shall refer the determination that a reported violation or possible violation of the statutory prohibitions has an impact on the pending award or selection of a contractor, along with all related information available, to the HCA. The HCA shall—

(i) Refer the matter immediately to the Associate Deputy Assistant Secretary—Acquisition (ADAS–A) for review, who may consult with the appropriate legal office representative and the Office of Inspector General (OIG) as appropriate; and

(ii) Determine the necessary action in accordance with FAR 3.104–7(c) and (d). The HCA shall obtain the approval or concurrence of the ADAS–A before proceeding with an action.

(b) The HCA (non-delegable) shall act with respect to actions taken under the Federal Acquisition Regulation (FAR) clause at 52.203–10, Price or Fee Adjustment for Illegal or Improper Authority.

Subpart 303.2—Contractor Gratuities to Government Personnel

303.203 Reporting suspected violations of the Gratuities clause.

HHS personnel shall report suspected violations of the clause at FAR 52.203–3, Gratuities, to the contracting officer, who will in turn report the matter to the Office of General Counsel (OGC), Ethics Division for disposition.

Subpart 303.6—Contracts with Government Employees or Organizations Owned or Controlled by Them

303.602 Exceptions.

The HCA (non-delegable) is the official authorized to approve an exception to the policy stated in FAR 3.601.

Subpart 303.7—Voiding and Rescinding Contracts

303.704 Policy.

(a) For purposes of supplementing FAR subpart 3.7, the HCA (non-delegable) is the designee. Coordination with the Senior Procurement Executive is required.

Subpart 303.8—Limitation on the Payment of Funds to Influence Federal Transactions

303.808–70 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.203–70, Anti-lobbying, in solicitations and contracts that exceed the simplified acquisition threshold.

Subpart 303.10—Contractor Code of Business Ethics and Conduct

303.1003 Requirements.

(b) The contracting officer, when notified of a possible contractor violation, in accordance with FAR 3.1003(b), shall notify the OIG and the HCA.

(c)(2) The contracting officer shall specify the title of HHS' OIG hotline poster and the Web site where the poster can be obtained in paragraph (b)(3) of the clause at FAR 52.203–14.

PART 304—ADMINISTRATIVE MATTERS

Subpart 304.6—Contract Reporting

Sec.
304.602 General.
304.604 Responsibilities.

Subpart 304.13—Personal Identity Verification

304.1300 Policy.

Subpart 304.16—Unique Procurement Instrument Identifiers

304.1600 Scope of subpart.

Subpart 304.70—[Reserved]

Subpart 304.71—Review and Approval of Proposed Contract Actions

304.7100 Policy.

Subpart 304.72—Affordable Care Act Prevention and Public Health Fund—Reporting Requirements

Sec.
304.7200 Scope of subpart.
304.7201 Procedures.
304.7202 Contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 304.6—Contract Reporting

304.602 General.

Follow internal department procedures for reporting information to the Federal Procurement Data System (FPDS) and for resolving technical or policy issues relating to FPDS contract reporting.

304.604 Responsibilities.

The Department of Health and Human Services (HHS) acquisition officials and staff shall report their contract information in FPDS accurately and timely.

Subpart 304.13—Personal Identity Verification

304.1300 Policy.

To ensure compliance with Homeland Security Presidential Directive-12: Policy for a Common Identification Standard for Federal Employees and Contractors (HSPD–12) and the Presidential Cross Agency Priority for strong authentication, contracting officers shall provide in each acquisition those HSPD–12 requirements necessary for contract performance.

Subpart 304.16—Unique Procurement Instrument Identifiers

304.1600 Scope of subpart.

This subpart provides guidance for assigning identification numbers to solicitation or contract actions. The Senior Procurement Executive shall be responsible for establishing a numbering system within the department that conforms to Federal Acquisition Regulation (FAR) subpart 4.16.

Subpart 304.70—[Reserved]

Subpart 304.71—Review and Approval of Proposed Contract Actions

304.7100 Policy.

In accordance with HHS delegated acquisition authority, the FAR, this regulation, internal policies and guidance, the head of the contracting activity (non-delegable) shall establish review and approval procedures for proposed contract actions to ensure that—

(a) Contractual documents are in conformance with law, established policies and procedures, and sound business practices;

(b) Contract actions properly reflect the mutual understanding of the parties; and

(c) The contracting officer is informed of deficiencies and items of questionable acceptability, and takes corrective action.

Subpart 304.72—Affordable Care Act Prevention and Public Health Fund—Reporting Requirements

304.7200 Scope of subpart.

This subpart implements Section 220 of Public Law 112–74, FY 2012 Labor, HHS and Education Appropriations Act, which requires, semi-annual reporting on the use of funds from the Prevention and Public Health Fund (PPHF), Public Law 111–148, sec. 4002. Contractors that receive awards (or modifications to existing awards) with a value of $25,000 or more funded, in whole or in part, from the PPHF, shall report information specified in the clause at 352.204–70, Prevention and Public Health Fund—Reporting Requirements, including, but not limited to—

(a) The dollar amount of contractor invoices;

(b) The supplies delivered and services performed; and

(c) Specific information on subcontracts with a value of $25,000 or more.

304.7201 Procedures.

(a) In any contract action funded in whole or in part by the PPHF, the

contracting officer shall indicate that the contract action is being made under the PPHF, and indicate which products or services are funded under the PPHF. This requirement applies whenever PPHF funds are used, regardless of the contract instrument.

(b) To maximize transparency of PPHF funds that shall be reported by the contractor, the contracting officer shall structure contract awards to allow for separately tracking PPHF funds. For example, the contracting officer may consider awarding dedicated separate contracts when using PPHF funds or establishing contract line item number structures to prevent commingling of PPHF funds with other funds.

(c) Contracting officers shall ensure that the contractor complies with the reporting requirements of 352.204–70. Upon receipt of each report, the contracting officer shall review it for completeness, address any clarity or completeness issues with the contractor, and submit the final approved report in Section 508 compliant format to an Assistant Secretary for Public Affairs point-of-contact for posting on HHS' PPHF Web site at *http://www.hhs.gov/open/prevention/index.html* no later than 30 days after the end of the reporting period. If the contractor fails to comply with the reporting requirements, the contracting officer shall exercise appropriate contractual remedies.

(d) The contracting officer shall make the contractor's failure to comply with the reporting requirements a part of the contractor's performance information under FAR subpart 42.15.

304.7202 Contract clause.

Insert the clause at 352.204–70, Prevention and Public Health Fund—Reporting Requirements, in all solicitations and contract actions funded in whole or in part with PPHF funds, except classified solicitations and contracts. This includes, but is not limited to, awarding or modifying orders against existing or new contracts issued under FAR subparts 8.4 and 16.5 that will be funded with PPHF funds. Contracting officers shall include this clause in any existing contract or order that will be funded with PPHF funds. This clause is not required for any contract or order which contains a prior version of the clause at 352.204–70.

SUBCHAPTER B—COMPETITION AND ACQUISITION PLANNING

PART 305—PUBLICIZING CONTRACT ACTIONS

Subpart 305.3—Synopses of Contract Awards

Sec.
305.303 Announcement of contract awards.

Subpart 305.5—Paid Advertisements

305.502 Authority.

Subpart 305.70—Publicizing Requirements Funded From the Affordable Care Act Prevention and Public Health Fund

305.7001 Scope.
305.7002 Applicability.
305.7003 Publicizing preaward.
305.7004 Publicizing postaward.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 305.3—Synopses of Contract Awards

305.303 Announcement of contract awards.

(a) *Public announcement.* The contracting officer shall report awards, not exempt under Federal Acquisition Regulation (FAR) 5.303, to the Office of the Assistant Secretary for Legislation (Congressional Liaison Office.)

Subpart 305.5—Paid Advertisements

305.502 Authority.

Written approval at least one level above the contracting officer shall be obtained prior to placing advertisements or notices in newspapers.

Subpart 305.70—Publicizing Requirements Funded From the Affordable Care Act Prevention and Public Health Fund

305.7001 Scope.

Pursuant to appropriations acts, this subpart prescribes requirements for posting presolicitation and award notices for actions funded in whole or in part from the Prevention and Public Health Fund (PPHF). The requirements of this subpart enhance transparency to the public.

305.7002 Applicability.

This subpart applies to all actions funded in whole or in part by the PPHF.

305.7003 Publicizing preaward.

Notices of all proposed contract actions, funded in whole or in part by the PPHF, shall be identified on HHS' Prevention and Public Health Fund Web site at *http://www.hhs.gov/open/prevention/index.html* no later than 1-day after issuance of the solicitation or other request for proposal or quotation document. When applicable, the notice shall provide a link to the full text; for example, a link to the FedBizOpps notice required by FAR 5.201.

305.7004 Publicizing postaward.

Notices of contract actions exceeding $25,000, funded in whole or in part by the PPHF, shall be identified on HHS' PPHF Web site at *http://www.hhs.gov/open/prevention/index.html* no later than 5 days after the contract action occurs.

PART 306—COMPETITION REQUIREMENTS

Subpart 306.2—Full and Open Competition After Exclusion of Sources

Sec.
306.202 Establishing or maintaining alternative sources.

Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.
306.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements.

Subpart 306.5—Competition Advocates

306.501 Requirement.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 306.2—Full and Open Competition After Exclusion of Sources

306.202 Establishing or maintaining alternative sources.

(a) The Senior Procurement Executive (SPE) shall make the determination required in Federal Acquisition Regulation (FAR) 6.202(a).

(b)(1) The contracting officer shall prepare the required determination and findings (D&F), see FAR 6.202(b)(1), based on the data provided by program personnel. The appropriate Competition Advocate (CA) (non-delegable) shall sign the D&F, indicating concurrence. The final determination will be made by the SPE.

Subpart 306.3—Other Than Full and Open Competition

306.302 Circumstances permitting other than full and open competition.

306.302–1 Only one responsible source and no other supplies or services will satisfy agency requirements. See FAR 6.302–1.

For acquisitions covered by 42 U.S.C. 247d–6a(b)(2)(A), ''available from only one responsible source'' shall be deemed to mean ''available from only one responsible source or only from a limited number of responsible sources''.

Subpart 306.5—Competition Advocates

306.501 Requirement.

The Department Competition Advocate for Health and Human Services is located in the Division of Acquisition.

PART 307—ACQUISITION PLANNING

Sec.
307.105 Contents of written acquisition plans.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

307.105 Contents of written acquisition plans.

Federal Acquisition Regulation 7.105 specifies the content requirements for a written Acquisition Plan (AP). The Department of Health and Human Services requires a written AP for all acquisitions above the simplified acquisition threshold.

PART 308—REQUIRED SOURCES OF SUPPLIES AND SERVICES

Subpart 308.4—Federal Supply Schedules

Sec.
308.405–6 Limited source justification and approval.

Subpart 308.8—Acquisition of Printing and Related Supplies

308.800 Scope of subpart.
308.801 Definitions.
308.802 Policy.
308.803 Solicitation provision and contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 308.4—Federal Supply Schedules

308.405–6 Limited source justification and approval.

(d)(1) As required by Federal Acquisition Regulation (FAR) 8.405–1 or 8.405–2, the responsible program office must provide a written justification for an acquisition under the Federal Supply Service program that restricts the number of schedule contractors or when procuring an item peculiar to one manufacturer.

Subpart 308.8—Acquisition of Printing and Related Supplies

308.800 Scope of subpart.

This subpart provides the Department of Health and Human Services (HHS) policy for the acquisition of Government printing and related supplies. The HHS Office of the Assistant Secretary for Public Affairs is responsible for the review and clearance of print and electronic publications, printing and related supplies, audiovisual products, and communication service contracts. See FAR 8.802 for exceptions.

308.801 Definitions.

The terms ''printing'' and ''duplicating/copying'' are defined in the Government Printing and Binding Regulations of the Joint Committee on Printing. The regulations are available at *http://www.gpo.gov*.

308.802 Policy.

In accordance with FAR 8.802(b), the Central Printing and Publications Management Organization at Program Support Center is the HHS designated central printing authority.

308.803 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.208–70, Printing and Duplication, in all solicitations, contracts, and orders over the simplified acquisition threshold, unless printing or increased duplication is authorized by statute.

PART 309—CONTRACTOR QUALIFICATIONS

Subpart 309.4—Debarment, Suspension, and Ineligibility

Sec.
309.403 Definitions.
309.404 System for Award Management (SAM) exclusions.
309.405 Effect of listing (compelling reason determinations).
309.406 Debarment.
309.406–3 Procedures.
309.407 Suspension.
309.407–3 Procedures.
309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions.
309.470–1 Situations where reports are required.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 309.4 Debarment, Suspension, and Ineligibility

309.403 Definitions.

The following definition applies to this subpart:

The HHS Suspension and Debarment Official is the Deputy Assistant Secretary (DAS) for the Office of Grants and Acquisition Policy and Accountability (OGAPA).

309.404 System for Award Management (SAM) exclusions.

(c) For actions made by HHS pursuant to FAR 9.406 and 9.407, the Office of Recipient Integrity Coordination shall perform the actions required by FAR 9.404(c).

309.405 Effect of listing (compelling reason determinations).

(a) The head of the contracting activity (HCA) (non-delegable) may, with the written concurrence of the Suspension and Debarment Official, make the determinations referenced in FAR 9.405(a) regarding contracts.

(1) If a contracting officer considers it necessary to award a contract, or consent to a subcontract with a debarred or suspended contractor, the contracting officer shall prepare a determination, including all pertinent documentation, and submit it through appropriate acquisition channels to the HCA. The documentation shall include the date by which approval is required and a compelling reason for the proposed action. Compelling reasons for award of a contract or consent to a subcontract with a debarred or suspended contractor include the following:

(i) Only the cited contractor can provide the property or services, and

(ii) The urgency of the requirement dictates that HHS conduct business with the cited contractor.

(2) If the HCA decides to approve the requested action, the HCA shall request the concurrence of the Suspension and Debarment Official and, if given, shall inform the contracting officer in writing of the determination within the required time period.

309.406 Debarment.

309.406–3 Procedures.

Refer all matters appropriate for consideration by an agency Suspension and Debarment Official as soon as practicable to the appropriate Suspension and Debarment Official identified in 309.403. Any person may refer a matter to the Suspension and Debarment Official.

309.407 Suspension.

309.407–3 Procedures.

Refer all matters appropriate for consideration by an agency Suspension and Debarment Official as soon as practicable to the appropriate Suspension and Debarment Official identified in 309.403. Any person may refer a matter to the Suspension and Debarment Official.

309.470 Reporting of suspected causes for debarment or suspension or the taking of evasive actions.

309.470–1 Situations where reports are required.

The contracting officer shall report to the HCA and the Associate Deputy

Assistant Secretary—Acquisition whenever the contracting officer—

(a) Knows or suspects that a contractor is committing or has committed any of the acts described in FAR 9.406–2 or 9.407–2; or

(b) Suspects a contractor is attempting to evade the prohibitions of debarment or suspension imposed under FAR 9.405, or any other comparable regulation, by changes of address, multiple addresses, formation of new companies, or by other devices.

PART 310—MARKET RESEARCH

Sec.
310.001 Policy.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

310.001 Policy.

Market research shall be conducted as prescribed in Federal Acquisition Regulation part 10.

PART 311—DESCRIBING AGENCY NEEDS

Subpart 311.70—Section 508 Accessibility Standards

Sec.
311.7000 Defining electronic information technology requirements.

Subpart 311.71—Public Accommodations and Commercial Facilities

311.7100 Policy.
311.7101 Responsibilities.
311.7102 Contract clause.

Subpart 311.72—Conference Funding and Sponsorship

311.7200 Policy.
311.7201 Funding and sponsorship.
311.7202 Contract clause.

Subpart 311.73—Contractor Collection of Information

311.7300 Policy.
311.7301 Contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 311.70—Section 508 Accessibility Standards

311.7000 Defining electronic and information technology requirements.

The contracting officer shall ensure that requiring activities specify agency needs for electronic and information technology (EIT) supplies and services, and document market research, document EIT requirements, and identify the applicable Section 508 accessibility standards. See FAR 11.002(f) and HHSAR subpart 339.2.

Subpart 311.71—Public Accommodations and Commercial Facilities.

311.7100 Policy.

(a) It is HHS policy that all contractors comply with current and any future changes to 28 CFR part 36—Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities. For the purpose of this policy, accessibility is defined as both physical access to public accommodations and commercial facilities, and access to aids and services enabling individuals with sensory disabilities to fully participate in events in public accommodations and commercial facilities.

(b) This policy applies to all contracts requiring contractors to conduct events in public accommodations and commercial facilities open to the public or involving HHS personnel, but not ad hoc meetings necessary or incidental to contract performance.

311.7101 Responsibilities.

The contractor shall submit a plan assuring that any event held will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36. A consolidated or master plan for contracts requiring numerous events in public accommodations and commercial facilities is acceptable.

311.7102 Contract clause.

The contracting officer shall insert the clause at 352.211–1, Public Accommodations and Commercial Facilities, in solicitations, contracts, and orders requiring the contractor to conduct events in accordance with 311.7100(b).

Subpart 311.72—Conference Funding and Sponsorship

311.7200 Policy.

HHS policy requires that all conferences the agency funds or sponsors shall: be consistent with HHS missions, objectives, and policies; represent an efficient and effective use of taxpayer funds; and withstand public scrutiny.

311.7201 Funding and sponsorship.

Funding a conference through a HHS contract does not automatically imply HHS sponsorship, unless the conference is funded entirely by the agency. Also, HHS staff attendance or participation at a conference does not imply HHS conference sponsorship. Accordingly, for non-conference contracts funded entirely by HHS prior to a contractor claiming HHS sponsorship, the contractor must provide the contracting officer a written request for permission to designate HHS the conference sponsor. The OPDIV or STAFFDIV (operating division or staff division) head, or designee, shall approve such requests. The determination on what constitutes a ''conference contract'' or a ''non-conference contract'' shall be made by the contracting officer.

311.7202 Contract clause.

To ensure that a contractor:

(a) Properly requests approval to designate HHS the conference sponsor, where HHS is not the sole provider of conference funding; and

(b) Includes an appropriate Federal funding disclosure and content disclaimer statement for conference materials, the contracting officer shall include the clause at 352.211–2, Conference Sponsorship Request and Conference Materials Disclaimer, in solicitations, contracts, and orders providing funding which partially or fully supports a conference.

Subpart 311.73—Contractor Collection of Information

311.7300 Policy.

In accordance with the Paperwork Reduction Act (PRA), contractors shall not proceed with collecting information from surveys, questionnaires, or interviews until the COR obtains an Office of Management and Budget clearance and the contracting officer issues written approval to proceed. For any contract involving a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal Government or disclosure to third parties, the contracting officer must comply with the PRA of 1995 (44 U.S.C. 3501 *et seq.*).

311.7301 Contract clause.

The contracting officer shall insert the clause at 352.211–3, Paperwork Reduction Act, in solicitations, contracts, and orders that require a contractor to collect the same information from 10 or more persons.

PART 312—ACQUISITION OF COMMERCIAL ITEMS

Subpart 312.1—Acquisition of Commercial Items—General

Sec.
312.101 Policy.

Subpart 312.2—Special Requirements for the Acquisition of Commercial Items

312.202(d) Market research and description of agency need.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 312.1—Acquisition of Commercial Items—General

312.101 Policy.

Contracting offices shall use the HHS Smarter Buying Program to the maximum extent practicable. See HHS Acquisition Regulation part 307, Acquisition Planning.

Subpart 312.2—Special Requirements for the Acquisition of Commercial Items

312.202(d) Market research and description of agency need.

Whenever a requiring activity specifies electronic and information technology (EIT) supplies and services subject to Section 508 of the Rehabilitation Act of 1973, as amended, the requiring activity shall acquire commercially available supplies and services to the maximum extent possible while ensuring Section 508 compliance. See part 339.

SUBCHAPTER C—CONTRACTING METHODS AND CONTRACT TYPES

PART 313—SIMPLIFIED ACQUISITION PROCEDURES

Sec.

313.003 Policy.

Subpart 313.3—Simplified Acquisition Methods

313.301 Government-wide commercial purchase card.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

313.003 Policy.

Electronic and information technology (EIT) supplies and services acquired pursuant to Federal Acquisition Regulation part 13 shall comply with Section 508 of the Rehabilitation Act of 1973, as amended. See part 339.

Subpart 313.3—Simplified Acquisition Methods

313.301 Government-wide commercial purchase card.

(b) Make all HHS transactions utilizing the government-wide commercial purchase card in accordance with the HHS Purchase Card Program.

PART 314—SEALED BIDDING

Subpart 314.1—Use of Sealed Bidding

Sec.

314.103 Policy.

Subpart 314.4—Opening of Bids and Award of Contract

314.404 Rejection of bids.
314.404–1 Cancellation of invitations after opening.
314.407 Mistakes in bids.
314.407–3 Other mistakes disclosed before award.
314.407–4 Mistakes after award.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 314.1—Use of Sealed Bidding

314.103 Policy.

Electronic and information technology (EIT) supplies and services acquired using sealed-bid procedures shall comply with Section 508 of the Rehabilitation Act of 1973, as amended. See part 339.

Subpart 314.4—Opening of Bids and Award of Contract

314.404 Rejection of bids.

314.404–1 Cancellation of invitations after opening.

(c) The head of the contracting activity (HCA) shall make the determinations specified in FAR 14.404–1(c).

314.407 Mistakes in bids.

314.407–3 Other mistakes disclosed before award.

(e) The HCA has the authority to make determinations under paragraphs (a), (b), (c), and (d) of FAR 14.407–3.

314.407–4 Mistakes after award.

(c) The HCA has the authority to make administrative determinations in connection with alleged post-award mistakes.

PART 315—CONTRACTING BY NEGOTIATION

Subpart 315.2—Solicitation and Receipt of Proposals and Information

Sec.

315.204–5 Part IV—Representations and instructions.
315.208 Submission, modification, revision, and withdrawal of proposals.

Subpart 315.3—Source Selection

315.303–70 Policy.
315.304 Evaluation factors and significant subfactors.
315.305 Proposal evaluation.

Subpart 315.4—Contract Pricing

315.404 Proposal analysis.
315.404–2 Information to support proposal analysis.

Subpart 315.6—Unsolicited Proposals

315.605 Content of unsolicited proposals.
315.606 Agency procedures.
315.606–1 Receipt and initial review.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 315.2—Solicitation and Receipt of Proposals and Information

315.204–5 Part IV—Representations and instructions.

(c) *Section M, Evaluation factors for award.* (1) The requiring activity shall develop technical evaluation factors and submit them to the contracting officer as part of the acquisition plan or other acquisition request documentation for inclusion in a solicitation. The requiring activity shall indicate the relative importance or weight of the evaluation factors based on the requirements of an individual acquisition.

(2) Only a formal amendment to a solicitation can change the evaluation factors.

315.208 Submission, modification, revision, and withdrawal of proposals.

(b) In addition to the provision in Federal Acquisition Regulation (FAR) 52.215–1, Instructions to Offerors—Competitive Acquisition, if the head of the contracting activity (HCA) determines that biomedical or behavioral research and development (R&D) acquisitions are subject to conditions other than those specified in FAR 52.215–1(c)(3), the HCA may authorize for use in competitive solicitations for R&D, the provision at 352.215–70, Late Proposals and Revisions. This is an authorized FAR deviation.

(2) When the provision at 352.215–70 is included in the solicitation and if the HCA intends to consider a proposal or proposals received after the exact time specified for receipt, the contracting officer, with the assistance of cost or technical personnel as appropriate, shall determine in writing that the proposal(s) meets the requirements of the provision at 352.215–70.

Subpart 315.3—Source Selection

315.303–70 Policy.

(a) If an operating division (OPDIV) is required by statute to use peer review for technical review of proposals, the requirements of those statutes, any implementing regulatory requirements, the Federal Advisory Committee Act, and as applicable, any approved Department of Health and Human Services Acquisition Regulation (HHSAR) deviation(s) from this subpart take precedence over the otherwise applicable requirements of this subpart.

(b) The statutes that require such review and implementing regulations are as follows: National Institutes of Health—42 U.S.C. 289a, Peer Review

Requirements and 42 CFR part 52h, Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects; Substance Abuse and Mental Health Services Administration—42 U.S.C. 290aa–3, Peer Review and Agency for Healthcare Research and Quality—42 U.S.C. 299c–1, Peer review with respect to grants and contracts.

315.304 Evaluation factors and significant subfactors.

When acquiring electronic and information technology supplies and services (EIT) using negotiated procedures, contracting officers shall comply with Section 508 of the Rehabilitation Act of 1973, as amended.

315.305 Proposal evaluation.

(c) *Use of non-Federal evaluators.* (1) Except when peer review is required by statute as provided in 315.303–70(a), decisions to disclose proposals to non-Federal evaluators shall be made by the official responsible for appointing Source Selection Evaluation Team members in accordance with OPDIV procedures. The avoidance of organizational and personal conflicts of interest must be taken into consideration when making the decision to use non-Federal evaluators.

(2) When a solicited proposal will be disclosed outside the Government to a contractor or a contractor employee for evaluation purposes, the following or similar conditions shall be part of the written agreement with the contractor prior to disclosure:

CONDITIONS FOR EVALUATING PROPOSALS

The contractor agrees that it and its employees, as well as any subcontractors and their employees (in these conditions, ''evaluator'') will use the data (trade secrets, business data, and technical data) contained in the proposal for evaluation purposes only. The foregoing requirement does not apply to data obtained from another source without restriction. Any notice or legend placed on the proposal by either HHS or the offeror shall be applied to any reproduction or abstract provided to the evaluator or made by the evaluator. Upon completion of the evaluation, the evaluator shall return to the Government the furnished copy of the proposal or abstract, and all copies thereof, to the HHS office which initially furnished the proposal for evaluation. The evaluator shall not contact the offeror concerning any aspects of a proposal's contents.

Subpart 315.4—Contract Pricing

315.404 Proposal analysis.

315.404–2 Information to support proposal analysis.

(a)(2) When some or all information sufficient to determine the reasonableness of the proposed cost or price is already available or can be obtained from the cognizant audit agency, or by other means including data obtained through market research (See FAR part 10 and HHSAR part 310) the contracting officer may request less-than-complete field pricing support (specifying in the request the information needed) or may waive in writing the requirement for audit and field pricing support by documenting the file to indicate what information will be used. When field-pricing support is required, contracting officers shall make the request through the HCA.

Subpart 315.6—Unsolicited Proposals

315.605 Content of unsolicited proposals.

(d) *Warranty by offeror.* To ensure against contacts between HHS personnel and prospective offerors that would exceed the limits of advance guidance set forth in FAR 15.604 and potentially result in an unfair advantage to an offeror, the prospective offeror of an unsolicited proposal must include the following warranty in any unsolicited proposal. Contracting officers receiving an unsolicited proposal without this warranty shall not process the proposal until the offeror is notified of the missing language and given an opportunity to submit a proper warranty. If no warranty is provided in a reasonable time, the contracting officer shall reject the unsolicited proposal, notify the offeror of the rejection, and document the actions in the file.

UNSOLICITED PROPOSAL

WARRANTY BY OFFEROR

This is to warrant that—

(a) This proposal has not been prepared under Government supervision;

(b) The methods and approaches stated in the proposal were developed by this offeror;

(c) Any contact with HHS personnel has been within the limits of appropriate advance guidance set forth in FAR 15.604; and,

(d) No prior commitments were received from HHS personnel regarding acceptance of this proposal.

Date: _____

Organization: _____

Name: _____

Title: _____

(This warranty shall be signed by a responsible management official of the proposing organization who is a person authorized to contractually obligate the organization.)

315.606 Agency procedures.

(a) The HCA is responsible for establishing procedures to comply with FAR 15.606(a).

(b) The HCA or designee shall be the point of contact for coordinating the receipt and processing of unsolicited proposals.

315.606–1 Receipt and initial review.

(d) OPDIVs may consider an unsolicited proposal even though an organization initially submitted it as a grant application. However, OPDIVs shall not award contracts based on unsolicited proposals that have been rejected for grant awards due to lack of scientific merit.

PART 316—TYPES OF CONTRACTS

Subpart 316.3—Cost-Reimbursement Contracts

Sec.
316.307 Contract clauses.

Subpart 316.5—Indefinite-Delivery Contracts

316.505 Ordering.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.
316.603–3 Limitations.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 316.3—Cost-Reimbursement Contracts

316.307 Contract clauses.

(a)(1) If a contract for research and development is with a hospital (profit or nonprofit), the contracting officer shall modify the ''Allowable Cost and Payment'' clause at FAR 52.216–7 by deleting from paragraph (a) the words ''Federal Acquisition Regulation (FAR) subpart 31.2'' and substituting ''45 CFR part 75.''

(2) The contracting officer shall also insert the clause at 352.216–70, Additional Cost Principles for Hospitals (Profit or Non-Profit), in solicitations and contracts with a hospital (profit or non-profit) when a cost-reimbursement contract is contemplated.

Subpart 316.5—Indefinite-Delivery Contracts

316.505 Ordering.

(b)(8) The Department of Health and Human Services (HHS) Competition Advocate is the task-order and delivery-

order ombudsman for the department. Ombudsmen for each of the HHS contracting activities shall be designated in writing by the head of the contracting activity. See part 306.

Subpart 316.6—Time-and-Materials, Labor-Hour, and Letter Contracts

316.603 Letter contracts.

316.603–3 Limitations.

An official one level above the contracting officer shall make the written determination, to be included in the contract file, that no other contract type is suitable and to approve all letter contract modifications. No letter contract or modification can exceed the limits prescribed in FAR 16.603–2(c).

PART 317—SPECIAL CONTRACTING METHODS

Subpart 317.1—Multi-Year Contracting

Sec.
317.104 General.
317.105 Policy.
317.105–1 Uses.
317.107 Options.
317.108 Congressional notification.

Subpart 317.2—Options

317.204 Contracts.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 317.1—Multi-Year Contracting

317.104 General.

(b) The Senior Procurement Executive (SPE) is the agency approving official for determinations under Federal Acquisition Regulation (FAR) 17.104(b).

317.105 Policy.

317.105–1 Uses.

(a) Each head of the contracting activity (HCA) determination to use multi-year contracting, as defined in FAR 17.103, is limited to individual acquisitions where the full estimated cancellation ceiling does not exceed 20 percent of the total contract value over the multi-year term or $12.5 million, whichever is less. Cancellation ceiling provisions shall conform to the requirements of FAR 17.106–1(c). The determination is not delegable and shall address the issues in FAR 17.105–1(a).

(b)(1) SPE approval is required for any—

(i) Individual determination to use multi-year contracting with a cancellation ceiling in excess of the limits in 317.105–1(a); or

(ii) Class determination (see FAR subpart 1.7).

(2) A determination involving a cancellation ceiling in excess of the limits in 317.105–1(a) shall present a well-documented justification for the estimated cancellation ceiling. When the estimated cancellation ceiling exceeds $12.5 million, the determination shall accompany a draft congressional notification letter pursuant to FAR 17.108 and 317.108.

317.107 Options.

When included as part of a multi-year contract, use of options shall not extend the performance of the original requirement beyond 5 years. Options may serve as a means to acquire related services (severable or non-severable) and, upon their exercise, shall receive funding from the then-current fiscal year's appropriation.

317.108 Congressional notification.

(a) The SPE shall give the approval of the written notification required by FAR 17.108(a). Upon approval of the determination required by 317.105–1(b)(1), the HCA will finalize and sign the congressional notification letter and provide it to the appropriate House and Senate committees.

Subpart 317.2—Options

317.204 Contracts.

(e)(1) *Information technology contracts.* Notwithstanding FAR 17.204(e), the 5-year limitations apply also to information technology contracts unless a longer period is authorized by statute.

(2) *Requests to exceed 5-year limitation.* A request to exceed the 5-year limitation specified in FAR 17.204(e) must follow guidance in FAR Part 1.7.

(3) *Approval authority.* All requests to exceed the 5-year limitations specified in FAR 17.204(e) must be supported with a Determination and Finding and approved by:

(i) The HCA; and

(ii) The HHS SPE.

SUBCHAPTER D—SOCIOECONOMIC PROGRAMS

PART 319—SMALL BUSINESS PROGRAMS

Subpart 319.2—Policies

Sec.
319.201 General policy.
319.270–1 Mentor Protégé Program Solicitation provision and contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 319.2—Policies

319.201 General policy.

(d) The functional management responsibilities for the Department of Health and Human Services' (HHS) small business program are delegated to the Office of Small and Disadvantaged Business Utilization (OSDBU) Director.

(e)(1) The HHS OSDBU Director shall exercise full management authority over the small business program. The small business specialist (SBS) shall review and make recommendations for all acquisitions, unless exempted by statute, that are not being set aside for small business in accordance with Federal Acquisition Regulation (FAR) 19.502. The review must take place prior to issuing the solicitation.

(2) Within the Indian Health Service (IHS), the primary SBSs are responsible for IHS' overall implementation of the HHS small business program; however, each IHS contracting office will assign a small business technical advisor (SBTA) to perform those functions and responsibilities necessary to implement the small business program. The primary IHS SBS shall assist and provide guidance to respective SBTAs.

319.270–1 Mentor Protégé Program Solicitation provision and contract clause.

(a) The contacting officer shall insert the provision at 352.219–70, Mentor-Protégé Program, in solicitations that include the clause at FAR 52.219–9, Small Business Subcontracting Plan. The provision requires offerors to provide the contracting officer a copy of their HHS Office of OSDBU-approved mentor-protégé agreement in response to a solicitation.

(b) The contacting officer shall insert the clause at 352.219–71, Mentor-Protégé Program Reporting Requirements, in contracts that include the clause at FAR 52.219–9, Small Business Subcontracting Plan, and which are awarded to a contractor with an HHS OSDBU-approved mentor-protégé agreement.

PART 322—APPLICATION OF LABOR LAWS TO GOVERNMENT ACQUISITIONS

Subpart 322.8—Equal Employment Opportunity

Sec.
322.810 Solicitation provisions and contract clauses.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 322.8—Equal Employment Opportunity

322.810 Solicitation provisions and contract clauses.

(h) The contracting officer shall insert the clause at 352.222–70, Contractor Cooperation in Equal Employment Opportunity Investigations, in

solicitations, contracts, and orders that include the clause at FAR 52.222–26, Equal Opportunity.

PART 323—ENVIRONMENT, ENERGY AND WATER EFFICIENCY, RENEWABLE ENERGY TECHNOLOGIES, OCCUPATIONAL SAFETY, AND DRUG-FREE WORKPLACE

Subpart 323.70—Safety and Health

Sec.
323.7000 Scope of subpart.
323.7001 Policy.
323.7002 Actions required.

Subpart 323.71—Sustainable Acquisition Requirements

323.7100 Policy.
323.7101 Applicability.
323.7102 Procedures.
323.7103 Solicitation Provision.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

323.7000 Scope of subpart.

This subpart provides procedures for administering safety and health requirements.

323.7001 Policy.

The contracting officer shall follow the guidance in this subpart when additional requirements for safety and health are necessary for an acquisition.

323.7002 Actions required.

Contracting activities. The contracting officer shall insert the clause at 352.223–70, Safety and Health, or a clause substantially the same, in solicitations and contracts that involve hazardous materials or hazardous operations for the following types of requirements:

(a) Services or products.

(b) Research, development, or test projects.

(c) Transportation of hazardous materials.

(d) Construction, including construction of facilities on the contractor's premises.

Subpart 323.71—Sustainable Acquisition Requirements

323.7100 Policy.

This subpart provides procedures for sustainable acquisitions and use of the following: Designated recycled content; energy efficient, environmentally preferred, Electronic Product Environmental Assessment Tool (EPEAT)-registered, bio-based, water efficient, non-ozone depleting products and services; and alternate fuel vehicles and fuels. The Department of Health and Human Services (HHS) has designated product and service codes for supplies and services having sustainable acquisition attributes. See FAR part 23.

323.7101 Applicability.

It is HHS policy to include a solicitation provision and to include an evaluation factor for an offeror's Sustainable Action Plan when acquiring sustainable products and services. This applies only to new contracts and orders above the micro-purchase threshold. Such contracts and orders include, but are not limited to: Office supplies; construction, renovation or repair; building operations and maintenance; landscaping services; pest management; electronic equipment, including leasing; fleet maintenance; janitorial services; laundry services; cafeteria operations; and meetings and conference services. If using a product or service code designated for supplies or services having sustainable acquisition attributes but a review of the requirement determines that no opportunity exists to acquire sustainable acquisition supplies or services, document the determination in the contract file and make note in the solicitation.

323.7102 Procedures.

(a) When required by the solicitation, offerors or quoters must include a Sustainable Acquisition Plan in their technical proposal addressing the environmental products and services for delivery under the resulting contract.

(b) The contracting officer shall incorporate the final Sustainable Acquisition Plan into the contract.

(c) The contracting officer shall ensure that sustainability is included as an evaluation factor in all applicable new contracts and orders when the acquisition utilizes a product or service code designated by HHS for supplies or services having sustainable acquisition attributes.

323.7103 Solicitation Provision.

The contracting officer shall insert the provision at 352.223–71, Instruction to Offerors—Sustainable Acquisition, in solicitations above the micro-purchase threshold when the acquisition utilizes a product or service code designated by HHS as having sustainable acquisition attributes.

PART 324—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Subpart 324.1—Protection of Individual Privacy

Sec.
324.103 Procedures for the Privacy Act.
324.104 Restrictions on Contractor Access to Government or Third Party Information.
324.105 Contract clauses.

Subpart 324.70—Health Insurance Portability and Accountability Act of 1996 (HIPAA)

324.7000 Scope of subpart.
324.7001 Policy on Compliance with HIPAA Business Associate Contract Requirements.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 324.1—Protection of Individual Privacy

324.103 Procedures for the Privacy Act.

(a) The contracting officer shall review all acquisition request documentation to determine whether the requirements of the Privacy Act of 1974 (5 U.S.C. 552a) are applicable. The Privacy Act requirements apply when a contract or order requires the contractor to design, develop, or operate any Privacy Act system of records on individuals to accomplish an agency function. When applicable, the contracting officer shall include the two Privacy Act clauses required by Federal Acquisition Regulation (FAR) 24.104 in the solicitation and contract or order. In addition, the contracting officer shall include the two FAR Privacy Act clauses, and other pertinent information specified in this subpart, in any modification which results in the Privacy Act requirements becoming applicable to a contract or order.

(b) The contracting officer shall ensure that the statement of work or performance work statement (SOW or PWS) specifies the system(s) of records or proposed system(s) of records to which the Privacy Act and the implementing regulations are applicable or may be applicable. The contracting officer shall send the contractor a copy of 45 CFR part 5b, which includes the rules of conduct and other Privacy Act requirements.

(c) The contracting officer shall ensure that the contract SOW or PWS specifies for both the Privacy Act and the Federal Records Act the disposition to be made of the system(s) of records upon completion of contract performance. The contract SOW or PWS may require the contractor to destroy the records, remove personal identifiers, or turn the records over to the contracting officer. If there is a legitimate need for a contractor to keep copies of the records after completion of a contract, the contractor must take measures, as approved by the contracting officer, to keep the records

confidential and protect the individuals' privacy.

(d) For any acquisition subject to Privacy Act requirements, the requiring activity prior to award shall prepare and have published in the **Federal Register** a ''system notice,'' describing the Department of Health and Human Services' (HHS) intent to establish a new system of records on individuals, to make modifications to an existing system, or to disclose information in regard to an existing system. The requiring activity shall attach a copy of the system notice to the acquisition plan or other acquisition request documentation. If a system notice is not attached, the contracting officer shall inquire about its status and shall obtain a copy from the requiring activity for inclusion in the contract file. If a notice for the system of records has not been published in the **Federal Register**, the contracting officer may proceed with the acquisition but shall not award the contract until the system notice is published and the contracting officer verifies its publication.

324.104 Restrictions on Contractor Access to Government or Third Party Information.

The contracting officer shall establish the restrictions that govern the contractor employees' access to Government or third party information in order to protect the information from unauthorized use or disclosure.

324.105 Contract clauses.

(a) The contracting officer shall insert the clause at 352.224–70, Privacy Act, in solicitations, contracts, and orders that require the design, development, or operation of a system of records to notify the contractor that it and its employees are subject to criminal penalties for violations of the Privacy Act (5 U.S.C. 552a(i)) to the same extent as HHS employees. The clause also requires the contractor to ensure each of its employees knows the prescribed rules of conduct in 45 CFR part 5b and each contractor employee is aware that he or she is subject to criminal penalties for violations of the Privacy Act. These requirements also apply to all subcontracts awarded under the contract or order that require the design, development, or operation of a system of records.

(b) The contracting officer shall insert the clause at 352.224–71, Confidential Information, in solicitations, contracts, and orders that require access to Government or to third party information.

Subpart 324.70—Health Insurance Portability and Accountability Act of 1996

324.7000 Scope of subpart.

All individually identifiable health information that is Protected Health Information (PHI), as defined in 45 CFR 160.103 shall be administered in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) implementing regulations at 45 CFR parts 160 and 164 (the HIPAA Privacy, Security, and Breach Notification Rules). The term ''HIPAA'' is used in this part to refer to title II, subtitle F of the HIPAA statute, at part C of title XI of the Social Security Act, 42 U.S.C. 1320d *et seq.,* section 264 of HIPAA, subtitle D of title XIII of the American Recovery and Reinvestment Act of 2009, and regulations under such provisions.

324.7001 Policy on Compliance with HIPAA business associate contract requirements.

(a) HHS is a HIPAA ''covered entity'' that is a ''hybrid entity'' as these terms are defined at sections 160.103 and 164.103 respectively. As such, only the portions of HHS that the Secretary has designated as ''health care components'' (HCC) as defined at section 164.103, are subject to HIPAA. HHS' HCCs may utilize persons or entities known as ''business associates,'' as defined at section 160.103. Generally, ''business associate'' means a ''person'' as defined by section 160.103 (including contractors, and third-party vendors, etc.) if or when the person or entity:

(1) Creates, receives, maintains, or transmits ''protected health information'', as the term is defined at section 160.103, on behalf of an HHS HCC to carry out HHS HIPAA ''covered functions'' as that term is defined at 164.103; or

(2) Provides certain services to an HHS HCC that involve PHI.

(b) Where the Department as a covered entity is required by 45 CFR 164.502(e)(1) and 164.504(e) and, if applicable, sections 164.308(b)(3) and 164.314(a), to enter into a HIPAA business associate contract, the relevant HCC contracting officer, acting on behalf of the Department, shall ensure that such contract meets the requirements at section 164.504(e)(2) and, if applicable, section 164.314(a)(2).

PART 326—OTHER SOCIOECONOMIC PROGRAMS

Subpart 326.5—Indian Preference in Employment, Training, and Subcontracting Opportunities

Sec.

326.501 Statutory requirements.
326.502 Definitions.
326.503 Compliance enforcement.
326.504 Tribal Preference requirement.
326.505 Applicability.

Subpart 326.6—Acquisitions Under the Buy Indian Act

326.600 Scope of subpart.
326.601 Policy.
326.602 Definitions.
326.603 Requirements.
326.604 Competition.
326.605 Responsibility determinations.

Subpart 326.7—Acquisitions Requiring the Native American Graves Protection and Repatriation Act

326.700 Scope of subpart.
326.701 Applicability.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 326.5—Indian Preference in Employment, Training, and Subcontracting Opportunities

326.501 Statutory requirements.

Any contract or subcontract pursuant to subchapter II, chapter 14, title 25 of the United States Code, the Act of April 16, 1934 (48 Stat. 596), as amended, or any other Act authorizing Federal contracts with or grants to Indian organizations or for the benefit of Indians, shall, to the greatest extent feasible, comply with section 7(b) of the Indian Self-Determination and Education Assistance Act, Public Law 93–638, 88 Stat. 2205, 25 U.S.C. 450e(b) which provides preferences and opportunities for training and employment in connection with the administration of such contracts, and preference in the award of subcontracts in connection with the administration of such contracts to Indian organizations and to Indian-owned economic enterprises as defined in section 1452 of title 25, United States Code.

326.502 Definitions.

For purposes of this subpart, the following definitions shall apply:

(a) *Indian* means a person who is a member of an Indian tribe. If the contractor has reason to doubt that a person seeking employment preference is an Indian, the contractor shall grant the preference but shall require the individual provide evidence within 30 days from the tribe concerned that the person is a member of the tribe.

(b) *Indian tribe* means an Indian tribe, pueblo, band, nation, or other organized group or community, including any Alaska Native Village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601), which the United

States recognizes as eligible for special programs and services because of its status as Indian.

(c) *Indian organization* means the governing body of any Indian tribe, or entity established or recognized by such governing body, in accordance with the Indian Financing Act of 1974 (88 Stat. 77, 25 U.S.C. 1451).

(d) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and the ownership shall encompass active operation and control of the enterprise.

(e) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601 *et seq.*).

(f) *On or near an Indian reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably commute to and from in the course of a work day.

326.503 Compliance enforcement.

The contracting officer shall promptly investigate and resolve written complaints of noncompliance with the requirements of the clauses at 352.226–1, Indian Preference and 352.226–2, Indian Preference Program filed with the contracting activity.

326.504 Tribal preference requirements.

(a) When the contractor will perform work under a contract on an Indian reservation, the contracting officer may supplement the clause at 352.226–2, Indian Preference Program by adding specific Indian preference requirements of the tribe on whose reservation the contractor will work. The contracting activity and the tribe shall jointly develop supplemental requirements for the contract. Supplemental preference requirements shall represent a further implementation of the requirements of section 7(b) of Public Law 93–638 and require the approval of the affected program director and the appropriate legal office, or a regional attorney, before the contracting officer adds them to a solicitation and resultant contract. Any supplemental preference requirements the contracting officer adds to the clause at 352.226–2, Indian Preference Program shall also clearly identify in the solicitation the additional requirements.

(b) Nothing in this part shall preclude tribes from independently developing and enforcing their own tribal preference requirements. Such independently-developed tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this subpart, and shall not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

326.505 Applicability.

The contracting officer shall insert the clause at 352.226–1, Indian Preference, and the clause at 352.226–2, Indian Preference Program, in contracts to implement section 7(b) of Public Law 93–638 for all Department of Health and Human Services (HHS) activities. Contracting activities shall use the clauses as follows, except for those exempted solicitations and contracts issued and or awarded pursuant to Title I of Public Law 93–638 (25 U.S.C. 450 *et seq.*):

(a) The contracting officer shall insert the clause at 352.226–1, Indian Preference, in solicitations, contracts, and orders when—

(1) The award is (or will be) pursuant to an act specifically authorizing such awards with Indian organizations; or

(2) The work is specifically for the benefit of Indians and is in addition to any incidental benefits which might otherwise accrue to the general public.

(b) The contracting officer shall insert the clause at 352.226–2, Indian Preference Program, in solicitations, contracts, and orders when—

(1) The dollar amount of the acquisition is expected to equal or exceed $650,000 for non-construction work or $1.5 million for construction work;

(2) The solicitation, contract, or order includes the Indian Preference clause; and

(3) The contracting officer makes the determination, prior to solicitation, that performance will take place in whole or in substantial part on or near an Indian reservation(s). In addition, the contracting officer may insert the Indian Preference Program clause in solicitations, contracts, and orders below the $650,000 or $1.5 million level for non-construction or construction contracts, respectively, but which meet the requirements of paragraphs (b)(2) and (3) of this section, and in the opinion of the contracting officer, offer substantial opportunities for Indian employment, training, and subcontracting.

Subpart 326.6—Acquisitions Under the Buy Indian Act

326.600 Scope of subpart.

This subpart sets forth the policy on preferential acquisition from Indians under the negotiation authority of the Buy Indian Act. This subpart applies only to acquisitions made by or on behalf of Indian Health Service (IHS).

326.601 Policy.

(a) IHS shall utilize the negotiation authority of the Buy Indian Act to give preference to Indians whenever authorized and practicable. The Buy Indian Act, 25 U.S.C. 47, prescribes the application of the advertising requirements of 41 U.S.C. 6101 to the acquisition of Indian supplies. As specified in 25 U.S.C. 47, the Buy Indian Act provides that, so far as practicable, the Government shall employ Indian labor and, at the discretion of the Secretary of the Interior, purchase products of Indian industry (including, but not limited to printing, notwithstanding any other law) from the open market.

(b) Due to the transfer of authority from the Department of the Interior to HHS, the Secretary of HHS may use the Buy Indian Act to acquire products of Indian industry in connection with the maintenance and operation of Indian hospital and health facilities, and for the overall conservation of Indian health. This authority is exclusively delegated to IHS and is not available for use by any other HHS component (unless that component makes an acquisition on behalf of IHS). However, the Buy Indian Act itself does not exempt IHS from meeting the statutorily mandated small business goals.

(c) Subsequent legislation, particularly Public Law 94–437 and Public Law 96–537, emphasize using the Buy Indian Act negotiation authority.

326.602 Definitions.

(a) *Buy Indian contract* means any contract involving activities covered by the Buy Indian Act and negotiated under the provisions of 41 U.S.C. 3104 and 25 U.S.C. 47 between an Indian firm and a contracting officer representing IHS.

(b) *Indian* means a member of any tribe, pueblo, band, group, village, or community recognized by the Secretary of the Interior as being Indian or any individual or group of individuals recognized by the Secretary of the Interior or the Secretary of HHS. The

Secretary of HHS in making determinations may take into account the determination of the tribe with which affiliation is claimed.

(c) *Indian firm* means a sole enterprise, partnership, corporation, or other type of business organization owned, controlled, and operated by:

(1) One or more Indians (including, for the purpose of sections 301 and 302 of Public Law 94–437, former or currently federally recognized Indian tribes in the State of New York); or

(2) By an Indian firm (as defined in paragraph (1) of this definition); or

(3) A nonprofit firm organized for the benefit of Indians and controlled by Indians (see 326.601(a)).

(d) *Product of Indian industry* means anything produced by Indians through either physical labor or intellectual effort involving the use and application of their skills. To classify as a product of Indian industry, the total cost of the item's production must equal or exceed 51 percent Indian effort.

326.603 Requirements.

(a) *Indian ownership.* Indian ownership shall constitute at least 51 percent of an Indian firm during the period covered by a Buy Indian contract.

(b) *Joint ventures.* An Indian firm may enter into a joint venture with other entities for specific projects as long as the Indian firm is the managing partner. However, the contracting officer shall approve the joint venture prior to the award of a contract under the Buy Indian Act.

(c) *Bonds.* In the case of contracts for the construction, alteration, or repair of public buildings or public works, the Miller Act (40 U.S.C. 3131 *et seq.*) and Federal Acquisition Regulation (FAR) part 28 require performance and payment bonds. Bonds are not required in the case of contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe. However, bonds are required when dealing with private business entities owned by an Indian tribe or members of an Indian tribe. The contracting officer may require bonds of private business entities that are joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe. A bid guarantee or bid bond is required only when a performance or payment bond is required.

(d) *Indian preference in employment, training and subcontracting.* Contracts awarded under the Buy Indian Act are subject to the requirements of section 7(b) of the Indian Self-Determination and Education Assistance Act 25 U.S.C. 450e, which requires giving preference to Indians in employment, training, and subcontracting. The contracting officer shall include the Indian Preference clause specified at 326.505(a) in all Buy Indian solicitations and resultant contracts. The contracting officer shall use the Indian Preference Program clause specified at 326.505(b). The contracting officer shall follow all requirements specified in subpart 326.2 which apply to a Buy Indian acquisition (*e.g.,* 326.604 and 326.605).

(e) *Subcontracting.* A contractor shall not subcontract more than 50 percent of the work under a prime contract awarded pursuant to the Buy Indian Act to non-Indian firms. For this purpose, contract work does not include the provision of materials, supplies, or equipment.

(f) *Wage rates.* The contracting officer shall include a determination of the minimum wage rates by the Secretary of Labor as required by the Davis-Bacon Act (40 U.S.C. 276a) in all contracts awarded under the Buy Indian Act for over $2,000 for construction, alteration, or repair, including painting and decorating, of public buildings and public works, except contracts with Indian tribes or public nonprofit organizations serving as governmental instrumentalities of an Indian tribe.

The contracting officer shall include the wage rate determination in contracts with private business entities, even when owned by an Indian tribe or a member of an Indian tribe and in connection with joint ventures with, or subcontractors of, an Indian tribe or a public nonprofit organization serving as a governmental instrumentality of an Indian tribe.

326.604 Competition.

(a) Contracts awarded under the Buy Indian Act are subject to competition among Indians or Indian firms to the maximum extent practicable. When the contracting officer determines that competition is not practicable, a justification and approval is required in accordance with subpart 306.3.

(b) The contracting officer shall: Synopsize and publicize solicitations in the Government point of entry and provide copies of the synopses to the tribal office of the Indian tribal government directly concerned with the proposed acquisition as well as to Indian firms and others having a legitimate interest. The synopses shall state that the acquisitions are restricted to Indian firms under the Buy Indian Act.

326.605 Responsibility determinations.

(a) The contracting officer may award a contract under the Buy Indian Act only if it is determined that the contractor will likely perform satisfactorily and properly complete or maintain the contracted project or function.

(b) The contracting officer shall make the written determination specified in paragraph (a) of this section prior to the award of a contract. The determination shall reflect an analysis of FAR 9.104–1 standards.

Subpart 326.7—Acquisitions Requiring the Native American Graves Protection and Repatriation Act

326.700 Scope of subpart.

Public Law 101–601, dated November 16, 1990, also known as the Native American Graves Protection and Repatriation Act, imposes certain responsibilities on individuals and organizations when they discover Native American cultural items (including human remains) on Federal or tribal lands.

326.701 Applicability.

The contracting officer shall insert the clause at 352.226–3, Native American Graves Protection and Repatriation Act, in solicitations, contracts, and orders requiring performance on tribal lands or those for construction projects on Federal or tribal lands.

SUBCHAPTER E—GENERAL CONTRACTING REQUIREMENTS

PART 327—PATENTS, DATA, AND COPYRIGHTS

Subpart 327.3—Patent Rights Under Government Contracts

Sec.
327.303 Solicitation provision and contract clause.

Subpart 327.4—Rights in Data and Copyrights

327.404–70 Solicitation provision and contract clause.
327.409 Solicitation provision and contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 327.3—Patent Rights Under Government Contracts

327.303 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.227–11, Patent Rights—Exceptional Circumstances and any appropriate alternates in lieu of Federal Acquisition Regulation (FAR) 52.227–11 whenever a Determination of

Exceptional Circumstances (DEC) involving the provision of materials that has been executed in accordance with Agency policy and procedures calls for its use and the clause at 352.227–11, Patent Rights—Exceptional Circumstances, appropriately covers the circumstances. The contracting officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.

Subpart 327.4—Rights in Data and Copyrights

327.404–70 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.227–70, Publications and Publicity, in solicitations, contracts, and orders that involve requirements which could lead to the contractor's publishing the results of its work under the contract.

327.409 Solicitation provision and contract clause.

The contracting officer shall insert the clause at 352.227–14, Rights in Data—Exceptional Circumstances, and any appropriate alternates in lieu of the FAR clause at 52.227–14, Rights in Data-General, whenever a DEC executed in accordance with Agency policy and procedures calls for its use. Prior to using this clause, a DEC must be executed in accordance with Agency policy and procedures. The contracting officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.

PART 328—[RESERVED]

PART 330—COST ACCOUNTING STANDARDS

Subpart 330.2—CAS Program Requirements

Sec.
330.201 Contract requirements.
330.201–5 Waiver.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 330.2—CAS Program Requirements

330.201 Contract requirements.

330.201–5 Waiver.

The Senior Procurement Executive (SPE) shall exercise the waiver authority under Federal Acquisition Regulation 30.201–5(a)(2). Operating Divisions and Staff Divisions shall forward waiver requests to the SPE.

PART 331—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 331.1—Applicability

Sec.
331.101–70 Salary rate limitation.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 331.1—Applicability

331.101–70 Salary rate limitation.

(a) Beginning in fiscal year 1990, Congress has stipulated in the Department of Health and Human Services appropriations acts and continuing resolutions that, under applicable contracts, appropriated funds cannot be used to pay the direct salary of an individual above the stipulated rates. The applicable rates for each year are identified at *www.opm.gov*.

(b) The contracting officer shall insert the clause at 352.231–70, Salary Rate Limitation, in solicitations and contracts when a cost-reimbursement; fixed-price level-of-effort; time-and-materials; or labor-hour contract is contemplated.

PART 332—CONTRACT FINANCING

Subpart 332.4—Advance Payments for Non-Commercial Items

Sec.
332.402 General.
332.407 Interest.

Subpart 332.5—Progress Payments Based on Cost

332.501 General.
332.501–2 Unusual progress payments.

Subpart 332.7—Contract Funding

332.702 Policy.
332.703 Contract funding requirements.
332.703–1 General.
332.703–71 Incrementally funded cost-reimbursement contracts.
332.703–72 Incremental Funding Table.
332.706 Solicitation provision and contract clauses.
332.706–2 Provision and clauses for limitation of cost or funds.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 332.4—Advance Payments for Non-Commercial Items

332.402 General.

(e) The head of the contracting activity (HCA) (non-delegable) shall make determinations related to advanced payments and assure compliance with FAR 32.402.

332.407 Interest.

(d) The HCA (non-delegable) shall make the determinations in FAR 32.407(d).

Subpart 332.5—Progress Payments Based on Cost

332.501 General.

332.501–2 Unusual progress payments.

(a)(3) The HCA (non-delegable) shall approve unusual progress payments.

Subpart 332.7—Contract Funding

332.702 Policy.

Departmental employees shall report any suspected violation of the Anti-Deficiency Act (31 U.S.C. 1341, 13 U.S.C. 1342, and 31 U.S.C. 1517) immediately to the Operating Division's Chief Financial Officer (CFO), who in turn will report the matter to the HHS Deputy CFO.

332.703 Contract funding requirements.

332.703–1 General.

(b) The following requirements govern all solicitations and contracts using incremental funding, as appropriate:

(1) The contracting officer shall consider the estimated total cost of the contract, including all planned increments of performance when determining the requirements that must be met before contract execution (*e.g.,* Justification and Approvals, clearances, and approvals).

(2) The solicitation and resultant contract shall include a statement of work or performance work statement that describes the total project, covers all proposed increments of performance, and contains a schedule of planned increments of performance. No funding increment may exceed 1 year, and the services rendered during each increment of performance must provide a specific material benefit that can stand alone if the remaining effort is not funded. The resultant contract shall also include the corresponding amount of funds planned for obligation for each increment of performance.

(3) The contracting officer shall request that offerors respond to the solicitation with technical and cost proposals for the entire project, and shall require distinct technical and cost break-outs of the planned increments of performance.

(4) Proposals shall be evaluated and any discussions and negotiations shall be conducted based upon the total project, including all planned increments of performance.

332.703–71 Incrementally funded cost-reimbursement contracts.

Incremental funding may be used in cost-reimbursement contracts for severable services only when all of the following circumstances are present:

(a) Funding of increments after the initial increment of performance is provided from the appropriation account available for obligation at that time;

(b) The project represents a *bona fide* need of the fiscal year in which the contract is awarded and initially funded (*i.e.,* the initial increment of performance) and is also a *bona fide* need of each subsequent fiscal year whose appropriation will be used; and

(c) The project's significance provides reasonable assurance that subsequent year appropriations will be made available to fund the project's continuation and completion.

332.703–72 Incremental Funding Table.

(a) The contracting officer shall insert substantially the following language in Section B: Supplies or Services and Prices or Costs, Table 1, in all cost-reimbursement contracts for severable services using incremental funding. The language requires the contracting officer to:

(1) Insert the initial funding obligated by the award;

(2) Identify the increment of performance covered by the funding provided; and

(3) Specify the start and end dates for each increment of performance, as required by the ''Limitation of Funds'' clause at FAR 52.232–22.

(b) Modification of the language is permitted to fit specific circumstances of the contract, including but not limited to language necessary to reflect the specific type of cost reimbursement contract awarded, but the language may not be omitted completely.

Table 1—B. ____Estimated Cost—Incrementally Funded Contract

(a) The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is $____ [*insert full amount*].

(b) The following represents the schedule* by which the Government expects to allot funds to this contract:

CLIN, task number, or description	Start date of increment of performance	End date of increment of performance	Estimated cost ($)	Fee ($) (as appropriate)	Estimated cost plus fee ($) (as appropriate)
	.....	.....	.....	.....	
	.....	.....	.....	.....	
	.....	.....	.....	.....	
	.....	.....	.....	.....	
	.....	.....	.....	.....	
	.....	.....	[Total]	[Total]	[Total]

* To be inserted after negotiation

(c) Total funds currently obligated and available for payment under this contract are $____ [*insert amount funded to date*].

(d) The contracting officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs (b) and/or (c) above.

(e) Until this contract is fully funded, the requirements of the clause at FAR 52.232–22, *Limitation of Funds,* shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232–20, *Limitation of Cost,* govern.

332.706 Solicitation provision and contract clauses.

332.706–2 Provision and clauses for limitation of cost or funds.

(b) In addition to the clause at FAR 52.232–22, Limitation of Funds, the contracting officer shall insert the provision at 352.232–70, Incremental Funding, in all solicitations when a cost-reimbursement contract for severable services using incremental funding is contemplated. The provision requires the contracting officer to insert a specific increment of performance that the initial funding is expected to cover.

PART 333—PROTESTS, DISPUTES, AND APPEALS

Subpart 333.1—Protests

Sec.
333.102 General.
333.103 Protests to the agency.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.
333.209 Suspected fraudulent claims.
333.215–70 Contract clauses.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 333.1—Protests

333.102 General.

(g)(1) The Office of General Counsel-General Law Division serves as the liaison for protests lodged with the Government Accountability Office (GAO); is designated as the office responsible for all protests within the Department of Health and Human Services; and serves as the notification point with GAO for all protests.

(2) The contracting officer will follow the direction of the Operating Division's protest control officer for responding to protests whether they are filed with GAO or directly with the contracting officer.

333.103 Protests to the agency.

(f)(1) Protests to the contracting officer must be in writing. The contracting officer is authorized to make the determination, using the criteria in Federal Acquisition Regulation 33.104(b), to award a contract notwithstanding the protest after obtaining the concurrence of the contracting activity's protest control officer and consulting with the appropriate legal office.

Subpart 333.2—Disputes and Appeals

333.203 Applicability.

(c) The Civilian Board of Contract Appeals is the authorized ''Board'' to hear and determine disputes for the Department.

333.209 Suspected fraudulent claims.

The contracting officer shall submit any instance of a contractor's suspected fraudulent claim to the Office of Inspector General for investigation.

333.215–70 Contract clauses.

(a) The contracting officer shall insert the clause at 352.233–70, Choice of Law (Overseas), in solicitations and contracts when performance will be outside the United States, its possessions, and Puerto Rico, except as otherwise

provided in a government-to-government agreement.

(b) The contracting officer shall insert the clause at 352.233–71, Litigation and Claims, in solicitations and contracts when a cost-reimbursement, time-and-materials, or labor-hour contract is contemplated (other than a contract for a commercial item).

SUBCHAPTER F—SPECIAL CATEGORIES OF CONTRACTING

PART 334—MAJOR SYSTEM ACQUISITION

Subpart 334.2—Earned Value Management System

Sec.
334.201 Policy.
334.202 Integrated Baseline Reviews (IBRs).

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 334.2—Earned Value Management System

334.201 Policy.

The Department of Health and Human Services applies the earned value management system requirement as follows:

(a) For cost or incentive contracts and subcontracts valued at $20 million or more, the contractor's earned value management system shall comply with the guidelines in the American National Standards Institute/Electronic Industries Alliance Standard 748, Earned Value Management Systems (ANSI/EIA–748).

(b) For cost or incentive contracts and subcontracts valued at $50 million or more, the contractor shall have an earned value management system that has been determined by the cognizant Federal agency to be in compliance with the guidelines in ANSI/EIA–748.

(c) For cost or incentive contracts and subcontracts valued at less than $20 million—

(1) The application of earned value management is optional at the discretion of the program/project manager and is a risk-based decision that must be supported by a cost/benefit analysis; and

(2) A decision to apply earned value management shall be documented in the contract file.

(d) For firm-fixed-price contracts and subcontracts of any dollar value the application of earned value management is discouraged.

334.202 Integrated Baseline Reviews (IBRs).

(a) An IBR normally should be conducted as a post-award activity. A pre-award IBR may be conducted only if—

(1) The acquisition plan contains documentation that demonstrates the need and rationale for a pre-award IBR, including an assessment of the impact on the source selection schedule and the expected benefits;

(2) The use of a pre-award IBR is approved in writing by the head of the contracting activity prior to the issuance of the solicitation;

(3) The source selection plan and solicitation specifically addresses how the results of a pre-award IBR will be used during source selection, including any weight to be given to it in source evaluation; and

(4) Specific arrangements are made, and budget authority is provided, to compensate all offerors who prepare for or participate in a pre-award IBR; and the solicitation informs prospective offerors of the means for and conditions of such compensation.

PART 335—RESEARCH AND DEVELOPMENT CONTRACTING

Sec.
335.070 Cost-sharing.
335.070–1 Policy.
335.070–2 Amount of cost-sharing.
335.070–3 Method of cost-sharing.
335.071 [Reserved]
335.072 Key personnel.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

335.070 Cost-sharing.

335.070–1 Policy.

(a) Contracting activities should encourage contractors to contribute to the cost of performing research and development (R&D), through the use of cost-sharing contracts, where there is a probability that the contractor will receive present or future benefits from participation as described in Federal Acquisition Regulation (FAR) 16.303. Examples include increased technical know-how, training for employees, acquisition of goods or services, development of a commercially viable product that can be sold in the commercial market and use of background knowledge in future contracts. Cost-sharing is intended to serve the mutual interests of the Government and its contractors by helping to ensure efficient utilization of the resources available for the conduct of R&D projects and by promoting sound planning and prudent fiscal policies of the contractor. The Government's interest includes positive impact on the community at large.

(b) The contracting officer should use a cost-sharing contract for R&D contracts, unless the contracting officer determines that a request for cost-sharing would not be appropriate.

(c) Any determination made by a contracting officer as described in this section shall be evidenced by appropriate documentation in the contract file.

335.070–2 Amount of cost-sharing.

When cost-sharing is appropriate, the contracting officer shall use the following guidelines to determine the amount of cost participation by the contractor:

(a) The amount of cost participation depends on the extent to which the R&D effort or results are likely to enhance the contractor's capability, expertise, or competitive position, and the value of this enhancement to the contractor. Therefore, contractor cost participation could reasonably range from as little as one percent or less of the total project cost to more than 50 percent of the total project cost. Ultimately, cost-sharing is a negotiable item. As such, the amount of cost-sharing shall be proportional to the anticipated value of the contractor's gain.

(b) If the contractor will not acquire title to, or the right to use, inventions, patents, or technical information resulting from the R&D project, it is normally appropriate to obtain less cost-sharing than in cases in which the contractor acquires these rights.

(c) If the R&D is expected to be of only minor value to the contractor, and if a statute does not require cost-sharing, it may be appropriate for the contractor to make a contribution in the form of a reduced fee or profit rather than sharing costs of the project. Alternatively, a limitation on indirect cost rates might be appropriate. See FAR 42.707. See also, FAR 16.303.

(d) The contractor's participation may be considered over the total term of the project, so that a relatively high contribution in 1 year may be offset by a relatively low contribution in another. Care must be exercised that the intent to cost-share in future years does not become illusory. Redetermination of the cost sharing arrangement might be appropriate depending on future circumstances.

(e) A relatively low degree of cost-sharing may be appropriate if an area of R&D requires special stimulus in the national interest.

335.070–3 Method of cost-sharing.

Cost-sharing on individual contracts may be accomplished either by a contribution of part or all of one or more elements of allowable cost of the work being performed or by a fixed amount or stated percentage of the total allowable

costs of the project. Contractors shall not charge costs contributed to the Government under any other instrument (*e.g.,* grant or contract), including allocations to other instruments as part of any independent R&D program.

335.071 [Reserved]

335.072 Key personnel.

If the contracting officer determines that the personnel to be assigned to perform effort on an R&D contract are critical to the success of the R&D effort, or were a critical factor in the award of the contract, then the contracting officer should consider using the key personnel clause at 352.237–75, Key Personnel.

PART 336—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

Subpart 336.1—General

Sec.
336.104 Policy.

Subpart 336.5—Contract Clause

336.570 Contract clause.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 336.1—General

336.104 Policy.

Contracting officers shall follow the policies described in Federal Acquisition Regulation 36.104 and the guidance promulgated by the Department of Health and Human Services Facilities Management.

Subpart 336.5—Contract Clause

336.570 Contract clause.

(a) The contracting officer shall insert the clause at 352.236–70, Design-Build Contracts, in all solicitations and contracts for all design-build requirements.

(b) The contracting officer shall use Alternate I to the clause at 352.236–70, Design-Build Contracts, in all solicitations and contracts for construction when Fast-Track procedures are being used.

(c) Due to the importance of maintaining consistency in the contractor's personnel during design–build construction, the contracting officer should consider including the clause at 352.237–75, Key personnel.

PART 337—SERVICE CONTRACTING—GENERAL

Subpart 337.1—Service Contracts—General

Sec.
337.103 Contracting officer responsibility.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 337.1—Service Contracts—General

337.103 Contracting officer responsibility.

(d)(1) The contracting officer shall insert the clause at 352.237–70, Pro-Children Act, in solicitations, contracts, and orders that involve:

(i) Kindergarten, elementary, or secondary education or library services; or

(ii) Health or daycare services that are provided to children under the age of 18 on a routine or regular basis pursuant to the Pro-Children Act of 1994 (20 U.S.C. 6081–6084).

(2) The contracting officer shall insert the clause at 352.237–71, Crime Control Act—Reporting of Child Abuse, in solicitations, contracts, and orders that require performance on Federal land or in a federally operated (or contracted) facility and involve the professions/activities performed by persons specified in the Crime Control Act of 1990 (42 U.S.C. 13031) including, but not limited to, teachers, social workers, physicians, nurses, dentists, health care practitioners, optometrists, psychologists, emergency medical technicians, alcohol or drug treatment personnel, child care workers and administrators, emergency medical technicians and ambulance drivers.

(3) The contracting officer shall insert the clause at 352.237–72, Crime Control Act—Requirement for Background Checks, in solicitations, contracts, and orders that involve providing child care services to children under the age of 18, including social services, health and mental health care, child- (day) care, education (whether or not directly involved in teaching), and rehabilitative programs covered under the Crime Control Act of 1990 (42 U.S.C. 13041).

(4) Contracting officers supporting the Indian Health Service shall insert the clause at 352.237–73, Indian Child Protection and Family Violence Act in all solicitations, contracts, and orders when performance of the contract may involve regular contact with or control over Indian children. The required declaration shall also be included in Section J of the solicitation and contract.

(e) The contracting officer shall insert the clause at 352.237–74, Non-Discrimination in Service Delivery, in solicitations, contracts, and orders to deliver services under HHS' programs directly to the public.

(f) The contracting officer shall insert the clause at 352.237–75, Key Personnel, in solicitations and contracts when the contracting officer will require the contractor to designate contractor key personnel.

PART 339—ACQUISITION OF INFORMATION TECHNOLOGY

Subpart 339.1—General

Sec.
339.101 Policy.

Subpart 339.2—Electronic and Information Technology

339.203 Applicability.
339.203–70 Contract clauses for electronic and information technology (EIT) acquisitions.
339.204 Exceptions.
339.204–1 Approval of exceptions.
339.205 Section 508 accessibility standards for contracts.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 339.1—General

339.101 Policy

In addition to the regulatory guidance in Federal Acquisition Regulation part 39, contracting officers shall collaborate with the requiring activity to ensure information technology (IT) acquisitions for supplies, services, and systems meet the requirements established by the Department of Health and Human Services (HHS).

Subpart 339.2—Electronic and Information Technology

339.203 Applicability.

(a) Electronic and information technology (EIT) supplies and services must comply with Section 508 of the Rehabilitation Act (the Act) of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board (Access Board) Electronic and Information Accessibility Standards (36 CFR part 1194). Requiring activities must consult with their Section 508 Official or designee to determine if the contractor should be responsible for compliance with EIT accessibility standards which apply to Web site content and communications material.

(1) When conducting a procurement and employing the best value continuum, the solicitation shall include a separate technical evaluation factor developed by the contracting officer, requiring activity, and the Operating Division (OPDIV) Section 508 Official or designee.

(2) At a minimum, solicitations for supplies and services shall require the submission of a Section 508 Product Assessment Template (See *http://www.hhs.gov/web/508* for the template). Solicitations for services shall include any other pertinent information that the contracting officer deems necessary to evaluate the offeror's ability to meet the

applicable Section 508 accessibility standards.

(3) The HHS Operating Division or Staff Division (OPDIV or STAFFDIV) Section 508 Official or designee is responsible for providing technical assistance in development of Section 508 evaluation factors.

(4) Before conducting negotiations or making an award, the contracting officer shall provide a summary of the Source Selection Evaluation Team's (SSET) assessment of offeror responses to the solicitation's Section 508 evaluation factor. This summary shall be submitted for review by the Section 508 Official or designee. The Section 508 Official or designee shall indicate approval or disapproval of the SSET assessment. The contracting officer shall coordinate the resolution of any issues raised by the Section 508 Official or designee with the chair of the SSET or requiring activity representative, as appropriate. The acquisition process shall not proceed until the Section 508 Official or designee approves the SSET assessment. The contracting officer shall include the assessment in the official contract file. See 339.204–1 regarding processing exception determination requests.

(b) When acquiring commercial items, if no commercially available supplies or services meet all of the applicable Section 508 accessibility standards, OPDIVs or STAFFDIVs shall, under the direction and approval of the Section 508 Official or designee, acquire the supplies and services that best meet the applicable Section 508 accessibility standards. Process exception determinations for EIT supplies and services not meeting applicable Section 508 accessibility standards in accordance with 339.204–1.

339.203–70 Contract clauses for electronic and information technology (EIT) acquisitions.

(a) The contracting officer shall insert the provision at 352.239–73, Electronic and Information Technology Accessibility Notice, in all solicitations.

(b) The contracting officer shall insert the clause at 352.239–74, Electronic and Information Technology Accessibility, in all contracts and orders.

339.204 Exceptions.

339.204–1 Approval of exceptions.

(a) Procedures to document exception and determination requests are set by the OPDIV Section 508 Official.

(b) In the development of an acquisition plan (AP) or other acquisition request document, the contracting officer shall ensure that all Section 508 exception determination requests for applicable EIT requirements are:

(1) Documented and certified in accordance with the requirements of the HHS Section 508 policy;

(2) Signed by the requestor in the requiring activity;

(3) Certified and approved by the OPDIV Section 508 Official or designee; and

(4) Included in the AP or other acquisition request document provided by the requiring activity to the contracting office.

(c) For instances with an existing technical evaluation and no organization's proposed supplies or services meet all of the Section 508 accessibility standards; in order to proceed with the acquisition, the requiring activity shall provide an exception determination request along with the technical evaluation team's assessment of the Section 508 evaluation factor to the designated Section 508 Official or designee for review and approval or disapproval. The contracting officer shall include the Section 508 Official's or designee's approval or disapproval of the exception determination request in the official contract file and reference it, as appropriate, in all source selection documents. For further information, see HHS Section 508 Policy on *http://www.hhs.gov/web/508*.

339.205 Section 508 accessibility standards for contracts.

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794(d)), as amended by the Workforce Investment Act of 1998 (Section 508), specifies the applicable accessibility standards for all new solicitations and new or existing contracts or orders, regardless of EIT dollar amount.

(b) The requiring activity shall consult with the OPDIV or STAFFDIV Section 508 Official or designee, as necessary, to determine the applicability of Section 508, identify applicable Section 508 accessibility standards, and resolve any related issues before forwarding a request to the contracting or procurement office for the acquisition of EIT supplies and services—including Web site content and communications material for which the contractor must meet EIT accessibility standards.

(c) Based on those discussions, the requiring activity shall provide a statement in the AP (or other acquisition request document) for Section 508 applicability. See 307.105. If Section 508 applies to an acquisition, include the provision at 352.239–73, Electronic and Information Technology and Accessibility Notice, language in a separate, clearly designated, section of the statement of work or performance work statement, along with any additional information applicable to the acquisition's Section 508 accessibility standards (*e.g.,* the list of applicable accessibility standards of the Access Board EIT Accessibility Standards (36 CFR part 1194)). If an AP does not address Section 508 applicability and it appears an acquisition involves Section 508, or if the discussion of Section 508 applicability to the acquisition is inadequate or incomplete, the contracting officer shall request the requiring activity modify the AP accordingly.

(d) Items provided incidental to contract administration are not subject to this section.

(e) The OPDIV Section 508 Official or designee may, at his or her discretion, require review and approval of solicitations and contracts for EIT supplies and services.

SUBCHAPTER G—CONTRACT MANAGEMENT

PART 342—CONTRACT ADMINISTRATION

Subpart 342.7—Indirect Cost Rates

Sec.
342.705 Final indirect cost rates.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 342.7—Indirect Cost Rates

342.705 Final indirect cost rates.

Contract actions for which the Department of Health and Human Services is the cognizant Federal agency:

(a) The Financial Management Services, Division of Cost Allocation, Program Support Center, shall establish facilities and administration costs, also known as indirect cost rates, research patient care rates, and, as necessary, fringe benefits, computer, and other special costing rates for use in contracts awarded to State and local governments, colleges and universities, hospitals, and other nonprofit organizations.

(b) The National Institute of Health, Division of Financial Advisory Services, shall establish indirect cost rates and similar rates for use in contracts awarded to for profit organizations.

SUBCHAPTER H—CLAUSES AND FORMS

PART 352—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Subpart 352.1—Instructions for Using Provisions and Clauses

Sec.
352.100 Scope of subpart.
352.101–70 Application of provisions and clauses.

Subpart 352.2—Texts of Provisions and Clauses

352.203–70 Anti-Lobbying.
352.204–70 Prevention and Public Health Fund–Reporting Requirements.
352.208–70 Printing and Duplication.
352.211–1 Public Accommodations and Commercial Facilities.
352.211–2 Conference Sponsorship Request and Conference Materials Disclaimer.
352.211–3 Paperwork Reduction Act.
352.215–70 Late Proposals and Revisions.
352.216–70 Additional Cost Principles for Hospitals (Profit or Non-Profit).
352.219–70 Mentor-Protégé Program.
352.219–71 Mentor-Protégé Program Reporting Requirements.
352.222–70 Contractor Cooperation in Equal Employment Opportunity Investigations.
352.223–70 Safety and Health.
352.223–71 Instructions to Offerors–Sustainable Acquisition.
352.224–70 Privacy Act.
352.224–71 Confidential Information.
352.226–1 Indian Preference.
352.226–2 Indian Preference Program.
352.226–3 Native American Graves Protection and Repatriation Act.
352.227–11 Patent Rights—Exceptional Circumstances.
352.227–14 Rights in Data—Exceptional Circumstances.
352.227–70 Publications and Publicity.
352.231–70 Salary Rate Limitation.
352.232–70 Incremental Funding.
352.233–70 Choice of Law (Overseas).
352.233–71 Litigation and Claims.
352.236–70 Design-Build Contracts.
352.237–70 Pro-Children Act.
352.237–71 Crime Control Act—Reporting of Child Abuse.
352.237–72 Crime Control Act—Requirement for Background Checks.
352.237–73 Indian Child Protection and Family Violence Act.
352.237–74 Non-Discrimination in Service Delivery.
352.237–75 Key Personnel.
352.239–73 Electronic Information and Technology Accessibility Notice.
352.239–74 Electronic Information and Technology Accessibility.
352.270–1 [Reserved]
352.270–2 [Reserved]
352.270–3 [Reserved]
352.270–4a Notice to Offerors, Protection of Human Subjects.
352.270–4b Protection of Human Subjects.
352.270–5a Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.
352.270–5b Care of Live Vertebrate Animals.
352.270–6 Restriction on Use of Human Subjects.
352.270–7 [Reserved]
352.270–8 [Reserved]
352.270–9 Non-Discrimination for Conscience.
352.270–10 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.
352.270–11 Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.
352.270–12 Needle Exchange.
352.270–13 Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2).

Subpart 352.1—Instructions for Using Provisions and Clauses

352.100 Scope of subpart.

This subpart provides guidance for applying the Department of Health and Human Services provisions and clauses in solicitations, contracts, and orders.

352.101–70 Application of provisions and clauses.

(a) If a clause is included in the master instrument (*e.g.,* in an indefinite delivery/indefinite quantity contract or a blanket purchase agreement), it is not necessary to also include the clause in a task order or delivery order thereunder.

(b) When a dollar amount or dollar threshold is specified (*e.g.,* $25 million or simplified acquisition threshold), the dollar amount of the award (contract or order) includes any options thereunder.

Subpart 352.2—Texts of Provisions and Clauses

352.203–70 Anti-Lobbying.

As prescribed in HHSAR 303.808–70, the Contracting Officer shall insert the following clause:

Anti-Lobbying (DEC 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive-legislative relationships, the Contractor shall not use any HHS contract funds for:

(a) Publicity or propaganda purposes;

(b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or

(c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.

(d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

(End of clause)

352.204–70 Prevention and Public Health Fund—Reporting Requirements.

As prescribed in HHSAR 304.7201, insert the following clause:

Prevention and Public Health Fund—Reporting Requirements (DEC 2015)

(a) Pursuant to public law this contract requires the contractor to provide products or services or both that are funded from the Prevention and Public Health Fund (PPHF), Public Law 111–148, sec. 4002. Section 220(b)(5) requires each contractor to report on its use of these funds under this contract. These reports will be made available to the public.

(b) Semi-annual reports from the Contractor for all work funded, in whole or in part, by the PPHF, are due no later than 20 days following the end of each 6-month period. The 6-month reporting periods are January through June and July through December. The first report is due no later than 20 days after the end of the 6-month period following contract award. Subsequent reports are due no later than 20 days after the end of each reporting period. If applicable, the Contractor shall submit its final report for the remainder of the contract period no later than 20 days after the end of the reporting period in which the contract ended.

(c) The Contractor shall provide the following information in an electronic and Section 508 compliant format to the Contracting Officer.

(1) The Government contract and order number, as applicable.

(2) The amount of PPHF funds invoiced by the contractor for the reporting period and the cumulative amount invoiced for the contract or order.

(3) A list of all significant services performed or supplies delivered, including construction, for which the contractor invoiced in the reporting period.

(4) Program or project title, if any.

(5) The Contractor shall report any subcontract funded in whole or in part with PPHF funding, that is valued at $25,000 or more. The Contractor shall advise the subcontractor that the information will be made available to the public. The Contractor shall report:

(i) Name and address of the subcontractor.

(ii) Amount of the subcontract award.

(iii) Date of the subcontract award.

(iv) A description of the products or services (including construction) being provided under the subcontract.

(End of clause)

352.208–70 Printing and Duplication.

As prescribed in HHSAR 308.803, the Contracting Officer shall insert the following clause:

Printing and Duplication (DEC 2015)

(a) Unless otherwise specified in this contract, no printing by the Contractor or any subcontractor is authorized under this contract. All printing required must be performed by the Government Printing Office except as authorized by the Contracting Officer. The Contractor shall submit camera-ready copies to the Contracting Officer's Representative (COR). The terms ''printing'' and ''duplicating/copying'' are defined in the Government Printing and Binding Regulations of the Joint Committee on Printing.

(b) If necessary for performance of the contract, the Contractor may duplicate or copy less than 5,000 production units of only one page, or less than 25,000 production units in aggregate of multiple pages for the use of a department or agency. A production unit is defined as one sheet, size 8.5 x 11 inches, one side only, and one color. The pages may not exceed a maximum image size of 10¾ by 14¼ inches. This page limit applies to each printing requirement and not for all printing requirements under the entire contract.

(c) Approval for all printing, as well as duplicating/copying in excess of the stated limits, shall be obtained from the COR who will consult with the designated publishing services office and provide direction to the contractor. The cost of any unauthorized printing or duplicating/copying under this contract will be considered an unallowable cost for which the Contractor will not be reimbursed.

352.211–1 Public Accommodations and Commercial Facilities.

As prescribed in HHSAR 311.7102, the Contracting Officer shall insert the following clause:

Public Accommodations and Commercial Facilities (DEC 2015)

The Contractor agrees as follows:

(a) Except for ad hoc meetings necessary or incidental to contract performance, the Contractor shall develop a plan to assure that any event held pursuant to this contract will meet or exceed the minimum accessibility standards set forth in 28 CFR part 36—Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities. The Contractor shall submit the plan to the Contracting Officer and must receive approval prior to the event. The Contractor may submit a consolidated or master plan for contracts requiring numerous events in lieu of separate plans.

(b) The Contractor shall manage the contract in accordance with the standards set forth in 28 CFR part 36.

(End of clause)

352.211–2 Conference Sponsorship Requests and Conference Materials Disclaimer.

As prescribed in HHSAR 311.7202, the Contracting Officer shall insert the following clause:

Conference Sponsorship Request and Conference Materials Disclaimer (DEC 2015)

(a) If HHS is not the sole provider of funding under this contract, then, prior to the Contractor claiming HHS conference sponsorship, the Contractor shall submit a written request (including rationale) to the Contracting Officer for permission to claim such HHS sponsorship.

(b) Whether or not HHS is the conference sponsor, the Contractor shall include the following statement on conference materials, including promotional materials, agendas, and Web sites:

''This conference was funded, in whole or in part, through a contract (insert contract number) with the Department of Health and Human Services (HHS) (insert name of OPDIV or STAFFDIV). The views expressed in written conference materials and by speakers and moderators at this conference, do not necessarily reflect the official policies of HHS, nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.''

(c) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo on any conference materials.

(End of clause)

352.211–3 Paperwork Reduction Act.

As prescribed in HHSAR 311.7301, the Contracting Officer shall insert the following clause:

Paperwork Reduction Act (DEC 2015)

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

(End of clause)

352.215–70 Late Proposals and Revisions.

As prescribed in HHSAR 315.208, the Contracting Officer shall insert the following provision:

Late Proposals and Revisions (DEC 2015) Deviation

Notwithstanding the procedures contained in FAR 52.215–1(c)(3) of the provision of this solicitation entitled Instructions to Offerors–Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical advantage to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

352.216–70 Additional Cost Principles for Hospitals (Profit and Non-Profit).

As prescribed in HHSAR 316.307(a)(2), the Contracting Officer shall insert the following clause:

Additional Cost Principles for Hospitals (Profit or Non-Profit) (DEC 2015)

(a) *Bid and proposal (B&P) costs.* (1) B&P costs are the immediate costs of preparing bids, proposals, and applications for potential Federal and non-Federal contracts, grants, and agreements, including the development of scientific, cost, and other data needed to support the bids, proposals, and applications.

(2) B&P costs of the current accounting period are allowable as indirect costs.

(3) B&P costs of past accounting periods are unallowable in the current period. However, if the organization's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable.

(4) B&P costs do not include independent research and development (IR&D) costs

covered by the following paragraph, or pre-award costs covered by paragraph 36 of Attachment B to OMB Circular A–122.

(b) *IR&D costs.*

(1) IR&D is research and development conducted by an organization which is not sponsored by Federal or non-Federal contracts, grants, or other agreements.

(2) IR&D shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development.

(3) The cost of IR&D, including its proportionate share of indirect costs, is unallowable.

(End of clause)

352.219–70 Mentor-Protégé Program.

As prescribed in HHSAR 319.270–1(a), the Contracting Officer shall insert the following provision:

Mentor-Protégé Program (DEC 2015)

(a) Large business prime contractors serving as mentors in the HHS Mentor-Protégé Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor-protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at *www.esrs.gov*. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protégé firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

(b) The program consists of—

(1) *Mentor firms*—large businesses that:

(i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and

(ii) Have a Mentor-Protégé agreement approved by HHS' OSDBU;

(2) *Protégé firms*—firms that:

(i) Seek developmental assistance;

(ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and

(iii) Have a Mentor-Protégé agreement approved by HHS' OSDBU; and

(3) *Mentor-Protégé agreements*—joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

352.219–71 Mentor-Protégé Program Reporting Requirements.

As prescribed in HHSAR 319.270–1(b), the Contracting Officer shall insert the following clause:

Mentor-Protégé Program Reporting Requirements (January 2010)

The Contractor shall comply with all reporting requirements specified in its Mentor-Protégé agreement approved by HHS' OSDBU.

(End of clause)

352.222–70 Contractor Cooperation in Equal Employment Opportunity Investigations.

As prescribed in HHSAR 322.810(h), the Contracting Officer shall insert the following clause:

Contractor Cooperation in Equal Employment Opportunity Investigations (DEC 2015)

(a) In addition to complying with the clause at FAR 52.222–26, Equal Opportunity, the Contractor shall, in good faith, cooperate with the Department of Health and Human Services (Agency) in investigations of Equal Employment Opportunity (EEO) complaints processed pursuant to 29 CFR part 1614. For purposes of this clause, the following definitions apply:

(1) *Complaint* means a formal or informal complaint that has been lodged with Agency management, Agency EEO officials, the Equal Employment Opportunity Commission (EEOC), or a court of competent jurisdiction.

(2) *Contractor employee* means all current Contractor employees who work or worked under this contract. The term also includes current employees of subcontractors who work or worked under this contract. In the case of Contractor and subcontractor employees, who worked under this contract, but who are no longer employed by the Contractor or subcontractor, or who have been assigned to another entity within the Contractor's or subcontractor's organization, the Contractor shall provide the Agency with that employee's last known mailing address, email address, and telephone number, if that employee has been identified as a witness in an EEO complaint or investigation.

(3) *Good faith cooperation* cited in paragraph (a) includes, but is not limited to, making Contractor employees available for:

(i) Formal and informal interviews by EEO counselors or other Agency officials processing EEO complaints;

(ii) Formal or informal interviews by EEO investigators charged with investigating complaints of unlawful discrimination filed by Federal employees;

(iii) Reviewing and signing appropriate affidavits or declarations summarizing statements provided by such Contractor employees during the course of EEO investigations;

(iv) Producing documents requested by EEO counselors, EEO investigators, Agency employees, or the EEOC in connection with a pending EEO complaint; and

(v) Preparing for and providing testimony in depositions or in hearings before the MSPB, EEOC and U.S. District Court.

(b) The Contractor shall include the provisions of this clause in all subcontract solicitations and subcontracts awarded at any tier under this contract.

(c) Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause may be grounds for the Contracting Officer to terminate this contract for default.

(End of clause)

352.223–70 Safety and Health.

As prescribed in HHSAR 323.7002, the Contracting Officer shall insert the following clause:

Safety and Health (DEC 2015)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under this contract. These laws are implemented or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration (OSHA) and other regulatory/enforcement agencies at the Federal, State, and local levels.

(1) In addition, the Contractor shall comply with the following regulations when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:

(i) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by OSHA and included in 29 CFR part 1910. These regulations are available at *https://www.osha.gov/*.

(ii) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 *et seq.*). The Contractor may obtain copies from the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

(2) The following Government guidelines are recommended for developing and implementing health and safety operating procedures and practices for both personnel and facilities:

(i) Biosafety in Microbiological and Biomedical Laboratories, CDC. This publication is available at *http://www.cdc.gov/biosafety/publications/index.htm*.

(ii) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street NW., Lockbox 285, Washington, DC 20055 (ISBN 0–309–05229–7). This publication is available at *http://www.nap.edu/catalog/4911/prudent-practices-in-the-laboratory-handling-and-disposal-of-chemicals*.

(b) Further, the Contractor shall take or cause to be taken additional safety measures

as the Contracting Officer, in conjunction with the Contracting Officer's Representative or other appropriate officials, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, the Contracting Officer will make an equitable adjustment in accordance with the applicable ''Changes'' clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report citing all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; or damage to property incidental to work performed under the contract resulting from toxic or hazardous materials and resulting in any or all violations for which the Contractor has been cited shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall form the basis for a request for extension or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. The Contractor is responsible for the compliance of its subcontractors with the provisions of this clause.

(End of clause)

352.223–71 Instructions to Offerors—Sustainable Acquisition.

As prescribed in HHSAR 323.7103, the Contracting Officer shall insert the following provision:

Instructions to Offerors—Sustainable Acquisition (DEC 2015)

Offerors must include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR 23.1, Sustainable Acquisition Policy (and other Federal laws, regulations and Executive Orders governing sustainable acquisition purchasing) to this acquisition. The Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content, Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuel Vehicle and Alternative Fuels.

(End of provision)

352.224–70 Privacy Act.

As prescribed in HHSAR 324.105(a), the Contracting Officer shall insert the following clause:

Privacy Act (DEC 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term *system of records* means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in 45 CFR part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)). The contract work statement:

(a) Identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and

(b) Specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

352.224–71 Confidential Information.

As prescribed in HHSAR 324.105(b), insert the following clause:

Confidential Information (DEC 2015)

(a) Confidential Information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) Specific information or categories of information that the Government will furnish to the Contractor, or that the Contractor is expected to generate, which are confidential may be identified elsewhere in this contract. The Contracting Officer may modify this contract to identify Confidential Information from time to time during performance.

(c) Confidential Information or records shall not be disclosed by the Contractor until:

(1) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the Contractor's intent to release findings of studies or research, to which an agency response may be appropriate to protect the public interest or that of the agency.

(2) For information provided by or on behalf of the government,

(i) The publication or dissemination of the following types of information are restricted under this contract: [INSERT RESTRICTED TYPES OF INFORMATION. IF NONE, SO STATE.]

(ii) The reason(s) for restricting the types of information identified in subparagraph (i) is/are: [STATE WHY THE PUBLIC OR GOVERNMENT INTEREST REQUIRES THE RESTRICTION OF EACH TYPE OF INFORMATION. ANY BASIS FOR NONDISCLOSURE WHICH WOULD BE VALID UNDER THE FREEDOM OF INFORMATION ACT IS SUFFICIENT UNDER THIS CLAUSE.]

(iii) Written advance notice of at least 45 days shall be provided to the Contracting Officer of the Contractor's intent to disseminate or publish information identified in subparagraph (2)(i). The contractor shall not disseminate or publish such information without the written consent of the Contracting Officer.

(d) Whenever the Contractor is uncertain with regard to the confidentiality of or a property interest in information under this contract, the Contractor should consult with the Contracting Officer prior to any release, disclosure, dissemination, or publication.

352.226–1 Indian Preference.

As prescribed in HHSAR 326.505(a), the Contracting Officer shall insert the following clause:

Indian Preference (DEC 2015)

(a) The Contractor agrees to give preference in employment opportunities under this contract to Indians who can perform required work, regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. To the extent feasible and consistent with the efficient performance of this contract, the Contractor further agrees to give preference in employment and training opportunities under this contract to Indians who are not fully qualified to perform regardless of age (subject to existing laws and regulations), sex, religion, or tribal affiliation. The Contractor also agrees to give preference to Indian organizations and Indian-owned economic enterprises in the awarding of any subcontracts to the extent feasible and consistent with the efficient performance of this contract. The Contractor shall maintain

the necessary statistical records to demonstrate compliance with this paragraph.

(b) In connection with the Indian employment preference requirements of this clause, the Contractor shall provide reasonable opportunities for training, incident to such employment. Such training shall include on-the-job, classroom, or apprenticeship training designed to increase the vocational effectiveness of an Indian employee.

(c) If the Contractor is unable to fill its employment and training opportunities after giving full consideration to Indians as required by this clause, the Contractor may satisfy those needs by selecting non-Indian persons in accordance with the clause of this contract entitled ''Equal Opportunity.''

(d) If no Indian organizations or Indian-owned economic enterprises are available under reasonable terms and conditions, including price, for awarding of subcontracts in connection with the work performed under this contract, the Contractor agrees to comply with the provisions of this contract involving utilization of small businesses; HUBZone small businesses; service-disabled, veteran-owned small businesses; 8(a) small businesses; veteran-owned small businesses; women-owned small businesses; or small disadvantaged businesses.

(e) As used in this clause,

(1) *Indian* means a person who is a member of an Indian tribe. If the Contractor has reason to doubt that a person seeking employment preference is an Indian, the Contractor shall grant the preference but shall require the individual provide evidence within 30 days from the tribe concerned that the person is a member of the tribe.

(2) *Indian tribe* means an Indian tribe, pueblo, band, nation, or other organized group or community, including Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601) which the United States recognizes as eligible for the special programs and services provided to Indians because of its status as Indians.

(3) *Indian organization* means the governing body of any Indian Tribe or entity established or recognized by such governing body in accordance with the Indian Financing Act of 1974 (88 Stat. 77; 25 U.S.C. 1451).

(4) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and that ownership shall encompass active operation and control of the enterprise.

(f) The Contractor agrees to include the provisions of this clause, including this paragraph (f) of this clause, in each subcontract awarded at any tier under this contract.

(g) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may pursue any other remedies authorized by law or by other provisions of the contract.

(End of clause)

352.226–2 Indian Preference Program.

As prescribed in HHSAR 326.505(b), the Contracting Officer shall insert the following clause:

Indian Preference Program (DEC 2015)

(a) In addition to the requirements of the clause of this contract entitled ''Indian Preference,'' the Contractor agrees to establish and conduct an Indian preference program which will expand opportunities for Indians to receive preference for employment and training in connection with the work performed under this contract, and which will expand the opportunities for Indian organizations and Indian-owned economic enterprises to receive a preference in the awarding of subcontracts. In this connection, the Contractor shall perform the following:

(1) Designate a liaison officer who will maintain liaison with the Government and the Tribe(s) on Indian preference matters; supervise compliance with the provisions of this clause; and administer the Contractor's Indian preference program.

(2) Advise its recruitment sources in writing and include a statement in all employment advertisements that Indian applicants receive preference in employment and training incident to such employment.

(3) Not more than 20 calendar days after award of the contract, post a written notice setting forth the Contractor's employment needs and related training opportunities in the tribal office of any reservations on or near the contract work location. The notice shall include the approximate numbers and types of employees needed; the approximate dates of employment; any experience or special skills required for employment; training opportunities available; and other pertinent information necessary to advise prospective employees of any other employment requirements. The Contractor shall also request the tribe(s) on or near whose reservation(s) the Contractor will perform contract work to provide assistance filling its employment needs and training opportunities. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact regarding the posting of notices and requests for Tribal assistance.

(4) Establish and conduct a subcontracting program which gives preference to Indian organizations and Indian-owned economic enterprises as subcontractors (including suppliers) under this contract. The Contractor shall give public notice of existing subcontracting opportunities and, to the extent feasible and consistent with the efficient performance of this contract, shall solicit bids or proposals from Indian organizations or Indian-owned economic enterprises only. The Contractor shall request assistance and information on Indian firms qualified as subcontractors (including suppliers) from the Tribe(s) on or near whose reservation(s) the Contractor will perform contract work. The Contracting Officer will advise the Contractor of the name, location, and phone number of the Tribal officials to contact regarding the request for assistance and information. Public notices and solicitations for existing subcontracting opportunities shall provide an equitable opportunity for Indian firms to submit bids or proposals by including—

(i) A clear description of the supplies or services required, including quantities, specifications, and delivery schedules that facilitate the participation of Indian firms;

(ii) A statement indicating that Indian organizations and Indian-owned economic enterprises will receive preference in accordance with section 7(b) of Public Law 93–638; 88 Stat. 2205; 25 U.S.C. 450e(b);

(iii) Definitions for the terms ''Indian organization'' and ''Indian-owned economic enterprise'' prescribed under the ''Indian Preference'' clause of this contract;

(iv) A statement that the bidder or offeror shall complete certifying that it is an Indian organization or Indian-owned economic enterprise; and

(v) A closing date for receipt of bids or proposals which provides sufficient time for preparation and submission of a bid or proposal. If, after soliciting bids or proposals from Indian organizations and Indian-owned economic enterprises, the Contractor receives no responsive bid or acceptable proposal, the Contractor shall comply with the requirements of paragraph (d) of the ''Indian Preference'' clause of this contract. If the Contractor receives one or more responsive bids or conforming proposals, the Contractor shall award the contract to the low, responsive, responsible bidder or conforming offer from a responsible offeror if the price is reasonable. If the Contractor determines the low responsive bid or conforming proposal's price is unreasonable, the Contractor shall attempt to negotiate a reasonable price and award a subcontract. If parties cannot agree on a reasonable price, the Contractor shall comply with the requirements of paragraph (d) of the ''Indian Preference'' clause of this contract.

(5) Maintain written records under this contract which demonstrate—

(i) The numbers of Indians seeking employment for each employment position available under this contract;

(ii) The number and types of positions filled by Indians and non-Indians;

(iii) The total number of Indians employed under this contract;

(iv) For those positions having both Indian and non-Indian applicants, and a non-Indian is selected for employment, the reason(s) why the Contractor did not select the Indian applicant;

(v) Actions taken to give preference to Indian organizations and Indian-owned economic enterprises for subcontracting opportunities which exist under this contract;

(vi) Reasons why Indian subcontractors and or suppliers did not receive preference for each requirement where the Contractor determined that such preference was inconsistent with efficient contract performance; and

(vii) The number of Indian organizations and Indian-owned economic enterprises contacted, and the number receiving subcontract awards under this contract.

(6) Submit to the Contracting Officer for approval a quarterly report summarizing the Contractor's Indian preference program and

indicating the number and types of available positions filled by Indians and non-Indians, and the dollar amounts of all subcontracts awarded to Indian organizations and Indian-owned economic enterprises, and to all other firms.

(7) Maintain records pursuant to this clause and keep them available for review by the Government for one year after final payment under this contract, or for such longer period in accordance with requirements of any other clause of this contract or by applicable law or regulation.

(b) For purposes of this clause, the following definitions of terms shall apply:

(1) The terms *Indian, Indian tribe, Indian organization,* and *Indian-owned economic enterprise* are defined in the clause of this contract entitled *Indian Preference.*

(2) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688; 43 U.S.C. 1601 *et seq.*)

(3) *On or near an Indian reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably expect to commute to and from in the course of a work day.

(c) Nothing in the requirements of this clause shall preclude Indian tribes from independently developing and enforcing their own Indian preference requirements. Such requirements must not conflict with any Federal statutory or regulatory requirement dealing with the award and administration of contracts.

(d) The Contractor agrees to include the provisions of this clause, including this paragraph (d), in each subcontract awarded at any tier under this contract and to notify the Contracting Officer of such subcontracts.

(e) In the event of noncompliance with this clause, the Contracting Officer may terminate the contract in whole or in part or may pursue any other remedies authorized by law or by other provisions of the contract.

(End of clause)

352.226–3 Native American Graves Protection and Repatriation Act.

As prescribed in HHSAR 326.701, the Contracting Officer shall insert the following clause:

Native American Graves Protection and Repatriation Act (DEC 2015)

(a) Public Law 101–601, dated November 16, 1990, also known as the Native American Graves Protection and Repatriation Act, imposes certain responsibilities on individuals and organizations when they discover Native American cultural items (including human remains) on Federal or tribal lands.

(b) In the event the Contractor discovers Native American cultural items (including human remains, associated funerary objects, unassociated funerary objects, sacred objects and cultural patrimony), as defined in the Act during contract performance, the Contractor shall—

(1) Immediately cease activity in the area of the discovery;

(2) Notify the Contracting Officer of the discovery; and

(3) Make a reasonable effort to protect the items discovered before resuming such activity. Upon receipt of the Contractor's discovery notice, the Contracting Officer will notify the appropriate authorities as required by the Act.

(c) Unless otherwise specified by the Contracting Officer, the Contractor may resume activity in the area on the 31st calendar day following the date that the appropriate authorities certify receipt of the discovery notice. The Contracting Officer shall provide to the Contractor the date that the appropriate authorities certify receipt of the discovery notice and the date on which the Contractor may resume activities.

352.227–11 Patent Rights—Exceptional Circumstances.

As prescribed in HHSAR 327.303, the Contracting Officer shall insert the following clause:

Patent Rights—Exceptional Circumstances (SEPT 2014)

This clause applies to all Contractor and subcontractor (at all tiers) Subject Inventions.

(a) *Definitions.* As used in this clause—

Agency means the Agency of the U.S. Department of Health and Human Services that is entering into this contract.

Class 1 Subject Invention means a Subject Invention described and defined in the DEC that will be assigned to a third party assignee, or assigned as directed by the Agency.

Class 2 Subject Invention means a Subject Invention described and defined in the DEC.

Class 3 Subject Invention means a Subject Invention that does not fall into Class 1 or Class 2 as defined in this clause.

DEC means the Determination of Exceptional Circumstances signed by [insert approving official] _____ on ____ [insert date] _____ and titled ''[insert description].''

Invention means any invention or discovery, which is or may be patentable or otherwise protectable under Title 35 of United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, *et seq.*)

Made means: When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of such invention; or when used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Material means any proprietary material, method, product, composition, compound, or device, whether patented or unpatented, which is provided to the Contractor under this contract.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

Practical application means to manufacture, in the case of a composition or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Small business firm means a small business concern as defined at section 2 of Public Law 85–536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3–8 and 13 CFR 121.3–12, respectively, will be used.

Subject Invention means any invention of the Contractor made in the performance of work under this contract.

Third party assignee means any entity or organization that may, as described in the DEC, be assigned Class 1 inventions.

(b) *Allocation of principal rights.* (1) *Retention of pre-existing rights.* Third party assignees shall retain all preexisting rights to Material in which the Third party assignee has a proprietary interest.

(2) *Allocation of Subject Invention rights.* (i) *Disposition of Class 1 Subject Inventions.* (A) Assignment to the Third party assignee or as directed by the Agency. The Contractor shall assign to the Third party assignee designated by the Agency the entire right, title, and interest throughout the world to each Subject Invention, or otherwise dispose of or transfer those rights as directed by the Agency, except to the extent that rights are retained by the Contractor under paragraph (b)(3) of this clause. Any such assignment or other disposition or transfer of rights will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the U.S. Government to practice or have practiced the Subject Invention for or on behalf of the U.S. throughout the world. Any assignment shall additionally be subject to the ''March-in rights'' of 35 U.S.C. 203. If the Contractor is a U.S. nonprofit organization it may retain a royalty free, nonexclusive, nontransferable license to practice the invention for all nonprofit research including for educational purposes, and to permit other U.S. nonprofit organizations to do so.

(B) [Reserved]

(ii) *Disposition of Class 2 and 3 Subject Inventions.* Class 2 Subject Inventions shall be governed by FAR clause 52.227–11, Patent Rights-Ownership (December 2007) (incorporated herein by reference). However, the Contractor shall grant a license in the Class 2 Subject Inventions to the provider of the Material or other party designated by the Agency as set forth in Alternate I.

(iii) Class 3 Subject Inventions shall be governed by FAR clause 52.227–11, Patent Rights—Ownership by the Contractor (December 2007) (previously incorporated herein by reference).

(3) *Greater Rights Determinations.* The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (b)(1) of this clause in accordance with the procedures of FAR paragraph 27.304–1(c). In addition to the considerations set forth in paragraph 27.304–1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any Third party assignee or otherwise impede the ability of the Government or the Third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies, or other approaches with potential for the diagnosis, prognosis, prevention, and treatment of human diseases.

A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (c)(1) of this clause, or not later than 8 months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227–13 (incorporated herein by reference), and to any reservations and conditions deemed to be appropriate by the Agency such as the requirement to assign or exclusively license the rights to Subject Inventions to the Third party assignee.

A determination by the Agency denying a request by the Contractor for greater rights in a Subject Invention may be appealed within 30 days of the date the Contractor is notified of the determination to an Agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application on the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any Subject Invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) *Invention disclosure by Contractor.* The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the Agency Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was Made and all inventors. It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

In addition, after disclosure to the Agency, the Contractor will promptly notify the Contracting Officer and DEITR of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor. If the Contractor assigns a Subject Invention to the Third party assignee, then the Contractor and its employee inventors shall assist the Third party assignee in securing patent protection. All costs of securing the patent, including the cost of the Contractor's assistance, are at the Third party's expense. Any assistance provided by the Contractor and its employee inventors to the Third party assignee or other costs incurred in securing patent protection shall be solely at the Third party's expense and not billable to the contract.

(d) *Contractor action to protect the Third party assignee's and the Government's interest.* (1) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: Establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b) of this clause; convey title to a Third party assignee in accordance with paragraph (b) of this clause; and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention ''Made'' under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the Government's rights or a Third party assignee's rights in the Subject Inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) If the Contractor is granted greater rights, the Contractor agrees to include, within the specification of any United States non-provisional patent application it files, and any patent issuing thereon, covering a Subject Invention the following statement: ''This invention was made with Government support under (identify the Contract) awarded by (identify the specific Agency). The Government has certain rights in the invention.''

(4) The Contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all Subject Inventions or stating that there were none.

(e) *Subcontracts.* (1) The Contractor will include this clause in all subcontracts, regardless of tier, for experimental, developmental, or research work. At all tiers, the clause must be modified to identify the parties as follows: References to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's Subject Inventions.

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227–13.

(f) *Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor.* The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(g) Preference for United States industry in the event greater rights are granted to the Contractor. Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) *March-in rights in the event greater rights are granted to the Contractor.* The

Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (b)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

(i) *Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the Contractor.* If the Contractor is a nonprofit organization, it shall:

(1) Not assign rights to a Subject Invention in the United States without the written approval of the Agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a Subject Invention with the inventor, including Federal employee co-inventors (but through their Agency if the Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of Subject Inventions that are small business concerns, and give a preference to a small business concern when licensing a Subject Invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) *Communications.* All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as directed by the Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to:

[Insert Agency Address]

Agency Invention Reporting Web site: *https://public.era.nih.gov/iedison.*

Alternate I (Sept 2014). As prescribed in 327.303, the license to Class 2 inventions recited in 352.227–11(b)(2)(a) is as follows:

[Insert description of license to Class 2 inventions]

(End of clause)

352.227–14 Rights in Data—Exceptional Circumstances.

As prescribed in HHSAR 327.409, insert the following clause with any appropriate alternates:

Rights in Data—Exceptional Circumstances (SEPT 2014)

(a) *Definitions.* As used in this clause—Definitions may be added or modified in paragraph (a) as applicable.

Computer database or database means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

Computer software—(i) Means (A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

(B) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

(ii) Does not include computer databases or computer software documentation.

Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Form, fit, and function data means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

Limited rights means the rights of the Government in limited rights data as set forth in the Limited Rights Notice in Alternate II paragraph (g)(3) if included in this clause. ''Limited rights data'' means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

Restricted computer software means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

Restricted rights, as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of Alternate III paragraph (g)(4) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

Technical data means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).

Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) *Allocation of rights.* (1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in—

(i) Data first produced in the performance of this contract;

(ii) Form, fit, and function data delivered under this contract;

(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and

(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to—

(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;

(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) *Copyright*—(1) *Data first produced in the performance of this contract.* (i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number).

(iii) For data other than computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.

(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor—

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) *Removal of copyright notices.* The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except—

(1) As prohibited by Federal law or regulation (*e.g.,* export control or national security laws or regulations);

(2) As expressly set forth in this contract; or

(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer or in the following paragraphs.

(4) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 352.227–11, Patent Rights—Exceptional Circumstances (abbreviated month and year of Final Rule publication).

(5) *Data on Material(s).* The Contractor agrees that in accordance with paragraph (d)(2), proprietary data on Material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) *Confidentiality.* (i) The Contractor shall take all reasonable precautions to maintain Confidential Information as confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes/does not include [Government may define confidential information here.]

(e) *Unauthorized marking of data.* (1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (4) of this clause (if those alternate paragraphs are included in this clause), and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may cancel or ignore the markings. However, pursuant to 41 U.S.C. 253d, the following procedures shall apply prior to canceling or ignoring the markings.

(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the Head of the Contracting Activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final Agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph (e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with Agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request there under.

(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph (e) from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

(f) *Omitted or incorrect markings.* (1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor—

(i) Identifies the data to which the omitted notice is to be applied;

(ii) Demonstrates that the omission of the notice was inadvertent;

(iii) Establishes that the proposed notice is authorized; and

(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may—

(i) Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) *Protection of limited rights data and restricted computer software.* (1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs (b)(1)(i) through (iii) of this clause. As a condition to this withholding, the Contractor shall—

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) *Subcontracting.* The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) Relationship to patents or other rights. Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause)

Alternate I (Sept 2014). As prescribed in HHSAR 327.409, substitute the following definition for ''limited rights data'' in paragraph (a) of the basic clause:

Limited rights data means data, other than computer software, developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged.

Alternate II (Sept 2014). As prescribed in HHSAR *327.409,* insert the following paragraph (g)(3) in the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following ''Limited Rights Notice'' to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (SEPT 2014)

(a) These data are submitted with limited rights under Government Contract No. ____ (and subcontract ____, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: Agencies may list additional purposes or if none, so state.

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

Alternate III (Sept 2014). As prescribed in HHSAR 327.409, insert the following paragraph (g)(4) in the basic clause: (g)(4)(i) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of restricted computer software, or the Contracting Officer may require by written request the delivery of restricted computer software that has been withheld or would otherwise be entitled to be withheld. If delivery of that computer software is required, the Contractor shall affix the following ''Restricted Rights Notice'' to the computer software and the Government will treat the computer software, subject to paragraphs (e) and (f) of this clause, in accordance with the notice:

Restricted Rights Notice (SEPT 2014)

(a) This computer software is submitted with restricted rights under Government Contract No. ____ (and subcontract ____, if appropriate). It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract.

(b) This computer software may be—

(1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred;

(2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights;

(5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and

(6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice.

(d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract.

(e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice)

(ii) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form notice may be used instead:

Restricted Rights Notice Short Form (SEPT 2014)

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. __ (and subcontract, if appropriate) with __ (name of Contractor and subcontractor).

(End of notice)

(iii) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401, it will be presumed to be licensed to the Government without disclosure prohibitions, with the minimum rights set forth in paragraph (b) of this clause.

Alternate IV Sept 2014). As prescribed in HHSAR 327.409, substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c) *Copyright*—(1) *Data first produced in the performance of the contract.* Except as otherwise specifically provided in this contract, the Contractor may assert copyright in any data first produced in the performance of this contract. When asserting copyright, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number), to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public), by or on behalf of the Government.

Alternate V (Sept 2014). As prescribed in HHSAR 327.409, add the following paragraph (j) to the basic clause:

(j) The Contractor agrees, except as may be otherwise specified in this contract for

specific data deliverables listed as not subject to this paragraph, that the Contracting Officer may, up to 3 years after acceptance of all deliverables under this contract, inspect at the Contractor's facility any data withheld pursuant to paragraph (g)(1) of this clause, for purposes of verifying the Contractor's assertion of limited rights or restricted rights status of the data or for evaluating work performance. When the Contractor whose data are to be inspected demonstrates to the Contracting Officer that there would be a possible conflict of interest if a particular representative made the inspection, the Contracting Officer shall designate an alternate inspector.

(End of clause)

352.227–70 Publications and Publicity.

As prescribed in HHSAR 327.404–70, the Contracting Officer shall insert the following clause:

Publications and Publicity (DEC 2015)

(a) Unless otherwise specified in this contract, the Contractor may publish the results of its work under this contract. The Contractor shall promptly send a copy of each article submitted for publication to the Contracting Officer's Representative. The Contractor shall also inform the Contracting Officer's Representative when the article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the Contracting Officer, the Contractor shall not display the HHS logo including Operating Division or Staff Division logos on any publications.

(c) The Contractor shall not reference the product(s) or service(s) awarded under this contract in commercial advertising, as defined in FAR 31.205–1, in any manner which states or implies HHS approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract.

(End of clause)

352.231–70 Salary Rate Limitation.

As prescribed in HHSAR 331.101–70(b), the Contracting Officer shall insert the following clause:

Salary Rate Limitation (DEC 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms ''direct salary,'' ''salary,'' and ''institutional base salary,'' have the same meaning and are collectively referred to as ''direct salary,'' in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the Office of Personnel Management Web site for Federal Executive Schedule salary levels.

(End of clause)

352.232–70 Incremental Funding.

As prescribed in HHSAR 332.706–2(b), the Contracting Officer shall insert the provision provided below in all solicitations when a cost-reimbursement contract for severable services using incremental funding is contemplated.

Incremental Funding (DEC 2015)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clause at FAR 52.232–22, ''Limitation of Funds''. The initial obligation of funds under the contract is expected to cover [*insert the appropriate increment of performance*]. The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining periods of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

352.233–70 Choice of Law (Overseas).

As prescribed in HHSAR 333.215–70(a), the Contracting Officer shall insert the following clause:

Choice of Law (Overseas) (DEC 2015)

This contract shall be construed in accordance with the substantive laws of the United States of America. By the execution of this contract, the Contractor expressly agrees to waive any rights to invoke the jurisdiction of local national courts where this contract is performed and agrees to accept the exclusive jurisdiction of the United States Civilian Board of Contract Appeals or the United States Court of Federal Claims for hearing and determination of any and all disputes that may arise under the Disputes clause of this contract.

(End of clause)

352.233–71 Litigation and Claims.

As prescribed in HHSAR 333.215–70(b), the Contracting Officer shall insert the following clause:

Litigation and Claims (Dec 2015)

(a) The Contractor shall provide written notification immediately to the Contracting Officer of any action, including any proceeding before an administrative agency, filed against the Contractor arising out of the performance of this contract, including, but not limited to the performance of any subcontract hereunder; and any claim against the Contractor the cost and expense of which is allowable under the clause entitled ''Allowable Cost and Payment.''

(b) Except as otherwise directed by the Contracting Officer, the Contractor shall furnish immediately to the Contracting Officer copies of all pertinent documents received by the Contractor with respect to such action or claim. To the extent not in conflict with any applicable policy of insurance, the Contractor may, with the Contracting Officer's approval, settle any such action or claim. If required by the Contracting Officer, the Contractor shall effect an assignment and subrogation in favor of the Government of all the Contractor's rights and claims (except those against the Government) arising out of any such action or claim against the Contractor; and authorize representatives of the Government to settle or defend any such action or claim and to represent the Contractor in, or to take charge of, any action.

(c) If the Government undertakes a settlement or defense of an action or claim, the Contractor shall furnish all reasonable assistance in effecting a settlement or asserting a defense. Where an action against the Contractor is not covered by a policy of insurance, the Contractor shall, with the approval of the Contracting Officer, proceed with the defense of the action in good faith. The Government shall not be liable for the expense of defending any action or for any costs resulting from the loss thereof to the extent that the Contractor would have been compensated by insurance which was required by other terms or conditions of this contract, by law or regulation, or by written direction of the Contracting Officer, but which the Contractor failed to secure through its own fault or negligence. In any event, unless otherwise expressly provided in this contract, the Government shall not reimburse or indemnify the Contractor for any liability loss, cost, or expense, which the Contractor may incur or be subject to by reason of any loss, injury or damage, to the person or to real or personal property of any third parties as may accrue during, or arise from, the performance of this contract.

(End of clause)

352.236–70 Design-Build Contracts.

As prescribed in HHSAR 336.570(a), the Contracting Officer shall insert the following clause:

Design-Build Contracts (Dec 2015)

(a) *General.* (1) The contract constitutes and defines the entire agreement between the Contractor and the Government. This contract includes the standard or special contract clauses and schedules included at the time of award. This contract incorporates by reference:

(i) The solicitation in its entirety (with the exception of instructions to offerors and evaluation criteria which do not become part of the award document);

(ii) The specifications and statement of work;

(iii) All drawings, cuts and illustrations, included in the solicitation and any amendments during all proposal phases leading up to award;

(iv) Exhibits and other attachments; and

(v) The successful Offeror's accepted proposal.

(2) In the event of conflict or inconsistency between any of the requirements of the various portions of this contract, precedence shall be given in the following order:

(i) Betterments: Any portions of the Offeror's proposal which exceed the requirements of the solicitation and which go beyond repair and improve the value of the property.

(ii) The contract clauses and schedules included during the solicitation or at the time of award.

(iii) All requirements (other than betterments) of the accepted proposal.

(iv) Any design products, including but not limited to plans, specifications, engineering studies and analyses, shop drawings, equipment installation drawings, *etc.* These are ''deliverables'' under the contract and are not part of the contract itself.

(3) Design products must conform to all requirements of the contract, in the order of precedence stated here.

(b) *Responsibility of the contractor for design.* (1) The Contractor shall be responsible for the professional quality, technical accuracy, and the coordination of all designs, drawings, specifications, and other non-construction services furnished by the Contractor under this contract. The Contractor shall, without additional compensation, correct or revise any errors or deficiency in its designs, drawings, specifications, and other non-construction services and perform any necessary rework or modifications, including any damage to real or personal property, resulting from the design error or omission.

(2) Neither the Government's review, approval or acceptance of, nor payment for, the services required under this contract shall be construed to operate as a waiver of any rights under this contract or of any cause of action arising out of the performance of this contract. The Contractor shall be and remain liable to the Government in accordance with applicable law for all damages to the Government caused by the Contractor's negligent performance of any of these services furnished under this contract.

(3) The rights and remedies of the Government provided for under this contract are in addition to any other rights and remedies provided by law.

(4) If the Contractor is comprised of more than one legal entity each such entity shall be jointly and severally liable with respect to all rights and remedies of the Government.

(c) *Sequence of design—construction.* (1) After receipt of the Contract Award, the Contractor shall initiate design, comply with all design submission requirements, and obtain Government review of each submission. No construction may be started until the Government reviews the Final Design submission and determines it satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

(2) If the Government allows the Contractor to proceed with limited construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any completed or in-progress construction related to the pending revisions until they are completed, resubmitted, and are satisfactory to the Government.

(3) No payment will be made for any completed or in-progress construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

(d) *Constructor's role during design.* The Contractor's construction management key personnel shall be actively involved during the design process to effectively integrate the design and construction requirements of this contract. In addition to the typical required construction activities, the constructor's involvement includes, but is not limited to actions such as: integrating the design schedule into the Master Schedule to maximize the effectiveness of fast-tracking design and construction (within the limits, if any, allowed in the contract), ensuring constructability and economy of the design, integrating the shop drawing and installation drawing process into the design, executing the material and equipment acquisition programs to meet critical schedules, effectively interfacing the construction Quality Control (QC) program with the design QC program, and maintaining and providing the design team with accurate, up-to-date redline and as-built documentation. The Contractor shall require and manage the active involvement of key trade subcontractors in the above activities.

(e) *Preconstruction conference.* (1) A preconstruction conference will be arranged by the Contracting Officer after award of contract and before commencement of work. The Contracting Officer or designated representative will notify the Contractor of the time, date, and location for the meeting. At this conference, the Contractor shall be oriented with respect to Government procedures and line of authority, contractual, administrative, and construction matters.

(2) The Contractor shall bring to this conference, in completed form, a Certificate of Insurance, plus the following items in either completed or draft form:

(i) Accident Prevention Plan;

(ii) Quality Control Plan;

(iii) Letter Appointing Superintendent;

(iv) Transmittal Register;

(v) Power of Attorney and Certified Copy of Resolution;

(vi) Network Analysis System, (when identified in the contract schedule as applicable);

(vii) List of Subcontractors;

(viii) SF 1413;

(ix) Performance and Payment Bonds; and

(x) Schedule of Values.

(3) A letter of record will be written documenting all items discussed at the conference, and a copy will be furnished by the Contracting Officer to all in attendance.

(f) *Payment for design under fixed-price design-build contracts.* (1) The Contracting Officer may approve progress payments for work performed during the project design phase up to the maximum amount of ____ (*Contracting Officer to insert percent figure. If none stated, the amount is four (4) percent*) percent of the contract price.

(2) Contractor invoices for payment must be accompanied by satisfactory documentation supporting the amounts for which payments are requested. Progress payments approved by the Contracting Officer during the project design phase in no way constitute an acceptance of functional and aesthetic design elements nor acceptance of a final settlement amount in the event of a buy-out nor a waiver of any contractual requirements.

(g) *Unscheduled jobsite shutdowns.* Due to security reasons during the life of this contract the Government may on an unscheduled basis require the contractor to shut down its jobsite for 2 days per year at no additional cost. This shall not constitute a suspension of work under FAR 52.242–14, Suspension of Work

(End of clause)

Alternate I (DEC 2015).

When Fast Track procedures are being used, replace paragraph (c) of the basic clause with the following:

(c) *Sequence of design build.* (1) After receipt of the Contract Award the Contractor shall initiate design, comply with all design submissions requirements and obtain Government review of each submission. The contractor may begin construction on portions of the work for which the Government has reviewed the final design submission and has determined satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

(2) If the Government allows the Contractor to proceed with the construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place construction related to the pending revisions until they are completed, resubmitted, and are satisfactory to the Government.

(3) No payment will be made for any in-place construction until all required submittals have been made, reviewed, and are satisfactory to the Government.

(End of clause)

352.237–70 Pro-Children Act.

As prescribed in HHSAR 337.103(d)(1), the Contracting Officer shall insert the following clause:

Pro-Children Act (DEC 2015)

(a) Public Law 103–227, Title X, Part C, also known as the *Pro-Children Act of 1994* (Act), 20 U.S.C. 7183, imposes restrictions on smoking in facilities where certain federally funded children's services are provided. The Act prohibits smoking within any indoor facility (or portion thereof), whether owned, leased, or contracted for, that is used for the routine or regular provision of: (i) Kindergarten, elementary, or secondary education or library services or (ii) health or day care services that are provided to children under the age of 18. The statutory prohibition also applies to indoor facilities that are constructed, operated, or maintained with Federal funds.

(b) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all subcontracts awarded under this contract for the specified children's services. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act. Failure to comply with the Act may result in the imposition of a civil monetary penalty in an amount not to exceed $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity. Each day a violation continues constitutes a separate violation.

352.237–71 Crime Control Act—Reporting of Child Abuse.

As prescribed in HHSAR 337.103(d)(2), the Contracting Officer shall insert the following clause:

Crime Control Act of 1990—Reporting of Child Abuse (DEC 2015)

(a) Public Law 101–647, also known as the Crime Control Act of 1990 (Act), imposes responsibilities on certain individuals who, while engaged in a professional capacity or activity, as defined in the Act, on Federal land or in a federally-operated (or contracted) facility, learn of facts that give the individual reason to suspect that a child has suffered an incident of child abuse.

(b) The Act designates ''covered professionals'' as those persons engaged in professions and activities in eight different categories including, but not limited to, teachers, social workers, physicians, dentists, medical residents or interns, hospital personnel and administrators, nurses, health care practitioners, chiropractors, osteopaths, pharmacists, optometrists, podiatrists, emergency medical technicians, ambulance drivers, alcohol or drug treatment personnel, psychologists, psychiatrists, mental health professionals, child care workers and administrators, and commercial film and photo processors. The Act defines the term ''child abuse'' as the physical or mental injury, sexual abuse or exploitation, or negligent treatment of a child.

(c) Accordingly, any person engaged in a covered profession or activity under an HHS contract or subcontract, regardless of the purpose of the contract or subcontract, shall immediately report a suspected child abuse incident in accordance with the provisions of the Act. If a child is suspected of being harmed, the appropriate State Child Abuse Hotline, local child protective services (CPS), or law enforcement agency shall be contacted. For more information about where and how to file a report, the Childhelp USA, National Child Abuse Hotline (1–800–4–A–CHILD) shall be called. Any covered professional failing to make a timely report of such incident shall be guilty of a Class B misdemeanor.

(d) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(End of clause)

352.237–72 Crime Control Act—Requirement for Background Checks.

As prescribed in HHSAR 337.103(d)(3), the Contracting Officer shall insert the following clause:

Crime Control Act of 1990—Requirement for Background Checks (DEC 2015)

(a) Public Law 101–647, also known as the Crime Control Act of 1990 (Act), requires that all individuals involved with the provision of child care services to children under the age of 18 undergo a criminal background check. ''Child care services'' include, but are not limited to, social services, health and mental health care, child (day) care, education (whether or not directly involved in teaching), and rehabilitative programs. Any conviction for a sex crime, an offense involving a child victim, or a drug felony, may be grounds for denying employment or for dismissal of an employee providing any of the services listed above.

(b) The Contracting Officer will provide the necessary information to the Contractor regarding the process for obtaining the background check. The Contractor may hire a staff person provisionally prior to the completion of a background check, if at all times prior to the receipt of the background check during which children are in the care of the newly-hired person, the person is within the sight and under the supervision of a previously investigated staff person.

(c) By acceptance of this contract or order, the Contractor agrees to comply with the requirements of the Act. The Act also applies to all applicable subcontracts awarded under this contract. Accordingly, the Contractor shall ensure that each of its employees, and any subcontractor staff, is made aware of, understands, and complies with the provisions of the Act.

(End of clause)

352.237–73 Indian Child Protection and Family Violence Act.

As prescribed in HHSAR 337.103(d)(4) the Contracting Officer shall insert the following clause:

Indian Child Protection and Family Violence Act (DEC 2015)

(a) This contract is subject to the Indian Child Protection and Family Violence Act, Public Law 101–630 (25 U.S.C. 3201 *et seq.*) The duties and responsibilities required by this contract may involve regular contact with or control over Indian children. Public Law 101–630 prohibits employment, including Personal Service Contracts, with anyone who has been convicted of any crime of violence. Any such conviction should immediately be brought to the attention of the Contracting Officer. The contractor will be subject to a character investigation, conducted by the Indian Health Service, Office of Human Resources. Until such time as the contractor has been notified of completion of the investigation, the contractor shall have no unsupervised contact with Indian children. In order to initiate this background investigation, the contractor must provide information as required in this contract or as directed by the Contracting Officer.

(b) As a prerequisite to providing services under this contract, the Contractor is required to complete and sign the declaration found in Section J of this contract.

(End of clause)

352.237–74 Non-Discrimination in Service Delivery.

As prescribed in HHSAR 337.103(e), the Contracting Officer shall insert the following clause in solicitations and contracts:

Non-Discrimination In Service Delivery (DEC 2015)

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). By acceptance of this contract, the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The contractor shall include this clause in all sub-contracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

(End of clause)

352.237–75 Key Personnel.

As prescribed in HHSAR 337.103(f), the Contracting Officer shall insert the following clause:

Key Personnel (DEC 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause)

352.239–73 Electronic Information and Technology Accessibility Notice.

(a) As prescribed in HHSAR 339.203–70(a), the Contracting Officer shall insert the following provision:

Electronic and Information Technology Accessibility Notice (Dec 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at *http://www.hhs.gov/web/508*. The complete text of the Section 508 Final Provisions can be accessed at *http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards*.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239–74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site *http://www.hhs.gov/web/508*.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, *i.e.,* after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

352.239–74 Electronic and Information Technology Accessibility.

As prescribed in HHSAR 339.203–70(b), insert the following clause:

Electronic and Information Technology Accessibility (DEC 2015)

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the ''Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards'' set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the ''Access Board'') in 36 CFR part 1194. Information about Section 508 is available at *http://www.hhs.gov/web/508*. The complete text of Section 508 Final Provisions can be accessed at *http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards*.

(b) The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) The Section 508 accessibility standards applicable to this contract are:

_____

(Contract staff must list applicable standards)

(d) In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (*http://www.hhs.gov/web/508*). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at *http://www.hhs.gov/web/508*. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause)

352.270–1 [Reserved]

352.270–2 [Reserved]

352.270–3 [Reserved]

352.270–4a Notice to Offerors, Protection of Human Subjects.

As prescribed in HHSAR 370.303(a), the Contracting Officer shall insert the following provision:

Notice to Offerors, Protection of Human Subjects (DEC 2015)

(a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: *http://www.hhs.gov/ohrp/index.html*.

These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)–(6) are exempt from complying with 45 CFR part 46. See *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html*.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111* for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at *http://www.hhs.gov/ohrp/assurances/index.html*).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.

(g) The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

Alternate I (DEC 2015).

As prescribed in HHSAR 370.303(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic clause.

(g) The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within *(Contracting Officer must insert a time period in which the FWA must be obtained).* Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

352.270–4b Protection of Human Subjects.

As prescribed in HHSAR 370.304(a), the Contracting Officer shall insert the following clause:

Protection of Human Subjects (DEC 2015)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Web site at: *http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf*).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

352.270–5a Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals.

As prescribed in HHSAR 370.403(a), the Contracting Officer shall insert the following provision:

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (DEC 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892–7982 (Email: *olaw@od.nih.gov*; Phone: 301–496–7163).

(End of provision)

352.270–5b Care of Live Vertebrate Animals.

As prescribed in HHSAR 370.404, the Contracting Officer shall insert the following clause:

Care of Live Vertebrate Animals (DEC 2015)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1–2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (*see* 7 U.S.C. 2131 *et seq.* and 9 CFR subchapter A, Parts 1–4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: *ace@aphis.usda.gov*; Web site: (*http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare*).

(End of clause)

352.270–6 Restriction on Use of Human Subjects.

As prescribed in HHSAR 370–304(b), the Contracting Officer shall insert the following clause:

Restriction on Use of Human Subjects (DEC 2015)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause)

352.270–7 [Reserved]

352.270–8 [Reserved]

352.270–9 Non-Discrimination for Conscience.

As prescribed in HHSAR 370.701, the Contracting Officer shall insert the following provision:

Non-Discrimination for Conscience (DEC 2015)

(a) Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care—

(1) Shall not be required, as a condition of receiving such assistance, to—

(i) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(ii) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

(2) Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

(b) Accordingly, an offeror who believes this solicitation contains work requirements requiring it endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it excluded in its technical proposal.

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b), to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision)

352.270–10 Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

As prescribed in HHSAR 370.303(d), the Contracting Officer shall insert the following provision:

Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DEC 2015)

(a) All Offerors proposing research expected to involve human subjects shall comply with the regulations set forth in 45 CFR part 46, and with the provisions at HHSAR 352.270–4a.

(b) The Offeror shall have an acceptable Assurance of Compliance on file with the Office for Human Research Protections (OHRP), whenever it submits a proposal to the FDA for research expected to involve human subjects. Direct questions regarding Federal-wide Assurance to OHRP. The Offeror's proposal shall include a copy of the acceptable Assurance of Compliance.

(c) After the contract has been awarded, the Contractor shall take the following actions:

(1) The Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance, hereafter referred to as ''the local IRB,'' shall review the proposed research protocol. A letter from the local IRB stating that the proposed research protocol has been reviewed and approved, and thus adequately protects the rights and welfare of human subjects involved, or a letter stating that the proposed research is exempt under 45 CFR 46.101(b) shall be submitted to the Contracting Officer.

(2) Upon award, the successful Offeror, hereafter ''the Contractor,'' shall submit its proposed research protocol to the FDA's Research Involving Human Subjects Committee (RIHSC). The RIHSC or its designee will review and approve the research protocol to assure it adequately protects the rights and welfare of human subjects involved. The RIHSC or designee will also determine whether the proposed research is exempt under 45 CFR 46.101(b). The Contractor shall submit, to the Contracting Officer of record, a copy of the RIHSC's or its designee's letter stating that it reviewed and approved the proposed research protocol.

(d) The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects until RIHSC or its designee reviews and approves its research. The Contractor may begin other limited aspects of contract performance prior to receiving RIHSC's or designee's approval of the proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC's or designee's approval; however, the Contractor shall submit a copy of RIHSC's or its designee's approval to the Contracting Officer within three business days of its receipt.

(e) A Contractor's failure to obtain RIHSC's or its designee's approval of its proposed research may result in termination of its contract. However, failure to obtain RIHSC's or its designee's approval during initial review will not automatically result in termination of the contract. Instead, the Contractor may correct any deficiencies identified during the initial RIHSC or designee review and resubmit the proposed research protocol to RIHSC or its designee for a second review. The Contractor is encouraged to solicit the RIHSC's or its designee's input during the resubmission process.

(f) The Contractor shall seek RIHSC's or its designee's and local IRB review and approval whenever making modifications, amendments or other changes to the research protocol. Such modifications, amendments and changes include, but are not limited to changes in investigators, informed consent forms, and recruitment advertisements. The Contractor may institute changes immediately after receiving both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however, the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of provision)

352.270–11 Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required.

As prescribed in HHSAR 370.304(c), the Contracting Officer shall insert the following clause:

Protection of Human Subjects—Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required (DEC 2015)

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR part 46 and the clause at HHSAR 352.270–4b.

(b) Initial proof of compliance with 45 CFR part 46 shall consist of:

(1) A copy of a current Federal-wide Assurance on file with OHRP. The copy of a current Federal–wide Assurance shall be included with the Contractor's proposal;

(2) A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Office; and

(3) A copy of a letter from the RIHSC stating that it or its designee has reviewed and approved the proposed research protocol. This shall be submitted to the Contracting Officer within three business days of its issuance.

The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects under this contract, until RIHSC has reviewed and approved its research. The Contractor may commence other limited aspects of contract performance prior to receiving RIHSC or its designee approval of its proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC or its designee approval; however, the Contractor shall submit a copy of RIHSC's or its designee's letter of approval to the Contracting Officer within three business days of its receipt.

Failure to obtain RIHSC or its designee approval of proposed research protocols may result in the termination of this contract.

(c) The Contractor further agrees that:

(1) The Contractor will provide a letter from RIHSC, at least annually, stating that RIHSC or its designee has reviewed and approved the research protocols for research performed under this contract. This shall be submitted to the Contracting Officer for inclusion in the contract file.

(2) The Contractor will submit all proposed modifications and amendments to research protocols for research performed under this contract to RIHSC for review and approval. Modifications and amendments include, but are not limited, to changes to consent forms and advertising materials, and the addition or deletion of investigators. Changes may be instituted immediately after the Contractor has received both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject); however the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

(End of clause)

352.270–12 Needle Exchange.

As prescribed in HHSAR 370.304(d), the Contracting Officer shall insert the following clause:

Needle Exchange (DEC 2015)

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

(End of Clause)

352.270–13 Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research.

As prescribed in HHSAR 370.304(e), the Contracting Officer shall insert the following clause:

Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research (DEC 2015)

(a) The Contractor shall not use any funds obligated under this contract for any abortion.

(b) The Contractor shall not use any funds obligated under this contract for the following:

(1) The creation of a human embryo or embryos for research purposes; or

(2) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(c) The term ''human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

(d) The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

PART 353—FORMS

Subpart 353.3—[Reserved]

SUBCHAPTERS I—L [RESERVED]

SUBCHAPTER M—HHS SUPPLEMENTATIONS

PART 370—SPECIAL PROGRAMS AFFECTING ACQUISITION

Subpart 370.1—[Reserved]

Subpart 370.2—[Reserved]

Subpart 370.3—Acquisitions Involving Human Subjects

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November 17, 2015 Subpart 370.7—Acquisitions under the Leadership Act

370.700 Scope of subpart.
370.701 Contract clause.
370.702 Solicitation provision.

Authority: 5 U.S.C. 301; 40 U.S.C. 121(c)(2)

Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.

This subpart applies to all research activities conducted under contracts involving human subjects. See 45 CFR 46.102(d) and (f).

370.301 Policy.

It is the Department of Health and Human Services (HHS) policy that the contracting officer shall not award a contract involving human subjects until the prospective contractor provides assurance that the activity will undergo initial and continuing review by an appropriate Institutional Review Board (IRB) in accordance with HHS regulations at 45 CFR 46.103. The contracting officer shall require a Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or institution engaged in human subjects research in performance of a contract. OHRP administers the assurance covering all HHS-supported or HHS-conducted activities involving human subjects.

370.302 Federal-wide Assurance (FWA).

(a) OHRP-Approved FWAs are found at the following Web site: *http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc.*

(b) Normally a contractor, subcontractor, or institution must provide approval of a FWA before a contract is awarded. If a contractor, subcontractor, or institution does not currently hold an approved FWA, it shall submit an explanation with its proposal and an FWA application prior to submitting a proposal. The contracting officer, on a case by case basis, may make award without an approved assurance in consultation with OHRP.

(c) A contractor, subcontractor, or institution must submit all FWAs, including new FWAs, using the electronic submission system available through the OHRP Web site at *http://ohrp.cit.nih.gov/efile/*, unless an institution lacks the ability to do so electronically. If an institution believes it lacks the ability to submit its FWA electronically, it must contact OHRP by telephone or email (see *http://www.hhs.gov/ohrp/assurances/index.html*) and explain why it is unable to submit its FWA electronically.

370.303 Notice to offerors.

(a) The contracting officer shall insert the provision at 352.270–4a, Notice to Offerors, Protection of Human Subjects, in solicitations that involve human subjects. The contracting officer shall use the clause with its Alternate I when the agency is prescribing a date later than the proposal submission by which the offeror must have an approved FWA.

(b) Institutions having an OHRP-approved FWA shall certify IRB approval of submitted proposals in the manner required by instructions for completion of the contract proposal; by completion of an OMB Form No. 0990–0263, Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule); or by letter indicating the institution's OHRP-assigned FWA number, the date of IRB review and approval, and the type of review (convened or expedited). The date of IRB approval must not be more than 12 months prior to the deadline for proposal submission.

(c) The contracting officer generally will not request FWAs for contractors, subcontractors, or institutions prior to selecting a contract proposal for negotiation. When a contractor submits an FWA, it provides certification for the initial contract period; no additional documentation is required. If the contract provides for additional years to complete the project, the contractor shall certify annually in the manner described in 370.303(b).

(d) For the Food and Drug Administration (FDA), the contracting officer shall insert the provision at 352.270–10, Notice to Offerors—Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in solicitations that involve human subjects when the research is subject to RIHSC review and approval.

370.304 Contract clauses.

(a) The contracting officer shall insert the clause at 352.270–4b, Protection of Human Subjects, in solicitations, contracts and orders involving human subjects.

(b) The contracting officer shall insert the clause at 352.270–6, Restriction on Use of Human Subjects, in contracts and orders if the contractor has an approved FWA of compliance in place, but cannot certify prior to award that an IRB registered with OHRP reviewed and approved the research, because definite plans for involvement of human subjects are not set forth in the proposal (*e.g.,* projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds). Under these conditions, the contracting officer may make the award without the requisite certification, as long as the contracting officer includes appropriate conditions in the contract or order.

(c) For FDA, the contracting officer shall insert the clause at 352.270–11, Protection of Human Subjects, Research Involving Human Subjects Committee (RIHSC) Approval of Research Protocols Required, in contracts and orders that involve human subjects when the research is subject to RIHSC review and approval.

(d) The contracting officer shall insert the clause at 352.270–12, Needle Exchange, in solicitations, contracts, and orders involving human subjects.

(e) The contracting officer shall insert the clause at 352.270–13, Continued Ban on Funding Abortion and Continued Ban on Funding of Human

Embryo Research, in solicitations, contracts, and orders involving human subjects.

Subpart 370.4—Acquisitions Involving the Use of Laboratory Animals

370.400 Scope of subpart.

This subpart applies to all research, research training, biological testing, housing and maintenance, and other activities involving live vertebrate animals conducted under contract. Additional information can be found in Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals *http://grants.nih.gov/grants/olaw/references/phspolicylab animals.pdf*.

370.401 Policy.

(a) It is HHS policy that contracting activities shall not award a contract involving live vertebrate animals until the Contractor provides acceptable assurance the contract work is subject to initial and continuing review by an appropriate Institutional Animal Care and Use Committee (IACUC) as described in the PHS Policy at IV.B.6 and 7. The contracting officer shall require an applicable Animal Welfare Assurance approved by the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), of each contractor, subcontractor, or institution having responsibility for animal care and use involved in performance of the contract. Normally the assurance shall be approved before award. The contracting officer, on a case-by-case basis, may make award without an approved assurance in consultation with OLAW. For additional information see PHS Policy II., IV.A, and V.B.

(b) The OLAW, NIH, is responsible for negotiating assurances covering all HHS/PHS-supported or HHS/PHS-conducted activities involving the care and use of live vertebrate animals. OLAW shall provide guidance to contracting officers regarding adequate animal care and use, approval, disapproval, restriction, or withdrawal of approval of assurances. For additional information see PHS Policy V.A.

(c) If using live vertebrate animals, HHS policy requires that offerors address the points in the Vertebrate Animal Section (VAS) of the Technical Proposal. Each of the points must be addressed in the VAS portion of the Technical Proposal. For additional information see PHS Policy and use Contract Proposal VAS Worksheet. *http://grants.nih.gov/grants/olaw/references/phspol.htm#Information RequiredinApplications-Proposalsfor AwardsSubmittedtoPHS* and *http://grants.nih.gov/grants/olaw/VAScontracts.pdf*.

370.402 Assurances.

(a) Animal Welfare Assurances may be one of three types:

(1) *Domestic Assurance (DA).* A DA describes the institution's animal care and use program, including but not limited to the lines of authority and responsibility, veterinary care, IACUC composition and procedures, occupational health and safety, training, facilities, and species housed. A DA listed in OLAW's list of institutions with an approved DA is acceptable for purposes of this policy.

(2) *Inter-institutional Assurance (IA).* The offeror, its proposed subcontractor, or institution shall submit an IA when it does not have a proprietary animal care and use program, facilities to house animals or IACUC, and does not conduct animal research on-site. The offeror will perform the animal activity at an institution with an Animal Welfare Assurance named as a performance site. An IA approval extends to the full period of contract performance (up to 5 years) limited to the specific award or single project.

(3) *Foreign Assurance (FA).* The Foreign Assurance is required for institutions outside the U.S. that receive PHS funds directly through a contract award. The Foreign Assurance also applies to institutions outside the U.S. that receive PHS funds indirectly (named as a performance site). An FA listed in OLAW's list of institutions with an approved FA is acceptable for purposes of this policy.

(b) The contracting officer shall forward copies of proposals selected for negotiation and requiring an assurance to OLAW at *olawdoa@od.nih.gov*, as early as possible to secure the necessary assurances.

(c) A contractor providing animal care services at an institution with an Animal Welfare Assurance, such as a Government-owned, Contractor-operated (GOCO) site, does not need a separate assurance. GOCO site assurances normally cover such contractor services.

370.403 Notice to offerors.

(a) The contracting officer shall insert the provision at 352.270–5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, in solicitations involving live vertebrate animals.

(b) Offerors having a DA on file with OLAW shall submit IACUC approval of the use of animals in the manner required by the solicitation, but prior to award. The date of IACUC approval must not be more than 36 months prior to award.

(c) It is not necessary for offerors lacking an Animal Welfare Assurance to submit assurances or IACUC approval with proposals. OLAW shall contact contractors, subcontractors, and institutions to negotiate necessary assurances and verify IACUC approvals when requested by the contracting officer.

370.404 Contract clause.

The contracting officer shall insert the clause at 352.270–5b, Care of Live Vertebrate Animals, in solicitations, contracts, and orders that involve live vertebrate animals.

Subpart 370.5—[Reserved]

Subpart 370.6—[Reserved]

Subpart 370.7—Acquisitions Under the Leadership Act

370.700 Scope of subpart.

This subpart sets forth the acquisition requirements regarding implementation of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS) programs under the President's Emergency Plan for AIDS Relief as established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended (Pub. L. 108–25, Pub. L. 110–293, Pub. L. 113–56).

370.701 Solicitation provision.

The contracting officer shall insert the provision at 352.270–9, Non-Discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold:

(a) In connection with the implementation of HIV/AIDS programs under the President's Emergency Plan for AIDS Relief established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended; or

(b) Where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended. In resolving any issues or complaints that offerors may raise regarding meeting the requirements specified in the provision, the contracting officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Program Manager, and other HHS officials, as appropriate.

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 54

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2590

Department of Health and Human Services

45 CFR Parts 144, 146 and 147

Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections Under the Affordable Care Act; Final Rules

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 9744]

RIN 1545–BJ45, 1545–BJ50, 1545–BJ62, 1545–BJ57

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB72

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 144, 146 and 147

[CMS–9993–F]

RIN 0938–AS56

Final Rules for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding grandfathered health plans, preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, coverage of dependent children to age 26, internal claims and appeal and external review processes, and patient protections under the Affordable Care Act. It finalizes changes to the proposed and interim final rules based on comments and incorporates subregulatory guidance issued since publication of the proposed and interim final rules.

DATES:

Effective date. These final regulations are effective on January 19, 2016.

Applicability date. These final regulations apply to group health plans and health insurance issuers beginning on the first day of the first plan year (or, in the individual market, the first day of the first policy year) beginning on or after January 1, 2017. For information on requirements applicable prior to this date, see section II.I. of this preamble.

FOR FURTHER INFORMATION CONTACT: Elizabeth Schumacher or Amber Rivers, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 927–9639; Cam Clemmons, Centers for Medicare & Medicaid Services, Department of Health and Human Services, at (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act, Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010 (these are collectively known as the ''Affordable Care Act''). The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.[1] The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated into the Code and ERISA are sections 2701 through 2728.

The Departments of Labor (DOL), Health and Human Services (HHS) and the Treasury (collectively, the Departments) have issued regulations implementing the revised PHS Act sections 2701 through 2719A in several phases.[2] Throughout 2010, the Departments issued interim final regulations (or temporary and proposed regulations),[3] with requests for comment, implementing Affordable Care Act section 1251 (preservation of right to maintain existing coverage), and PHS Act sections 2704 (prohibition of preexisting condition exclusions), 2711 (prohibition on lifetime or annual limits), 2712 (prohibition on rescissions), 2714 (extension of dependent coverage), 2719 (internal claims and appeals and external review process), and 2719A (patient protections) (collectively, the 2010 interim final regulations). As discussed in more detail below, after consideration of comments[4] in response to the 2010 interim final regulations, the Departments are issuing these final regulations.

II. Overview of the Final Regulations

A. Section 1251 of the Affordable Care Act, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251, 29 CFR 2590.715–1251, and 45 CFR 147.140)

Section 1251 of the Affordable Care Act provides that certain group health plans and health insurance coverage existing as of March 23, 2010 (the date of enactment of the Affordable Care Act) (grandfathered health plans) are only subject to certain provisions of the Affordable Care Act (for as long as they maintain that status as grandfathered health plans under the applicable regulations).[5] On June 17, 2010, the Departments issued interim final regulations implementing section 1251 and requesting comment.[6] On

[1] The term ''group health plan'' is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term ''health plan,'' as used in other provisions of title I of the Affordable Care Act. The term ''health plan'' does not include self-insured group health plans.

[2] Note, however, that in sections under headings listing only two of the three Departments, the term ''Departments'' generally refers only to the two Departments listed in the heading.

[3] The Departments of Labor and HHS published their rules as interim final rules and are finalizing their interim final rules. The Department of the Treasury/Internal Revenue Service published temporary regulations and proposed regulations with the text of the temporary regulations serving as the text of the proposed regulations. The Department of the Treasury/Internal Revenue Service is finalizing its proposed rules.

[4] In response to the 2010 interim final regulations, the Departments received many comments that relate to early implementation issues, many of which were addressed through subregulatory guidance (addressed more fully below). While the Departments acknowledge and have reviewed the comments provided in response to the 2010 interim final regulations, to the extent the issues presented are now moot, such comments are not explicitly addressed below.

[5] For a list of the market reform provisions under title XXVII of the PHS Act, as added or amended by the Affordable Care Act and incorporated into ERISA and the Code, applicable to grandfathered health plans, visit *http://www.dol.gov/ebsa/pdf/grandfatherregtable.pdf.*

[6] 75 FR 34538.

November 17, 2010, the Departments issued an amendment to the interim final regulations to permit certain changes in policies, certificates, or contracts of insurance without loss of grandfathered status.[7] Also in 2010, the Departments released Affordable Care Act Implementation Frequently Asked Questions (FAQs) Parts I, II, IV, V, and VI to answer questions related to maintaining a plan's status as a grandfathered health plan.[8] After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations. As discussed in more detail below, these final regulations finalize the 2010 interim final regulations and amendment to the interim final regulations without substantial change and incorporate the clarifications issued thus far in subregulatory guidance.

1. Definition of Grandfathered Health Plan Coverage

Under the Affordable Care Act and paragraph (a)(1) of the interim final regulations implementing section 1251 of the Affordable Care Act, a group health plan or group or individual health insurance coverage is a grandfathered health plan with respect to individuals enrolled on March 23, 2010 (for as long as it maintains that status under the applicable regulations). The interim final regulations provided that a group health plan or coverage does not relinquish its grandfather status merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered at least one person (although not necessarily the same person) at all times since March 23, 2010. The interim final regulations also provided that the determination of grandfather status under the rules is made separately with respect to each benefit package made available under a group health plan or health insurance coverage.

Some commenters requested clarification with respect to the meaning of the term ''benefit package'' including requesting further guidance regarding what coverage option features constitute separate benefit packages. In response to the comments, the Departments issued Affordable Care Act Implementation FAQs Part II Q2 to further clarify the application of the rules on a benefit-package-by-benefit-package basis.[9] These final regulations continue to provide that the determination of grandfather status applies separately with respect to each benefit package and incorporate the clarifications issued in the FAQs. Therefore, as demonstrated by the example provided in the FAQs, if a group health plan offers three benefit package options—a PPO (preferred provider organization), a POS (point of service) arrangement, and an HMO (health maintenance organization)—the PPO, POS arrangement, and HMO are treated as separate benefit packages. Similarly, under these final regulations, if any benefit package ceases grandfather status, it will not affect the grandfather status of the other benefit packages.

2. Disclosure of Grandfather Status

Paragraph (a)(2) of the interim final regulations implementing section 1251 of the Affordable Care Act provided that to maintain status as a grandfathered health plan, a plan or health insurance coverage (1) must include a statement, in any plan materials provided to participants or beneficiaries (in the individual market, primary subscribers) describing the benefits provided under the plan or health insurance coverage, that the plan or health insurance coverage believes that it is a grandfathered health plan within the meaning of section 1251 of the Affordable Care Act and (2) must provide contact information for questions and complaints. The interim final regulations provided model language that can be used to satisfy this disclosure requirement.[10]

The Departments received several comments asking the Departments to require enhanced disclosure to participants that includes a more comprehensive explanation of grandfathered health plan status, information on the triggers that can result in a cessation of such status, a complete listing of the specific market reforms that are inapplicable to the plan by virtue of its status, and access to a formal process for obtaining a determination on a plan's status from the appropriate government agency. Other commenters stated that including this disclosure requirement in consumer materials may be confusing to participants, may not have the intended benefit, and that it may be more appropriate to include the applicable consumer protections in the employer plan documents or insurance coverage documents. Additional commenters stated this requirement is unnecessary because ERISA's disclosure requirements are already sufficient to explain to participants the information they need about their plan (including which benefits are included or excluded), and that including information about what benefits they could have had if their employers chose to relinquish their grandfathered plan status is unnecessary.

In response to these comments the Departments issued Affordable Care Act Implementation FAQs Part IV Q1, in which the Departments clarified that a grandfathered health plan is not required to provide the disclosure statement every time it sends out a communication, such as an explanation of benefits (EOB), to a participant or beneficiary. Instead, a grandfathered health plan will comply with this disclosure requirement if it includes the model disclosure language provided in the Departments' interim final grandfather regulations (or a similar statement) whenever a summary of the benefits under the plan is provided to participants and beneficiaries. For example, many plans distribute summary plan descriptions upon initial eligibility to receive benefits under the plan or coverage, during an open enrollment period, or upon other opportunities to enroll in, renew, or change coverage. The FAQs also provided that, while it is not necessary to include the disclosure statement with each plan or issuer communication to participants and beneficiaries (such as an EOB), the Departments encourage plan sponsors and issuers to identify other communications in which disclosure of grandfather status would be appropriate and consistent with the goal of providing participants and beneficiaries information necessary to

[7] 75 FR 70114.

[8] See Affordable Care Act Implementation FAQs Part I, available at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html*, Affordable Care Act Implementation FAQs Part II available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html*, Affordable Care Act Implementation FAQs Part IV, available at *http://www.dol.gov/ebsa/faqs/faq-aca4.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html* and Affordable Care Act Implementation FAQs Part V, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html* and Affordable Care Act Implementation FAQs Part VI, available at *http://www.dol.gov/ebsa/faqs/faq-aca6.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html*.

[9] See Affordable Care Act Implementation FAQs Part II, available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html*.

[10] 29 CFR 2590.715–1251(a)(2)(ii); 45 CFR 147.140(a)(2)(ii).

understand and make informed choices regarding health coverage.[11]

After consideration of the comments and feedback from stakeholders, the Departments retain the approach in the interim final regulations and subsequent subregulatory guidance because that approach provides consumers with information about the status of their plan or health insurance coverage, which assists them in identifying and enforcing their rights, without undue burden on plans and issuers. Therefore, these final regulations clarify that, to maintain status as a grandfathered health plan, a group health plan, or health insurance coverage, must include a statement that the plan or health insurance coverage believes it is a grandfathered health plan in any summary of benefits provided under the plan. It must also provide contact information for questions and complaints. These final regulations also retain the model disclosure language. Plans and issuers may (but are not required to) utilize the model disclosure language to satisfy this disclosure requirement. The Departments also note that the disclosure language is a model, and, thus, plans and issuers are permitted to include additional disclosure elements, such as the entire list of the market reform provisions that do not apply to grandfathered health plans.

3. Anti-Abuse Rules

The interim final regulations provided that a group health plan that provided coverage on March 23, 2010 generally is a grandfathered health plan with respect to new employees (whether newly hired or newly enrolled) and their families who enroll in the grandfathered health plan after March 23, 2010. The interim final regulations also provided two anti-abuse rules to curtail attempts to retain grandfather status by indirectly making changes that would otherwise result in a loss of grandfather status.

The first anti-abuse rule provided that if the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan. Under the second anti-abuse rule, the interim final regulations set forth specific criteria that, if met, would cause a plan that is transferring employees to relinquish its grandfather status. Specifically, the interim final regulations provided that a plan that is transferring employees would relinquish its grandfather status if, comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan, such amendment would cause a loss of grandfather status and there was no bona fide employment-based reason to transfer the employees into the transferee plan. The second anti-abuse rule was designed to prevent a plan or issuer from circumventing the limits on changes that cause a plan or health insurance coverage to cease to be a grandfathered health plan. This rule was intended to address situations in which employees who previously were covered by a grandfathered health plan are transferred to another grandfathered health plan without any bona fide employment-based reason.

a. Bona Fide Employment-Based Reasons

The Departments received several comments regarding the anti-abuse provisions. Stakeholders requested that the Departments clarify what constitutes a bona fide employment-based reason that would prevent a plan that is transferring employees from relinquishing its grandfather status. In response, the Departments issued Affordable Care Act Implementation FAQs Part VI Q1, which provided several examples of the variety of circumstances that would constitute a bona fide employment-based reason to transfer employees. Examples of a bona fide employment-based reason include: When a benefit package is being eliminated because the issuer is exiting the market; when a benefit package is being eliminated because the issuer no longer offers the product to the employer; when low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package; when a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or when a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.[12]

These final regulations include those examples of bona fide employment-based reasons. The Departments continue to interpret the term ''bona fide employment-based reason'' to embrace a variety of circumstances, and plans and issuers should evaluate all facts and circumstances carefully to determine whether a bona fide employment-based reason exists when considering transferring employees from one grandfathered health plan to another. The Departments may issue additional guidance if further questions regarding what constitutes a bona fide employment-based reason arise.

b. Clarification Regarding Multiemployer Plans

Section 1251 of the Affordable Care Act, as well as the 2010 interim final regulations, permit a grandfathered group health plan to cover new employees without any effect on its status as a grandfathered plan. Several commenters requested that the Departments clarify in the final regulations whether a multiemployer plan may add new contributing employers to the plan without triggering a loss of grandfather status. These final regulations clarify that the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfathered status, provided that the multiemployer plan has not made any other changes that would cause the plan to relinquish its grandfathered status.

4. Maintenance of Grandfather Status

The interim final regulations set forth rules for determining when changes to the terms of a plan or health insurance coverage cause the plan or coverage to cease to be a grandfathered health plan. Specifically, the interim final regulations outlined six changes to benefits, cost-sharing mechanisms, and contribution rates that will cause a plan or health insurance coverage to relinquish its grandfather status.[13] Since

[11] See Affordable Care Act Implementation FAQs Part IV, available at *http://www.dol.gov/ebsa/faqs/faq-aca4.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html.*

[12] See Affordable Care Act Implementation FAQs Part VI, available at *http://www.dol.gov/ebsa/faqs/faq-aca6.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.*

[13] The six changes (measured from March 23, 2010) outlined in paragraph (g)(1) of the interim final regulations that are considered to change a health plan so significantly that they will cause a group health plan or health insurance coverage to relinquish grandfather status include the following: (1) The elimination of all or substantially all benefits to diagnose or treat a particular condition, (2) any increase in percentage cost-sharing requirements, (3) an increase in a deductible or out-of-pocket maximum by an amount that exceeds medical inflation plus 15 percentage points, (4) an increase in a copayment by an amount that exceeds medical inflation plus 15 percentage points (or, if greater, $5 plus medical inflation), (5) a decrease in an employer's contribution rate towards the cost of coverage by more than 5 percentage points, or (6) the imposition of annual dollar limits below the restricted annual dollar limits that were in effect prior to 2014 (note that for plan years (or policy years in the individual market) beginning on and after January 1, 2014, annual dollar limits on

the promulgation of the interim final regulations, questions have been brought to the Departments' attention regarding other specific changes to a plan's design and the impact of such changes on a plan's grandfather status.

a. Elimination of All or Substantially All Benefits

The 2010 interim final regulations and these final regulations provide that the elimination of all or substantially all benefits to diagnose or treat a particular condition will cause a group health plan or health insurance coverage to relinquish its grandfathered status. One commenter requested that the Departments clarify what constitutes eliminating ''substantially all benefits'' to diagnose or treat a particular condition. As the interim final regulations stated, and these final regulations continue to provide, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. The Departments decline to establish a bright-line test establishing what constitutes ''substantially all benefits'' for purposes of these final regulations. Whether or not a plan has eliminated substantially all benefits to diagnose or treat a particular condition must be determined based on all the facts and circumstances, taking into account the items and services covered for a particular condition under the plan on March 23, 2010, as compared to the items and services covered at the time the plan makes the benefit change effective. The preamble to the 2010 interim final regulations provided two examples. First, if a plan or health insurance coverage eliminates all benefits for cystic fibrosis, the plan or coverage will lose its grandfathered status. Second, if a plan or insurance coverage provides benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs, and subsequently eliminates benefits for counseling, the plan is treated as having eliminated all or substantially all benefits for that mental health condition and will as a result lose its grandfathered status. These final regulations continue to provide that the elimination of all or substantially all benefits to diagnose or treat a particular condition will cause a group health plan or health insurance coverage to relinquish its grandfathered status and contain an example.

b. Increase in Fixed-Amount Copayments

The interim final regulations provided standards for when increases in fixed-amount copayments would cause a plan or coverage to relinquish its grandfather status. Under the interim final regulations, a plan or coverage ceases to be a grandfathered health plan if there is an increase since March 23, 2010 in a copayment that exceeds the greater of the maximum percentage increase [14] or five dollars increased by medical inflation.[15]

With respect to grandfathered health plans that utilize multiple levels of copayments for different benefits under the plan, stakeholders sought clarification on what degree of change would cause a plan to relinquish its grandfather status. Specifically, stakeholders wanted to know whether raising the copayment level for a category of services by an amount that would otherwise trigger a loss of grandfather status would cause a loss of grandfather status if the plan retained the level of copayment on other categories of services. The Departments clarified in Affordable Care Act Implementation FAQs Part II Q4 that a change to a copayment level for a category of services that exceeds the standards set forth in the interim final regulations will cause a plan to relinquish its grandfather status, even if a plan retains the level of copayment for other categories of services.[16] These final regulations retain this clarification, and continue to provide that each change in cost sharing must be separately evaluated under the standards set forth in the regulations. A plan or issuer may not exceed the standards set forth in these final regulations with respect to one level of copayment for a category of services, and retain its grandfather status by retaining the level of copayments for other categories of services.

c. Decrease in Contribution Rate by Employers and Employee Organization

The interim final regulations provided that a decrease in the employer contribution rate for coverage under a group health plan or group health insurance coverage beyond the permitted percentage would result in cessation of grandfather status. There are two rules related to decreases in employer contributions: One for a contribution based on the cost of coverage and one for a contribution based on a formula.

First, if the contribution rate is based on the cost of coverage, a group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate towards the cost of any tier of coverage for any class of similarly situated individuals [17] by more than 5 percentage points below the contribution rate on March 23, 2010. For this purpose, contribution rate is defined as the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The interim final regulations also provided that the total cost of coverage is determined in the same manner as the applicable premium is calculated under the Consolidated Omnibus Budget Reconciliation Act of 1986 (COBRA) continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Code, and section 2204 of the PHS Act. In the case of a self-insured group health plan, contributions by an employer or employee organization are calculated by subtracting the employee contributions towards the total cost of coverage from the total cost of coverage.

Second, if the contribution rate is based on a formula, such as hours worked or tons of coal mined, a group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate towards the cost of any tier of coverage for any class of similarly situated individuals by more than 5 percentage points below the contribution rate on March 23, 2010. These final regulations finalize these provisions without change but incorporate the additional clarifications issued in subregulatory guidance as discussed below.

The Departments received several comments relating to the employer

essential health benefits are prohibited, except for grandfathered individual health insurance coverage). See 26 CFR 54.9815–1251(g), 29 CFR 2590.715–1251(g), and 45 CFR 147.140(g).

[14] The interim final regulations defined the maximum percentage increase as medical inflation (from March 23, 2010) plus 15 percentage points. Medical inflation is defined in the interim final regulations by reference to the overall medical care component of the Consumer Price Index for All Urban Consumers, unadjusted (CPI), published by the Department of Labor. See 26 CFR 54.9815–1251(g)(3), 29 CFR 2590.715–1251(g)(3), and 45 CFR 147.140(g)(3).

[15] 75 FR 35538, 34543 (June 17, 2010).

[16] See Affordable Care Act Implementation FAQs Part II, available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html*.

[17] Similarly situated individuals are described in the HIPAA nondiscrimination regulations at 26 CFR 54.9802–1(d), 29 CFR 2590.702(d), and 45 CFR 146.121(d).

contribution limitations. Some commenters stated that issuers do not always have the information needed to know whether (or when) an employer plan sponsor changes its rate of contribution towards the cost of group health plan coverage. In response to this issue, the Departments issued Affordable Care Act Implementation FAQs Part I Q2 and Q3 providing relief if issuers and employer plan sponsors or contributing employers and multiemployer plans take certain steps to communicate regarding changes to the contribution rate for purposes of determining grandfather status.[18] These final regulations also provide relief to issuers, plan sponsors, employers, and plans that take certain steps to communicate changes in contribution rates. Specifically, these final regulations provide that an insured group health plan that is a grandfathered health plan will not relinquish its grandfather status immediately based on a change in the employer contribution rate if, upon renewal, an issuer requires a plan sponsor to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer does not already have it). Additionally, the issuer's policies, certificates, or contracts of insurance must disclose in a prominent and effective manner that plan sponsors are required to notify the issuer if the contribution rate changes at any point during the plan year. An insured grandfathered group health plan with a decrease in employer contributions relinquishes its grandfather status as of the earlier of the first date on which the issuer knows or reasonably should know that there has been at least a 5-percentage-point reduction or the first date on which the plan no longer qualifies for grandfathered status without regard to the 5-percentage-point reduction. Similarly, if multiemployer plans and contributing employers follow these steps, the plan will not relinquish its grandfather status unless or until the multiemployer plan knows or reasonably should know that the contribution rate has changed by at least the applicable 5-percentage point reduction or until the date the plan no longer qualifies for grandfathered status without regard to the 5-percentage point reduction. Moreover, nothing in the Affordable Care Act or these regulations prevents a policy, certificate, or contract of insurance from requiring a plan sponsor to notify an issuer in advance (for example, 30 or 60 days in advance) of a change in their contribution rate.

The Departments also received comments on the application of this provision to multiemployer plans with unique contribution structures. It is common for multiemployer plans to have either a fixed-dollar employee contribution or no employee contribution towards the cost of coverage. In such cases, a contributing employer's contribution rate may change (for example, after making up a funding deficit in the prior year or to reflect a surplus) but the employee contribution amount is not affected. The Departments issued Affordable Care Act Implementation FAQs Part I Q4 clarifying that in this case, provided any changes in the coverage terms would not otherwise cause the plan to cease to be grandfathered and there continues to be no employee contribution or no increase in the fixed-dollar employee contribution towards the cost of coverage, the plan would not relinquish its grandfather status.[19] These final regulations incorporate this clarification and apply the relief to all grandfathered group health plans. Therefore, under these final regulations a group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan if the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage and there are no corresponding changes in coverage terms that would otherwise cause the plan to cease to be a grandfathered plan.

The Departments also received comments requesting clarification on the application of the rules where a group health plan includes multiple tiers of coverage. In response, the Departments issued Affordable Care Act Implementation FAQs Part II Q3, explaining that the standards for employer contributions found in paragraph (g)(1)(v) of the interim final regulations on grandfathered health plans apply on a tier-by-tier basis.[20] These final regulations incorporate this guidance. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.,* self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.,* at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage could not cause the plan to lose grandfather status.

The Departments also received comments asking for clarification on when a decrease in the employer contribution rate for coverage under a group health plan or group health insurance beyond the permitted percentage would result in cessation of grandfather status for a contribution based on a formula. In response, the Departments issued Affordable Care Act Implementation FAQs Part VI Q6.[21] The FAQ provided an example under which a plan covers both retirees and active employees and the employer that sponsors the plan contributes $300 per year multiplied by the individual's years of service for the employer, capped at $10,000 per year. In the example, the employer makes contributions based on a formula, and accordingly, the plan will cease to be a grandfathered health plan if the employer decreases its contribution rate towards the cost of coverage by more than five percent below the contribution rate on March 23, 2010. If the formula does not change, the employer is not considered to have reduced its contribution rate, regardless of any

[18] See Affordable Care Act Implementation FAQs Part I, available at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.*

[19] See Affordable Care Act Implementation FAQs Part I, available at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.*

[20] See Affordable Care Act Implementation FAQs Part II, available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.*

[21] See Affordable Care Act Implementation FAQs Part VI, available at *http://www.dol.gov/ebsa/faqs/faq-aca6.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html.*

increase in the total cost of coverage. However, if the dollar amount that is multiplied by years of service decreases by more than five percent (or if the $10,000 maximum employer contribution cap decreases by more than five percent), the plan will cease to be a grandfathered health plan. Although this example has not been added to the text of the final regulations, this guidance continues to apply.

d. Changes in Annual Limits

PHS Act section 2711, as added by the Affordable Care Act, generally prohibits lifetime and annual limits on the dollar amount of essential health benefits, as defined in section 1302(b) of the Affordable Care Act. Under PHS Act section 2711 and its implementing regulations, plans and issuers were generally prohibited from imposing lifetime limits on the dollar value of essential health benefits for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

With respect to annual dollar limits, for plan or policy years beginning before January 1, 2014, plans and issuers were permitted to impose restricted annual dollar limits in accordance with the guidance set forth in the interim final regulations. For plans years beginning on or after January 1, 2014, plans and issuers generally are prohibited from imposing annual dollar limits on essential health benefits. However, grandfathered individual health insurance plans are not subject to the annual dollar limit prohibition. Accordingly, the final regulations retain the rules regarding loss of grandfathered status based on imposition of annual dollar limits to allow issuers of grandfathered individual health insurance coverage to analyze grandfathered status.

These final regulations, like the interim final regulations, address three different limit-related situations that would cause a plan or health insurance coverage to relinquish its grandfather status: (1) A plan or health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits; (2) A plan or health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010; and (3) A plan or health insurance coverage that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

e. Changes to Fixed Amount Cost-Sharing Based on a Formula

On December 22, 2010, the Departments issued Affordable Care Act Implementation FAQs Part V Q7 to provide clarification on the application of the thresholds under paragraph (g)(1) of the interim final regulations when a plan's terms include out-of-pocket spending limits that are based on a formula.[22] The Departments continue to interpret paragraph (g)(1) as clarified in the FAQ. Therefore, under these final regulations, if a plan or coverage has a fixed-amount cost-sharing requirement other than a copayment (for example, a deductible or out-of-pocket limit) that is based on a percentage-of-compensation formula, that cost-sharing arrangement will not cause the plan or coverage to cease to be a grandfathered health plan as long as the formula remains the same as that which was in effect on March 23, 2010. Accordingly, if the percentage-of-compensation formula for determining an out-of-pocket limit is unchanged and an employee's compensation increases, then the employee could face a higher out-of-pocket limit, but that change would not cause the plan to relinquish grandfather status.

f. Grandfather Status and Wellness Programs

Under PHS Act section 2705, ERISA section 702, and Code section 9802 and the Departments' implementing regulations, group health plans and health insurance issuers in the group and individual market are prohibited from discriminating against participants, beneficiaries, and individuals in eligibility, benefits, or premiums based on a health factor.[23] For group health plans and group health insurance coverage, an exception to this general prohibition allows premium discounts, rebates, or modification of otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) in return for adherence to certain programs of health promotion and disease prevention, commonly referred to as wellness programs.

Many stakeholders requested clarification with respect to how changes to contribution rates and cost-sharing mechanisms in the context of a wellness program would impact a plan's grandfather status. In light of these questions, the Departments issued Affordable Care Act Implementation FAQs Part II Q5, which stated that while group health plans may continue to provide incentives for wellness by providing premium discounts or additional benefits to reward healthy behaviors by participants and beneficiaries, penalties (such as cost-sharing surcharges) may implicate the standards outlined in paragraph (g)(1) of the grandfather interim final regulations and should be examined carefully.[24] If additional questions arise regarding the interaction of wellness programs and these requirements, the Departments may issue additional subregulatory guidance.

g. Changes to Multi-Tiered Prescription Drug Formularies

In Affordable Care Act Implementation FAQs Part VI Q2, the Departments addressed questions related to certain changes to the level of cost sharing for brand-name prescription drugs. Stakeholders requested that the Departments clarify whether changes to cost sharing for brand-name prescription drugs would cause a plan to relinquish its grandfather status in instances where a plan classifies and determines cost sharing for prescription drugs based on the availability of a generic alternative, and a generic drug becomes available and is added to the formulary. The Departments stated that if a drug was classified in a tier as a brand name drug

[22] See Affordable Care Act Implementation FAQs Part V and Mental Health Parity Implementation, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html*.

[23] The statute and its implementing regulations set forth eight health status-related factors, which the final regulations on Nondiscrimination and Wellness Programs in Health Coverage in the Group Market refer to as ''health factors'' for simplicity. 71 FR 75014, 75016 (Dec. 13, 2006) Under the statute and the regulations, the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. Id. In the Departments' view, ''[t]hese terms are largely overlapping and, in combination, include any factor related to an individual's health.'' 66 FR 1378, 1379 (Jan. 8, 2001).

[24] See Affordable Care Act Implementation FAQs Part II, available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html*.

with no generic available, and a generic alternative for the drug becomes available and is added to the formulary, moving the brand-name drug to a higher tier would not cause the plan or coverage to relinquish grandfather status.[25] These final regulations adopt this rule that such changes will not result in a loss of grandfather status.

h. Grandfather Status and Certain Changes in Individual Policies

Some individual health insurance policies in place on March 23, 2010 included a feature that allowed a policyholder to elect an option under which the individual would pay a reduced premium in exchange for higher cost sharing. The Departments received comments asking whether individuals enrolled in these policies as of March 23, 2010 could make such an election after March 23, 2010 without affecting the policy's grandfather status, even if the increase in cost sharing would exceed the limits set forth under the interim final regulations. In response, the Departments issued Affordable Care Act Implementation FAQs Part IV Q2, which stated that, as long as the policyholder had such option under the insurance policy that was in place on March 23, 2010, he or she could exercise the option after March 23, 2010 without affecting grandfather status, even if as a result of electing this option the individual's cost sharing would increase by an amount that exceeds the limits established under the interim final regulations.[26] The Departments maintain this approach in these final regulations.

i. Clarifications on Timing of the Loss of Grandfather Status

Since the promulgation of the 2010 interim final regulations, questions have arisen regarding whether or not a plan ceases to be a grandfathered health plan immediately after making a change that triggers a loss of grandfathered status, and whether or not there is an opportunity to cure a loss of grandfather status following a change made inadvertently or otherwise that triggers a loss of grandfather status. Several commenters have requested clarification on when the plan or coverage ceases to be a grandfathered health plan if it makes an amendment to plan terms that trigger loss of grandfather status in the middle of the plan year. The Departments issued Affordable Care Act Implementation FAQs Part VI Q4 and Q5 addressing timing of the loss of grandfather status with respect to mid-year plan amendments that exceed the thresholds described in the interim final regulations.[27] These final regulations adopt the clarification outlined in the FAQs that a plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that exceeds the thresholds described in paragraph (g)(1) of these final regulations becomes effective—regardless of when the amendment is adopted. Once grandfather status is lost there is no opportunity to cure the loss of grandfather status. A reversal after the effective date will not allow the plan or coverage to regain grandfather status. If a plan sponsor wishes to avoid relinquishing grandfathered status in the middle of a plan year, any changes that will cause a plan or coverage to relinquish grandfather status should not be effective before the first day of a plan year that begins after the change is adopted.

B. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108)

PHS Act section 2704, added by the Affordable Care Act, amends the HIPAA [28] rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage generally may not impose any preexisting condition exclusions.[29] HIPAA, as well as PHS Act section 2704 and its implementing regulations, define a preexisting condition exclusion as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, regardless of whether any medical advice, diagnosis, care, or treatment was recommended or received before that date. PHS Act section 2704,[30] which became effective for enrollees who are under 19 years of age for plan years (in the individual market, policy years) beginning on or after September 23, 2010, and effective for adults for plan years (in the individual market, policy years) beginning on or after January 1, 2014, prohibits preexisting condition exclusions for both group health plans and group or individual health insurance coverage (except for grandfathered individual health insurance). On June 28, 2010, the Departments issued interim final regulations implementing PHS Act section 2704 and requesting comment.[31] After issuance of regulations in 2010, the Departments also released Affordable Care Act Implementation FAQs Part V, Q6 [32] to provide additional clarification on the prohibition of preexisting condition exclusions. These final regulations finalize the 2010 interim final regulations without substantial change and incorporate the clarifications issued to date in subregulatory guidance.

1. Allowable Exclusion of Benefits

Prior to implementation of PHS Act section 2704, HIPAA rules limiting preexisting condition exclusions provided that a plan's or issuer's exclusion of benefits for a condition regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. With respect to such exclusions, the 2010 interim final regulations did not change this approach under HIPAA.[33]

Several commenters requested that the final regulations reiterate this rule. Other commenters requested that all exclusions of specific conditions be prohibited regardless of whether the exclusion relates to when the condition arose. Another commenter wrote that restrictions on benefits concerning

[25] Affordable Care Act Implementation FAQs Part VI, available at *http://www.dol.gov/ebsa/faqs/faq-aca6.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html*.

[26] See Affordable Care Act Implementation FAQs Part IV, available at *http://www.dol.gov/ebsa/faqs/faq-aca4.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html*.

[27] See Affordable Care Act Implementation FAQs Part VI, available at *http://www.dol.gov/ebsa/faqs/faq-aca6.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs6.html*.

[28] HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191).

[29] The HIPAA rules (that were in effect prior to the effective date of these amendments) applied only to group health plans and group health insurance coverage, and permitted limited exclusions of coverage based on a preexisting condition under certain circumstances. Section 2704 prohibits any preexisting condition exclusion from being imposed by group health plans or group health insurance coverage and extends this protection to non-grandfathered individual health insurance coverage but this prohibition does not apply to grandfathered individual health insurance coverage.

[30] Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1) was the applicable provision concerning preexisting condition exclusions; after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1) is the applicable provision. *See also* ERISA section 701(b)(1) and Code section 9801(b)(1).

[31] 75 FR 37188 (June 28, 2010).

[32] See Affordable Care Act Implementation FAQs Part V, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html*.

[33] The rule is illustrated with examples in the HIPAA regulations on preexisting condition exclusions. See Examples 6, 7, and 8 in 26 CFR 54.9801–3(a)(2), 29 CFR 2590.701–3(a)(2), 45 CFR 146.111(a)(2).

rehabilitation services and devices should be considered a form of preexisting condition exclusion and not be allowed.

Similar to the interim final regulations, these final regulations retain the approach set forth under HIPAA relating to exclusions for a specific benefit. More specifically, these final regulations continue to provide that a plan's or issuer's exclusion of benefits for a condition from the plan or policy regardless of when the condition arose relative to the effective date of coverage is not a preexisting condition exclusion. Other requirements of Federal or State law, however, may prohibit certain benefit exclusions, including the essential health benefits requirements applicable in the individual and small group health insurance markets at 45 CFR 156.110 *et seq.*

2. Enrollment Period

The 2010 interim final regulations did not impose any requirement on plans to provide for an open enrollment period. One commenter requested that the regulations clarify that issuers in the individual market may restrict enrollment of children under age 19 to specified open enrollment periods, consistent with guidance issued by HHS.[34] Another commenter requested that the regulations specify that after the initial enrollment period, health insurance issuers must make open enrollment periods available to families at least once a year during a standardized time period for at least 90 days and that insurers should fully advertise the availability. Another commenter stated that having at least one issuer that offers open enrollment at any time during the year, without a penalty for deferral, will be an economic incentive to defer the purchase of insurance which may encourage adverse selection and subsequently, higher claim costs. Additional commenters requested continuous open enrollment for children with preexisting conditions, clarification of whether guaranteed issue will be available only during open enrollment or all 12 months of the year, and that families be given the opportunity to enroll their children when certain life events occur. These final regulations do not adopt these suggestions. The provisions of the Affordable Care Act related to guaranteed availability of coverage, including open and special enrollment periods, are implemented in regulations issued by HHS under section 2702 of the PHS Act and are outside the scope of this rulemaking. Additionally, while HIPAA generally permits plans and issuers to treat participants and beneficiaries with adverse health factors more favorably, such as providing a longer open enrollment period, nothing in these regulations requires plans and issuers to do so.

3. Premiums

Commenters raised concerns about increasing premiums related to the prohibition on preexisting condition exclusions. Effective for plan years (or, in the individual market, policy years) beginning on or after January 1, 2014, section 2701 of the PHS Act and section 1312(c) of the Affordable Care Act govern the premium rates charged by an issuer for non-grandfathered health insurance coverage in the individual and small group markets, and section 2794 of the PHS Act provides for the annual review of unreasonable increases in premiums for health insurance coverage in the individual and small group markets. These provisions are implemented in regulations issued by HHS [35] and are outside the scope of this rulemaking. However, the rating rules under PHS Act section 2701 prohibit variations in premiums based on a child's health status.

4. Allowable Screenings To Determine Eligibility for Alternative Coverage in the Individual Market

Subsequent to the promulgation of the interim final regulations, questions arose regarding whether it would be permissible under the rules implementing PHS Act section 2704 for issuers in the individual market to screen certain applicants for eligibility for alternative coverage before issuing a child-only policy. Specifically, States expressed an interest in permitting such screenings. In response to these concerns, the Departments issued Affordable Care Act Implementation FAQs Part V, Q6, which provided that under certain circumstances, States can permit issuers in the individual market to screen applicants for eligibility for alternative coverage options before offering a child-only policy if (1) the practice is permitted under State law; (2) the screening applies to all child-only applicants, regardless of health status; and (3) the alternative coverage options include options for which healthy children would potentially be eligible, such as the Children's Health Insurance Program (CHIP) and group health insurance.[36] Screenings may not be limited to programs targeted to individuals with a preexisting condition, such as a State high risk pool. Note that Medicaid policy, under 42 U.S.C. 1396a (25)(G), prohibits participating States from allowing health insurance issuers to consider whether an individual is eligible for, or is provided medical assistance under, Medicaid in making enrollment decisions. Furthermore, issuers may not implement a screening process that by its operation significantly delays enrollment or artificially engineers eligibility of a child for a program targeted to individuals with a preexisting condition. Additionally, the screening process may not be applied to offers of dependent coverage for children. The FAQ provided that States are encouraged to require issuers that screen for other coverage to enroll and provide coverage to the applicant effective on the first date that the child-only policy would have been effective had the applicant not been screened for an alternative coverage option. It also provided that States are encouraged to impose a reasonable time limit, such as 30 days, at which time the issuer would have to enroll the child regardless of pending applications for other coverage. Subsequent to the issuance of the FAQ, the guaranteed availability requirements in section 2702 of the PHS Act took effect, similarly precluding an issuer from denying coverage. This screening, as permitted under State law, will continue to be allowed under these final regulations, consistent with both section 2704 and guaranteed availability obligations under section 2702.

C. PHS Act Section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126)

PHS Act section 2711, as added by the Affordable Care Act, generally prohibits annual and lifetime dollar limits on essential health benefits, as defined in section 1302(b) of the Affordable Care Act. With respect to annual dollar limits, PHS Act section 2711(a)(2) provided that for plan years beginning before January 1, 2014, restricted annual dollar limits were allowed. On June 28, 2010, the Departments issued interim final regulations implementing PHS Act

[34] Center for Consumer Information & Insurance Oversight, Questions and Answers on Enrollment of Children Under 19 Under the New Policy That Prohibits Pre-Existing Condition Exclusions, available at *https://www.cms.gov/CCIIO/Resources/Files/factsheet.html.*

[35] See 45 CFR 147.102, 154.101 *et seq.*, and 156.80.

[36] See Affordable Care Act Implementation FAQs Part V, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

section 2711 and requested comment.[37] After issuance of the 2010 interim final regulations, the Departments also released Affordable Care Act Implementation FAQs Parts IV, XI, XV, XXII, as well as Technical Release 2013–03, to address various requests for clarifications under PHS Act section 2711.[38] These final regulations adopt the 2010 interim final regulations without substantial change and incorporate certain pertinent clarifications issued thus far in subregulatory guidance.

1. Definition of Essential Health Benefits

On February 25, 2013, HHS issued final regulations addressing essential health benefits (EHB) under Affordable Care Act section 1302.[39] Among other things, HHS regulations defined EHB based on a State-specific benchmark plan and required each State to select a benchmark plan from among several options.[40] While self-insured, large group market, and grandfathered health plans are not required to offer EHB, PHS Act section 2711 prohibits such plans from imposing annual and lifetime dollar limits on covered benefits that fall within the definition of EHB. In the interim final regulations, the Departments said that ''[f]or plan years (in the individual market, policy years) beginning before the issuance of regulations defining 'essential health benefits,' for purposes of enforcement, the Departments will take into account good faith efforts to comply with a reasonable interpretation of the term 'essential health benefits.' ''

In a 2012 FAQ, HHS stated that the Departments would consider a self-insured group health plan, a large group market health plan, or a grandfathered group health plan to have used a permissible definition of EHB under section 1302(b) of the Affordable Care Act if the definition was one of the potential EHB base-benchmark plans that, at the time, States could have chosen from as the standard for EHB in their State.[41] At the time, this list of potential EHB-benchmark plans included over 510 EHB base-benchmark plans that were authorized by the Secretary for a State or the District of Columbia[42] to select, as each State and the District of Columbia has a choice of ten possible benchmark plans. All of these potential plans were ''authorized'' in the sense that they were potential EHB benchmark plans that could be selected by a State or the District of Columbia under the EHB regulations. This approach was intended to provide plans and issuers not subject to the EHB rules with flexibility to define what constitutes EHB under their respective plan for purposes of the limits in PHS Act section 2711. Since that time, each State and the District of Columbia has selected or defaulted to a single EHB-benchmark option, and that is the only benchmark plan ''authorized'' to be used for defining EHB in that State or the District of Columbia.

Given the enforcement challenges for Federal and State regulators and difficulties for participants, beneficiaries, and enrollees in ascertaining what benefits under their respective plans constitute EHB posed by a choice of over 500 plans, the Departments are codifying their interpretation that a ''reasonable interpretation of the term 'essential health benefits''' includes only those EHB base-benchmarks that, in fact, have been selected, whether by active State selection or by default to be the EHB base-benchmark plan for a State, rather than all plans that are potentially authorized.

In addition to the foregoing base-benchmark plans, there are three base-benchmark plan options not currently among those a State or the District of Columbia has either selected or had assigned by default that the Departments believe should also continue to be made available for plans and issuers not subject to EHB requirements. These three plan options are the current base-benchmark plan options under the Federal Employees Health Benefit Program (FEHBP) specified at 45 CFR 156.100(a)(3) (the three largest FEHBP plans available to all Federal employees nationally). These base-benchmark plan options are unique among base-benchmark plans in that they are available nationally, and thus can be utilized to determine what benefits would be categorized as EHBs for those employers who provide health coverage to employees throughout the United States and are not situated only in a single State.

Thus, under these final regulations, group health plans (and health insurance coverage offered in connection with such plans) and grandfathered individual market coverage that are not required to provide EHB may select among any of the 51 EHB base-benchmark plans identified under 45 CFR 156.100 and selected by a State or the District of Columbia and the FEHBP base-benchmark plan, as applicable for plan years beginning on or after January 1, 2017, for purposes of determining which benefits cannot be subject to annual and lifetime dollar limits. The current list of the 51 proposed EHB base-benchmark plans selected by the States for 2017 can be found at *https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html*. HHS anticipates publishing the final list later this month.

2. Out-of-Network Benefits

The Departments have been asked whether the scope of the prohibition on lifetime and annual dollar limits in PHS Act section 2711 applies only to in-network benefits as opposed to both in-network and out-of-network benefits. The statute and interim final regulations made no distinction between in-network or out-of-network benefits. Therefore, lifetime and annual dollar limits on essential health benefits are generally prohibited, regardless of whether such benefits are provided on an in-network or out-of-network basis. These final regulations incorporate this clarification.

3. End of Waiver Program

Under PHS Act section 2711, for plan years beginning before January 1, 2014,

[37] 75 FR 37188 (June 28, 2010).

[38] Affordable Care Act Implementation FAQs Parts IV, XI, XV, XXII, available at *http://www.dol.gov/ebsa/faqs/faq-aca4.html*, *http://www.dol.gov/ebsa/faqs/faq-aca11.html*, *http://www.dol.gov/ebsa/faqs/faq-aca15.html*, and *http://www.dol.gov/ebsa/faqs/faq-aca22.html*, or *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs4.html*, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11.html*, *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs15.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXII-FINAL.pdf*; Technical Release 2013–03, available at *http://www.dol.gov/ebsa/newsroom/tr13-03.html*. See footnote 51 for a list of additional items of guidance under PHS Act section 2711.

[39] 78 FR 12834.

[40] The benchmark plans from which a State could choose are: (1) The largest plan by enrollment in any of the three largest products in the State's small group market; (2) any of the largest three State employee health benefit plans options by enrollment; (3) any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by enrollment; or (4) the largest insured commercial HMO in the State. 45 CFR 156.100. The EHB-benchmark plan serves as a reference plan, reflecting both the scope of services and limits offered by a typical employer plan in each State. The term ''base-benchmark plan'' in 45 CFR 156.100 is distinct from the term ''EHB-benchmark plan'' as defined in 45 CFR 156.20.

[41] See Q10 of Frequently Asked Questions on Essential Health Benefits Bulletin, available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/ehb-faq-508.pdf*.

[42] Initially, issuers in the territories were subject to the EHB requirement and also had potential benchmarks to choose from under the EHB regulations. A change in the interpretation of the statute resulted in issuers in the territories being exempt from the EHB rules. See Letter to Gary R. Francis, Commissioner, Office of Lieutenant Governor, Virgin Islands, dated July 16, 2014, available at *https://www.cms.gov/CCIIO/Resources/Letters/Downloads/letter-to-Francis.pdf*.

the Departments were given authority to define restricted annual dollar limits to ensure that access to needed services was made available with minimal impact on premiums. As noted in the preamble to the 2010 interim final regulations, in order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to EHB, the interim final regulations adopted a three-year phased approach for restricted annual dollar limits, with the dollar limit increasing for each year of the three year period. Annual dollar limits, including restricted annual dollar limits, are not allowed for plan years (in the individual market, policy years) beginning on or after January 1, 2014, except for grandfathered individual health insurance coverage.

Some previously widely available low-cost coverage was designed with low maximum benefits and did not meet the phased in restricted annual dollar limits, such as stand-alone health reimbursement arrangements (HRAs) [43] and so-called ''mini med'' plans. In order to ensure that individuals with such limited coverage would not be denied access to needed services or experience more than a minimal impact on premiums, the interim final regulations also provided for HHS to establish a program under which the restricted annual dollar limit requirements would be waived if compliance with the limits would result in a significant decrease in access to benefits or a significant increase in premiums.[44] However, this waiver program was only available for the period during which the statute authorized restricted annual dollar limits, that is, plan years (in the individual market, policy years) beginning before January 1, 2014. Consequently such waivers are no longer available and the waiver program rules are not incorporated in these final regulations.

4. HRAs and Other Account Based Plans

In general, HRAs and other account-based group health plans are subject to the annual dollar limit prohibition under PHS Act section 2711 (annual dollar limit prohibition) [45] and will fail to comply with this prohibition because these arrangements impose an annual limit on the amount of expenses the arrangement will reimburse. However, special rules apply to certain types of account-based plans under which the HRA or other account-based health plan either is not subject to the annual dollar limit prohibition, or is considered to comply with the annual dollar limit prohibition if it is ''integrated'' with another group health plan that complies with the annual dollar limit prohibition.

The preamble to the interim final regulations noted that the annual dollar limit prohibition applies differently to certain account-based plans that are subject to other rules that limit the benefits available under those plans.[46] In particular, under the 2010 interim final regulations and these final regulations, certain health Flexible Spending Arrangements (health FSAs) [47] are not subject to the PHS Act section 2711 annual dollar limit prohibition because health FSAs are subject to specific limits under section 9005 of the Affordable Care Act. In addition, as noted in the preamble to the 2010 interim final regulations, the annual dollar limit prohibition does not apply to Archer Medical Savings Accounts (Archer MSAs) under section 220 of the Code and Health Savings Accounts (HSAs) under section 223 of the Code, because both types of plans are subject to specific statutory provisions that require that the contributions be limited.

These final regulations contain a clarification regarding the application of the annual dollar limit prohibition to health FSAs. Question and Answer 8 of DOL Technical Release 2013–03 [48] and IRS Notice 2013–54 [49] clarified that the annual dollar limit prohibition applies to a health FSA that is not offered through a Code section 125 plan. That is because the exemption for health FSAs from the annual dollar limit prohibition is intended to apply only to health FSAs that are subject to the separate annual limitation under Code section 125(i), and health FSAs that are not offered through a Code section 125 plan are not subject to that separate statutory limit. The prior guidance provided that this clarification was intended to apply beginning September 13, 2013 and the guidance noted that the Departments intended to amend the annual dollar limit prohibition regulations to conform to the Q&A. These final regulations include this amendment.

Other types of account-based plans, such as HRAs and employer payment plans,[50] are not exempt from the annual dollar limit prohibition. However, the preamble to the interim final regulations and subsequently issued subregulatory guidance [51] interpreting these rules included a number of rules regarding the application of the annual dollar limit prohibition to these types of arrangements. In particular, this guidance provides that if an HRA is ''integrated'' with other group health

[43] An HRA is an arrangement that is funded solely by an employer and that reimburses an employee for medical care expenses (as defined under Code section 213(d)) incurred by the employee, or his spouse, dependents, and any children who, as of the end of the taxable year, have not attained age 27, up to a maximum dollar amount for a coverage period. IRS Notice 2002–45, 2002–02 CB 93; Revenue Ruling 2002–41, 2002–2 CB 75. This reimbursement is excludable from the employee's income. Amounts that remain at the end of the year generally can be used to reimburse expenses incurred in later years. HRAs generally are considered to be group health plans within the meaning of Code section 9832(a), section 733(a) of ERISA, and section 2791(a) of the PHS Act and are subject to the rules applicable to group health plans.

[44] Guidance regarding the annual dollar limit waiver program was issued at *https://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Annual* Limits.

[45] In accordance with Code section 9831(a)(2) and ERISA section 732(a), the market reforms, including PHS Act section 2711, do not apply to a group health plan that has fewer than two participants who are current employees on the first day of the plan year, and, in accordance with Code section 9831(b), ERISA section 732(b), and PHS Act sections 2722(b) and 2763, the market reforms, including PHS Act section 2711, also do not apply to a group health plan in relation to its provision of excepted benefits described in Code section 9832(c), ERISA section 733(c) and PHS Act section 2791(c).

[46] See 75 FR 37188, 37190 (June 28, 2010).

[47] In general, a health FSA is a benefit designed to reimburse employees for medical care expenses (as defined in Code section 213(d), other than premiums) incurred by the employee, or the employee's spouse, dependents, and any children who, as of the end of the taxable year, have not attained age 27. See Employee Benefits—Cafeteria Plans, 72 FR 43938, 43957 (August 6, 2007) (proposed regulations; to be codified, in part, once final, at 26 CFR 1.125–5); Code section 105(b) and 106(c). Contributions to a health FSA offered through a cafeteria plan satisfying the requirements of Code section 125 do not result in gross income to the employee. Code section 125(a).

[48] Technical Release 2013–03, available at *www.dol.gov/ebsa/pdf/tr13-03.pdf.*

[49] 2013–40 IRB 287.

[50] An employer payment plan is a group health plan under which an employer reimburses an employee for some or all of the premium expenses incurred for an individual health insurance policy, such as a reimbursement arrangement described in Revenue Ruling 61–146, 1961–2 CB 25, or arrangements under which the employer uses its funds to directly pay the premium for an individual health insurance policy covering the employee.

[51] Five items of guidance have been issued on this topic: (1) Affordable Care Act Implementation FAQs Part XI, available at (*http://www.dol.gov/ebsa/faqs/faq-aca11.html*) or *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs11.html*; (2) IRS Notice 2013–54 and DOL Technical Release 2013–03, issued on September 13, 2013; (3) IRS FAQ on Employer Healthcare Arrangements available at *http://www.irs.gov/Affordable-Care-Act/Employer-Health-Care-Arrangements*; (4) Affordable Care Act Implementation FAQs Part XXII, available at *http://www.dol.gov/ebsa/faqs/faq-aca22.html* or *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-XXII-FINAL.pdf*; and (5) IRS Notice 2015–17, issued on February 18, 2015. See also 75 FR 37188 (June 28, 2010). This guidance, much of which is not directly addressed in these final regulations, continues to be in effect.

plan coverage, and the other group health plan coverage complies with the requirements of PHS Act section 2711, the combined arrangement satisfies the requirements even though the HRA imposes a dollar limit.[52] The basic principles for when an HRA is considered integrated with other group health plan coverage have been set forth in various forms of subregulatory guidance and have been included in these final regulations.

These final regulations clarify the scope of arrangements, in addition to HRAs, that can be integrated with other group health plan coverage by defining and referring to ''account-based plans.'' Account-based plans are employer-provided group health plans that provide reimbursements of medical expenses other than individual market policy premiums, with the reimbursement subject to a maximum fixed dollar amount for a period. Examples of account-based plans include health FSAs and medical reimbursement plans that are not HRAs, in addition to HRAs. Account-based plans that do not qualify as excepted benefits [53] generally are subject to the market reforms (except that health FSAs offered through a Code section 125 plan are not subject to the annual dollar limit prohibition), including the preventive services requirements under PHS Act section 2713. If the other group health plan coverage with which an account-based plan is integrated complies with the requirements under PHS Act sections 2711 and 2713, the account-based plan also complies with those requirements because, in that case, the combined benefit satisfies those requirements.[54]

The Departments' prior guidance regarding when an HRA is considered integrated with another group health plan provides two methods for integration, each of which has been added to the final regulations and extended to other account-based plans. In addition to various other requirements, each integration method requires that under the terms of the HRA or other account-based plan, (1) an employee (or former employee) must be permitted to permanently opt out of and waive future reimbursements from the account-based plan at least annually, and (2) upon termination of employment either remaining funds are forfeited or the employee is allowed to opt out of and waive future reimbursements under the account-based plan.

Stakeholders have requested clarification regarding whether for this purpose a forfeiture of amounts or a waiver of reimbursements under an HRA includes an otherwise permanent forfeiture or waiver, if the amounts will be reinstated or the waiver will be discontinued upon a fixed date or death. The Departments interpret the prior guidance to provide, and the final regulations clarify, that forfeiture or waiver occurs even if the forfeited amounts or waived reimbursements may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For this purpose, an HRA is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election, the participant and the participant's beneficiaries have no access to amounts credited to the HRA until the reinstatement event.[55] This means that the HRA may not be used to reimburse or pay medical expenses incurred during the period after the forfeiture or waiver and prior to reinstatement. An HRA need not provide for reinstatement of forfeited amounts or waived reimbursements to be integrated with a non-HRA group health plan. The final regulations reflect this clarification, and this clarification applies for integration of HRAs as well as other account-based plans, as defined in the regulations.

The Departments' prior guidance regarding integration of an HRA or other account-based plan with another group health plan further provides that integration requires, among other requirements, that the plan sponsor offering the HRA or other account-based plan also offer to the employee another group health plan (other than the HRA or other account-based plan). On February 18, 2015, Treasury and IRS issued Notice 2015–17, which, in Q&A3, provided for integration of a premium reimbursement arrangement for an employee's Medicare part B or D premiums for purposes of the annual dollar limit prohibition and the preventive services requirements under PHS Act section 2713 if the arrangement meets certain conditions and the employer offers the employee another group health plan.[56] However, Notice 2015–17 provided that the premium reimbursement arrangement for an employee's Medicare part B or D premiums could not be integrated with Medicare coverage to satisfy the market reforms because Medicare coverage is not a group health plan. In response to this prior guidance, stakeholders have indicated that employers with fewer than 20 employees are unable to meet the integration test set out in Notice 2015–17 for Medicare part B or D premium reimbursement arrangements. That is because these employers that offer group health plan coverage are not required by the applicable Medicare secondary payer rules to offer group health plan coverage to their employees who are eligible for Medicare coverage, and some issuers of insurance for group health plans do not allow these smaller employers to offer group health plan coverage to their employees who are eligible for Medicare coverage. In response to these concerns, these regulations now provide a special rule for employers with fewer than 20 employees that are not required to offer their group health plan coverage to employees who are eligible for Medicare

[52] Issues also arise for account-based group health plans under PHS Act section 2713, which requires non-grandfathered group health plans (or health insurance issuers offering group health insurance plans) to provide certain preventive services without imposing any cost-sharing requirements for these services. The Departments have issued guidance providing that, similar to the analysis of the annual dollar limit prohibition, an HRA that is integrated with a group health plan will comply with the preventive services requirements if the group health plan with which the HRA is integrated complies with the preventive services requirements. Also, a group health plan, including an HRA, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of the preventive services requirements and therefore will fail to comply with the preventive services requirements because an HRA or similar arrangement does not provide preventive services without cost-sharing in all instances. See DOL Technical Release 2013–03 and IRS Notice 2013–54.

[53] Health FSAs will be considered to provide only excepted benefits if the employer also makes available group health plan coverage that is not limited to excepted benefits and the health FSA is structured so that the maximum benefit payable to any participant cannot exceed two times the participant's salary reduction election for the health FSA for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). See 26 CFR 54.9831–1(c)(3)(v), 29 CFR 2590.732(c)(3)(v), and 45 CFR 146.145(c)(3)(v).

[54] See Affordable Care Act Implementation FAQs Part XIX, available at *http://www.dol.gov/ebsa/faqs/faq-aca19.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs19.html*.

[55] During a period in which an HRA has been forfeited or waived prior to a reinstatement event, the participant is considered not covered by the HRA. For a former employee (such as a retiree), an individual's right to have a forfeited or waived HRA reinstated upon a reinstatement event will not prevent the individual from receiving the premium tax credit under § 36B during the period after forfeiture or waiver and prior to reinstatement, if the individual is otherwise eligible for a premium tax credit. See 26 CFR 1.36B–2(c)(3)(i), proposed § 1.36B–2(c)(3)(iv).

[56] Notice 2015–17 provides special rules for integration of Medicare Part B and D premium reimbursement arrangements and TRICARE-related HRAs with other group health plans, along with various other related pieces of guidance. That guidance continues to apply but is not repeated in these final regulations.

coverage, and that offer group health plan coverage to their employees who are not eligible for Medicare, but not to their employees who are eligible for Medicare coverage. For these employers, a premium reimbursement arrangement for Medicare part B or D premiums may be integrated with Medicare (and deemed to satisfy) the annual dollar limit prohibition and the preventive services requirements under PHS Act section 2713 if the employees who are not offered the other group health plan coverage would be eligible for that group health plan but for their eligibility for Medicare. These employers may use either of the non-Medicare specific integration tests, as applicable, for account-based plans for employees who are not eligible for Medicare.

Although in certain circumstances HRAs and other account-based plans may be integrated with another group health plan to satisfy the annual dollar limit prohibition, these final regulations incorporate the general rule set forth in prior subregulatory guidance clarifying that an HRA and other account-based plans may not be integrated with individual market coverage, and therefore an HRA or other account-based plan used to reimburse premiums for the individual market coverage fails to comply with PHS Act section 2711.

These final regulations, however, do not incorporate all of the other subregulatory guidance concerning the application of the Affordable Care Act to HRAs and other account-based plans. It has come to the Departments' attention that there are a wide variety of account-based products being marketed, often with subtle but insubstantial differences, in an attempt to circumvent the guidance set forth by the Departments on the application of the annual dollar limit prohibition and the preventive services requirements to account-based plans. The Departments intend to continue to address these specific instances of noncompliance. The subregulatory guidance not specifically addressed in these final regulations continues to apply and the Departments will continue to address additional situations as necessary.

D. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128)

PHS Act section 2712, as added by the Affordable Care Act, provides that a group health plan or health insurance issuer offering group or individual health insurance coverage must not rescind coverage unless a covered individual commits fraud or makes an intentional misrepresentation of material fact. This standard applies to all rescissions, whether in the group or individual insurance market, or self-insured coverage. These rules also apply regardless of any contestability period of the plan or issuer. On June 28, 2010, the Departments issued interim final regulations implementing PHS Act section 2712.[57] The interim final regulations included several clarifications regarding the standards for rescission, including that the rules of PHS Act section 2712 apply whether the coverage is rescinded for an individual or a group. The Departments also issued Affordable Care Act Implementation FAQs Part II Q7, which clarified when retroactive terminations in the 'normal course of business' would not be considered rescissions.[58] These final regulations finalize the 2010 interim final regulations without substantial change and incorporate the clarifications issued thus far in subregulatory guidance.

1. Definition of Rescission

Under the interim final regulations and these final regulations, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats an insurance policy as void from the time of an individual's or group's enrollment is a rescission, whether the cancellation is a result of the issuer subsequently determining that a valid insurance contract does not exist or the insurance contract was entered into despite its noncompliance with applicable law. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission. However, a cancellation or discontinuance of coverage is not a rescission if it has only prospective effect or to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage. Other provisions of Federal and State law limit the grounds for prospective cancellations of coverage, including PHS Act section 2703 regarding guaranteed renewability of coverage and PHS Act section 2705 regarding non-discrimination in rules for eligibility (or continued eligibility) based on health status.

Under PHS Act section 2712, rescission is not prohibited if a covered individual commits fraud or makes an intentional misrepresentation of material fact. Some commenters recommended that the Departments define the term ''material fact.'' These final regulations decline this suggestion. However, the Departments have addressed whether providing false or inaccurate information concerning tobacco use is considered a misrepresentation of material fact for this purpose. HHS published final regulations under PHS Act section 2701 (regarding fair health insurance premiums) on February 13, 2013.[59] In the preamble to those regulations, HHS stated that, with respect to an individual who is found to have reported false or inaccurate information about their tobacco use, the individual may be charged the appropriate premium that should have been paid retroactive to the beginning of the plan year. However, as stated in the preamble, the ''remedy of recoupment renders any misrepresentation with regard to tobacco use no longer a 'material' fact for purposes of rescission under PHS Act section 2712 and its implementing regulations,'' and therefore, coverage cannot be rescinded on such basis. The Departments may provide further guidance regarding the definition of a ''material fact'' for purposes of rescission under PHS Act section 2712 if additional questions arise.

2. Scope and Application

The statutory prohibition related to rescissions is not limited to rescissions based on prior medical history, rather it precludes plans and issuers from rescinding coverage under any circumstances except as provided in the statute and regulations. For example, coverage cannot be rescinded because an individual makes a mistake on an insurance application or enrollment form. An example in both the interim final regulations and in these final regulations clarifies that some plan errors (such as mistakenly covering a part-time employee for a period of time under a plan that only covers full-time employees) may be cancelled prospectively once identified, but not retroactively rescinded unless there was fraud or intentional misrepresentation of a material fact by the employee.

The Departments received comments on the interim final regulations stating that some employers' human resource departments may reconcile lists of eligible individuals with their plan or issuer via data feed only once per month, and that routine enrollment adjustments in the normal course of business should not be considered a rescission.

In response to these comments, the Departments issued an FAQ concerning

[57] 75 FR 37188 (June 28, 2010).

[58] Affordable Care Act Implementation FAQs Part II, available at *http://www.dol.gov/ebsa/faqs/faq-aca2.html* or *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html.*

[59] 78 FR 13406, 13414 (February 13, 2013).

rescissions on October 8, 2010.[60] The FAQ stated that if a plan covers only active employees (subject to the COBRA continuation of coverage provisions) and an employee pays no premiums for coverage after termination of employment, the Departments do not consider the retroactive elimination of coverage back to the date of termination of employment, due to delay in administrative record-keeping, to be a rescission. Similarly, if a plan does not cover ex-spouses and the plan is not notified of a divorce (subject to the COBRA continuation coverage provisions), and the full COBRA premium is not paid by the employee or ex-spouse for coverage, the Departments do not consider a plan's termination of coverage retroactive to the divorce to be a rescission.[61]

3. Termination of Coverage Initiated by Participant, Beneficiary, or Enrollee

The Departments have been asked whether the rescission rules prohibit a plan or issuer from retroactively terminating coverage at the request of a participant, beneficiary, or enrollee. In the Departments' view, the statutory provision was enacted by Congress to protect individuals against potential abuses by group health plans and health insurance issuers; it was not intended to prevent individuals from exercising their rights and privileges under the terms of the plan or coverage in accordance with applicable State law, where they are acting voluntarily and without coercion by the plan or issuer. Moreover, HHS regulations at 45 CFR 155.430, which govern termination of enrollment in the Exchange, permit enrollees and the Exchange to initiate a retroactive termination of enrollment in a QHP through the Exchange, including instances where the enrollee has the right to terminate coverage under applicable State law (such as State ''free look'' cancellations laws).[62] For these reasons, the Departments clarify in these final regulations that a retroactive cancellation or discontinuance of coverage is not a rescission if (1) it is initiated by the individual (or by the individual's authorized representative) and the employer, sponsor, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively, or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or (2) it is initiated by the Exchange pursuant to 45 CFR 155.430 (other than under paragraph (b)(2)(iii)). The Departments may issue additional subregulatory guidance if abusive situations or questions arise.

4. Interaction With Internal Appeals and External Review

Commenters requested that these final regulations provide that individuals have the right to appeal a rescission to an independent third party. PHS Act section 2719 and its implementing regulations address internal claims and appeals and external review of adverse benefit determinations. Under the Department of Labor's claims procedure regulation at 29 CFR 2560.503–1 (the DOL claims procedure regulation), adverse benefit determinations eligible for internal claims and appeals processes generally include denial, reduction, termination of, or a failure to provide or make a payment (in whole or in part) for a benefit, including a denial, reduction, termination, or failure to make a payment based on the imposition of a preexisting condition exclusion, a source of injury exclusion, or other limitation on covered benefits. The Departments' regulations under PHS Act section 2719 broaden the definition of ''adverse benefit determination'' to include rescissions of coverage. Therefore, rescissions of coverage are also eligible for internal claims and appeals and external review for non-grandfathered health plans, whether or not the rescission has an adverse effect on any particular benefit at the time of an appeal. The regulations under PHS Act section 2719 also contain provisions requiring coverage to remain effective pending the outcome of an internal appeal.

5. Interaction With COBRA Continuation Coverage

COBRA provides for a temporary continuation of group health coverage that would otherwise be lost due to certain life events. COBRA requires group health plans to offer continuation coverage to covered employees, former employees, spouses, former spouses, and dependent children when group health coverage would be terminated due to the following: The death of a covered employee; termination or reduction in the hours of a covered employee's employment for reasons other than gross misconduct; a covered employee's becoming entitled to Medicare; divorce or legal separation of a covered employee and spouse; and a child's loss of dependent status (and therefore coverage) under the plan.

COBRA sets forth rules for how and when continuation coverage must be offered and provided, how employees and their families may elect continuation coverage, and what circumstances justify terminating continuation coverage. COBRA allows plans to continue coverage during an initial 60-day election period and allows plans to continue providing coverage during the 30-day grace periods for each premium payment. If a qualified beneficiary fails to pay for coverage during the initial election period, or fails to pay in full before the end of a grace period, continuation coverage may be terminated retroactively under COBRA.

Several commenters sought clarification about the interaction of the COBRA continuation provisions with the prohibition against rescissions. The Departments clarify that the regulatory exception to the prohibition on rescission for failure to timely pay required premiums or contributions toward the cost of coverage also includes failure to timely pay required premiums towards the cost of COBRA continuation coverage. Accordingly, if a group health plan requires the payment of a COBRA premium to continue coverage after a qualifying event and that premium is not paid by the applicable deadline, the prohibition on rescission is not violated if the plan retroactively terminates coverage due to a failure to elect and pay for COBRA continuation coverage.

6. Notice of Rescission

Consistent with PHS Act section 2712, under the interim final regulations and these final regulations, a plan or issuer must provide at least 30 calendar days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded (where permitted). This provides individuals time to appeal the decision or enroll into new coverage. This notice is required regardless of whether it is a rescission of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

Some commenters recommended the 30-day notice of rescission be coordinated with the rules for providing notices of adverse benefit determinations under the Departments'

[60] Affordable Care Act Implementation FAQs Part II, Q7 at *http://www.dol.gov/ebsa/pdf/faq-aca2.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs2.html*.

[61] In such situations, COBRA may require coverage to be offered for up to 36 months if the COBRA applicable premium is paid by the qualified beneficiary.

[62] State ''free look'' cancellation laws are laws permitting an individual to cancel coverage within a certain time period, even following the effectuation of the enrollment.

internal appeals and external review regulations under PHS Act section 2719. Other commenters made specific suggestions regarding the content of the notice, such as that the notice indicate the basis for the rescission and include an explanation of the remedies available to the individual.

Under PHS Act section 2719, the interim final regulations, and these final regulations, a plan or issuer must provide notice to individuals, in a culturally and linguistically appropriate manner, of the reason or reasons for an adverse benefit determination or final internal adverse benefit determination (including a rescission of coverage) and a description of available internal appeals and external review processes, including information on how to initiate an appeal. The Departments encourage plans and issuers to coordinate notices related to rescissions and appeal procedures to the extent possible.

E. PHS Act Section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120)

PHS Act section 2714, as added by the Affordable Care Act, provides that a group health plan or a health insurance issuer offering group or individual health insurance coverage that makes available dependent coverage [63] of children must make such coverage available for children until attainment of 26 years of age.[64] On May 13, 2010, the Departments issued interim final regulations implementing PHS Act section 2714 and requesting comment.[65] After issuance of the 2010 interim final regulations, the Departments released Affordable Care Act Implementation FAQs Parts I and V to address various requests for clarifications under PHS Act section 2714.[66] These final regulations adopt the 2010 interim final regulations without substantial change and incorporate the clarifications issued thus far in subregulatory guidance.

1. Restrictions on Plan Definition of Dependent

a. Definition of Dependent—Based on Relationship Between Child and Participant

PHS Act section 2714 provides that the ''Secretary shall promulgate regulations to define the dependents to which coverage shall be made available'' under the dependent coverage provision. The 2010 interim final regulations provided that with respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant. For example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the child's financial dependency (upon the participant or any other person), residency with the participant or with any other person, student status, employment, or any combination of those factors. Additional examples of factors that cannot be used for defining dependent for purposes of eligibility (or continued eligibility) include eligibility for other coverage [67] and marital status of a dependent child.[68] Because the statute does not distinguish between coverage for minor children and coverage for adult children under age 26, these factors also may not be used to determine eligibility for dependent coverage of minor children.

It has come to the Departments' attention that certain plans that utilize an HMO design impose restrictions on eligibility that require participants and beneficiaries to work, live or reside in the HMO service area. While these provisions on their face appear to be generally applicable, the overwhelming impact of such provisions affects dependent children, who would otherwise be required to be covered pursuant to PHS Act section 2714. For example, a plan that utilizes an HMO design that requires participants and beneficiaries to work, live or reside in the service area would not permit a dependent child covered under the parent's plan to continue to be eligible for the plan if the dependent child moves out of the HMO's service area to attend college. Under the same plan, however, most employees and their spouses would work, live or reside in the service area.

These final regulations provide that, to the extent such restrictions are applicable to dependent children up to age 26, eligibility restrictions under a plan or coverage that require individuals to work, live or reside in a service area violate PHS Act section 2714. (This rule does not relate to the extent to which a plan must cover participants or provide services outside of its service area). While eligibility provisions of general applicability are usually outside the scope of PHS Act section 2714, due to the disproportionate effect on dependent children, these final regulations do not permit eligibility provisions under a plan or coverage based on service area, to the extent such restrictions are applicable to dependent children up to age 26, even if such restrictions are intended to apply generally to all participants and beneficiaries under the plan.

b. Definition of Child

PHS Act section 2714 does not require a plan to provide dependent coverage of children but instead provides that if a plan does provide dependent coverage of children it must continue to make such coverage available until the child turns age 26.[69] Neither PHS Act section

[63] For purposes of these final regulations, dependent coverage means coverage of any individual under the terms of a group health plan, or group or individual health insurance coverage, because of the relationship to a participant (in the individual market, primary subscriber).

[64] Under section 1004(d) of the Reconciliation Act and IRS Notice 2010–38, 2010–20 IRB 682, released on April 27, 2010, employers may exclude from the employee's income the value of any employer-provided health coverage for an employee's child for the entire taxable year the child turns 26 if the coverage continues until the end of that taxable year. This means that if a child turns 26 in March, but stays on the plan past December 31st (the end of most individual's taxable year), the health benefits up to December 31st can be excluded from the employee's income.

[65] See 75 FR 27122 (May 13, 2010).

[66] Affordable Care Act Implementation FAQs Part I, Q&A–14, available at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html* and Affordable Care Act Implementation FAQs Part 5 and Mental Health Parity Implementation, Q&A 5, available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html. http://www.dol.gov/ebsa/faqs/faq-aca5.html.*

[67] *See* section II.H.1. of this preamble, entitled ''Special Rule Relating to Dependent Coverage of Children to Age 26 for Grandfathered Group Health Plans,'' for discussion of an out-of-date special rule for grandfathered plans regarding adult children eligible for other coverage.

[68] The Affordable Care Act, as originally enacted, required plans and issuers to make dependent coverage available only to a child ''who is not married.'' This language was struck by section 2301(b) of the Reconciliation Act. Accordingly, under the interim final regulations and these final regulations, plans and issuers may not limit dependent coverage of children based on whether a child is married (however, a plan or issuer is not required under the final regulations to cover the spouse of an eligible child).

[69] In general, under section 4980H of the Code, certain employers (applicable large employers) must either offer health coverage to their full-time employees (and their dependents) or potentially pay an assessable payment if at least one full-time employee receives a premium tax credit for purchasing individual coverage on an Affordable Insurance Exchange. For purposes of section 4980H, the term dependent means ''a child (as defined in section 152(f)(1) of the Code but excluding a stepson, stepdaughter or an eligible foster child (and excluding any individual who is excluded from the definition of dependent under section 152 of the Code by operation of section 152(b)(3) of the Code)) of an employee who has not attained age 26. A child attains age 26 on the 26th anniversary of the date the child was born. A child is a dependent for purposes of section 4980H for the entire calendar month during which he or she attains age 26. Absent knowledge to the contrary, applicable

Continued

2714 nor the interim final regulations defined the term child for purpose of the dependent coverage provision.[70]

In response to comments requesting guidance on the definition of the term child and questions from stakeholders, the Departments released an FAQ[71] stating that a group health plan or issuer will not fail to satisfy the dependent coverage provision merely because it conditions health coverage on support, residency, or other dependency factors for individuals under age 26 who are not described in section 152(f)(1) of the Code. For an individual not described in section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for health coverage, such as a condition that the individual be a dependent for income tax purposes. The FAQ also provided that a plan or issuer does not fail to satisfy the requirements of PHS Act section 2714 or its implementing regulations because the plan limits health coverage for children until the child turns 26 to only those children who are described in section 152(f)(1) of the Code. These final regulations incorporate the clarifications provided in the FAQ.

Some commenters requested that the Departments interpret PHS Act section 2714 to apply to grandchildren. The statute and the 2010 interim final regulations provided that nothing in PHS Act section 2714 requires a plan or issuer to make available coverage for a child of a child receiving dependent coverage. Because the statute specifically provides that plans and issuers are not required to make coverage available to grandchildren, these final regulations do not adopt this suggestion.

2. Uniformity Irrespective of Age

The 2010 interim final regulations provided that the terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on the age of a child, except for children age 26 or older. The 2010 interim final regulations contained examples illustrating that age-based surcharges violate the uniformity requirement but that cost of coverage increases for tiers with more covered individuals do not violate this requirement because such an increase applies without regard to the age of any child. The 2010 interim final regulations also contained an example demonstrating that a plan that limits the benefit packages offered based on the age of dependent children violates the uniformity requirement. These final regulations retain these examples.

Following the 2010 interim final regulations, the Departments issued an FAQ[72] that addressed an arrangement under which a group health plan charges a copayment for physician visits that do not constitute preventive services to individuals age 19 and over, including employees, spouses, and dependent children, but waives the copayment for children under age 19. The FAQ clarifies that the Departments do not consider such an arrangement to violate the dependent coverage provision. This arrangement is permissible under the dependent coverage provision because, while the dependent coverage provision prohibits distinctions based upon age in dependent coverage of children under age 26, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this situation, the copayments charged to dependent children are the same as those charged to employees and spouses. (However, with respect to individual and small group plans required to provide essential health benefits, distinctions based on age may be considered discriminatory under HHS regulations regarding essential health benefits.[73]) The final regulations reflect the clarification contained in this FAQ.

F. PHS Act Section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136)

PHS Act section 2719, as added by the Affordable Care Act, applies to group health plans that are not grandfathered health plans and health insurance issuers offering non-grandfathered coverage in the group and individual markets, and sets forth standards for plans and issuers regarding both internal claims and appeals and external review. With respect to internal claims and appeals processes for group health plans and health insurance issuers offering group health insurance coverage, PHS Act section 2719 provides that a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group coverage must initially incorporate the internal claims and appeals processes set forth in regulations promulgated by the Department of Labor (DOL) at 29 CFR 2560.503–1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor. Similarly, with respect to internal claims and appeals processes for individual health insurance coverage, issuers must initially incorporate the internal claims and appeals processes set forth in applicable State law and update such processes in accordance with standards established by the Secretary of HHS. With respect to external review, PHS Act section 2719 provides for either a State external review process or a Federal external review process.

The following list identifies certain regulations and subregulatory guidance that the Departments have issued to implement these requirements:

- Interim final regulations on July 23, 2010, at 75 FR 43329, implementing the internal claims and appeals and external review process requirements of PHS Act section 2719;
- Technical Release 2010–01, on August 23, 2010, setting forth interim procedures for Federal External Review;
- Technical Guidance, on August 26, 2010, setting forth interim procedures for Federal External Review for health insurance issuers in the group and individual markets under the Patient Protection and Affordable Care Act;
- Affordable Care Act Implementation FAQs part I, on September 20, 2010, providing guidance on outstanding questions regarding the internal claims and appeals and external review process requirements of PHS Act section 2719;
- Technical Release 2010–02, on September 20, 2010, establishing an enforcement grace period with respect to some of the internal claims and appeals standards set forth in the interim final regulations;
- Technical Release 2011–01, on March 18, 2011, extending the enforcement grace period set forth in Technical Release 2010–02;

large employer members may rely on an employee's representation about that employee's children and the ages of those children. The term dependent does not include the spouse of an employee.'' See 26 CFR 54.4980H–1(a)(12). Under section 152(f)(1) of the Code a child means an individual who is (i) a son, daughter, stepson, or stepdaughter of the taxpayer (including a legally adopted child or an individual lawfully placed for adoption with the taxpayer) or (ii) an eligible foster child of the taxpayer.

[70] Under section 1004(d) of the Reconciliation Act and IRS Notice 2010–38, child means child as defined in section 152(f)(1) of the Code.

[71] Affordable Care Act Implementation FAQs Part I, Q&A 14 (released on September 20, 2010), available at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.*

[72] Affordable Care Act Implementation Part V and Mental Health Parity Implementation FAQs, Q&A 5 (released on December 22, 2010), available at *http://www.dol.gov/ebsa/faqs/faq-aca5.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs5.html.*

[73] See 45 CFR 156.125.

• Technical Release 2011–02, on June 22, 2011, setting forth interim standards for a State-administered external review process authorized under section 2719(b)(2) of the PHS Act and paragraph (d) of the interim final regulations;

• Amendments to the interim final regulations on June 24, 2011, at 76 FR 37207, with respect to the internal claims and appeals and external review provisions of PHS Act section 2719 in response to comments received regarding the interim final regulations; and

• Technical Release 2013–01, on March 15, 2013, extending the interim standards for a State-administered external review process authorized under section 2719(b)(2) of the PHS Act and paragraph (d) of the interim final regulations set forth in Technical Release 2011–02.

After consideration of the comments and feedback received from stakeholders, the Departments are publishing these final regulations. These final regulations adopt the interim final regulations, as previously amended, without substantial change. These final regulations also codify some of the enforcement safe harbors, transition relief, and clarifications set forth through subregulatory guidance. Contemporaneous with the issuance of these final regulations, the Department of Labor is issuing a proposed regulation to amend the DOL claims procedure regulations under 29 CFR 2560.503–1, as applied to plans providing disability benefits. The amendment would revise and strengthen the current DOL claims procedure regulations regarding claims and appeals applicable to plans providing disability benefits primarily by adopting the protections and standards for internal claims and appeals applicable to group health plans under PHS Act section 2719 and these final regulations.

1. Internal Claims and Appeals

In addition to the requirement in PHS Act section 2719(a) that plans and issuers must initially incorporate the internal claims and appeals processes set forth in the DOL claims procedure regulation, the interim final regulations, as amended, provide further standards for compliance with the internal claims and appeals requirements of PHS Act 2719.[74] Specifically, under these requirements, in addition to complying with the internal claims and appeals processes set forth in the DOL claims procedure regulation, plans and issuers are required to comply with the following standards: (1) The scope of adverse benefit determinations eligible for internal claims and appeals includes a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at the time); (2) A plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim by the plan or issuer; (3) Clarifications with respect to full and fair review, such that plans and issuers are clearly required to provide the claimant (free of charge) with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or issuer in connection with the claim, as well as any new or additional rationale for a denial at the internal appeals stage, and a reasonable opportunity for the claimant to respond to such new evidence or rationale; (4) Clarifications regarding conflicts of interest, such that decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to an individual, such as a claims adjudicator or medical expert, must not be based upon the likelihood that the individual will support the denial of benefits; (5) Notices must be provided in a culturally and linguistically appropriate manner, as required by the statute, and as set forth in paragraph (e) of the interim final regulations, as amended; (6) Notices to claimants must provide additional content, including that any notice of adverse benefit determination or final internal adverse benefit determination must include information sufficient to identify the claim involved, including the date of the service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning; and (7) With the exception of de minimis violations under specified circumstances, if a plan or issuer fails to adhere to all the requirements of the interim final regulations, as amended, the claimant is deemed to have exhausted the plan's or issuer's internal claims and appeals process, and the claimant may initiate any available external review process or remedies available under ERISA or under State law.

To address certain relevant differences in the group and individual markets the interim final regulations, as amended, provided that health insurance issuers offering individual coverage must comply with three additional requirements for internal claims and appeals processes. First, initial eligibility determinations in the individual market must be included within the scope of claims eligible for internal appeals. Second, health insurance issuers offering individual coverage are only permitted to have one level of internal appeal. Third, health insurance issuers offering individual coverage must maintain records of all claims and notices associated with the internal claims and appeals process for six years. The issuer must make such records available for examination by the claimant or State, or Federal oversight agency upon request.

These final regulations generally incorporate the standards of the interim final regulations, as amended, and the Departments' associated guidance, without major change.

a. Full and Fair Review

The interim final regulations provided that plans and issuers must provide the claimant (free of charge) with new or additional evidence considered, relied upon, or generated by (or at the direction of) the plan or issuer in connection with the claim, as well as any new or additional rationale as soon as possible and sufficiently in advance of the date on which the notice of the final adverse benefit determination is required to be provided under the DOL claims procedure regulations. Since the issuance of the interim final regulations and subsequent subregulatory guidance, stakeholders have requested additional clarification regarding how to provide a full and fair review in accordance with the requirements set forth in the regulations.

Commenters requested additional guidance related to the timing and amount of information required to be provided in order to satisfy this requirement. Specifically, individuals asked whether such information actually must be provided automatically to participants and whether or not it would be sufficient to send participants a notice informing them of the availability of new or additional evidence or rationale. The Departments retain the requirement that plans and issuers provide the new or additional evidence or rationale automatically. In

[74] The statute requires the Secretary of Health and Human Services to set forth processes for internal claims and appeals in the individual market. Under the interim final regulations, the Secretary of Health and Human Services has determined that a health insurance issuer offering individual health insurance coverage must generally comply with all the requirements for the internal claims and appeals process that apply to group health coverage. Also, see 45 CFR 147.136 for additional requirements for coverage in the individual market.

the Departments' view, fundamental fairness requires that participants and beneficiaries have an opportunity to rebut or respond to any new or additional evidence upon which a plan or issuer may rely. Therefore, plans and issuers that wish to rely on any new or additional evidence or rationale in making a benefit determination must send such new or additional evidence or rationale to participants as soon as it becomes available to the plan or issuer.

In order to comply with this requirement, a plan or issuer must send the new or additional evidence or rationale to the participant. Merely sending a notice informing participants of the availability of such information fails to satisfy this requirement. To address the narrow circumstance raised by some comments that the new or additional information could be first received so late that it would be impossible to provide it, these final regulations provide that if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan or issuer must notify the claimant of the benefit determination as soon as a plan or issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

2. Culturally and Linguistically Appropriate Standard (CLAS)

PHS Act section 2719 requires group health plans and health insurance issuers to provide relevant notices in a culturally and linguistically appropriate manner. The interim final regulations, as amended, set forth a requirement to provide notices in a non-English language if at least a specified percentage of residents in a county are literate only in the same non-English language. Specifically, with respect to group health plans and health insurance issuers offering group or individual health insurance coverage, the interim final regulations established that the threshold percentage of people who are literate only in the same non-English language is set at ten percent or more of the population residing in the claimant's county, as determined in guidance based on American Community Survey data published by the United States Census Bureau. Furthermore, the interim final regulations, as amended, required that each notice sent by a plan or issuer to an address in a county that meets this threshold include a one-sentence statement in the relevant non-English language about the availability of language services. In addition, under the interim final regulations, as amended, plans and issuers must provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request.

In response to the culturally and linguistically appropriate standards (CLAS) set forth in the amendments to the interim final regulations described in the prior paragraph, the Departments received many comments from various stakeholders. Some commenters requested that the Departments incorporate the prior proposed CLAS (rather than the amended CLAS) into these final regulations, citing that the prior standard was less costly for plans and issuers than was stated in the proposed regulations. Other commenters requested that the threshold percentage that triggers the CLAS requirements be reduced to a lower percentage to capture a greater number of counties. Other stakeholders supported the CLAS requirements as set forth in the amendments to the interim final regulations. Stakeholders that support the amended CLAS reiterated prior comments that the Departments received that opposed the ''tagging and tracking'' requirement.[75]

In light of all the comments received, these final regulations retain the CLAS requirements as set forth in the amendment to the interim final regulations. The Departments believe that the CLAS requirements appropriately balance the objective of protecting consumers by providing understandable notices to individuals who speak primary languages other than English with the goal of imposing reasonable language access requirements on plans and issuers. Furthermore, the Departments note that nothing in these regulations should be construed as limiting an individual's rights under Federal or State civil rights statutes, such as section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964 (Title VI) which prohibits covered entities, including issuers participating in Medicare Advantage, from discriminating on the basis of race, color, or national origin. To ensure non-discrimination on the basis of national origin under Title VI, recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by limited English proficient persons. (For more information, see, ''Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons,'' available at *http://www.hhs.gov/ocr/civilrights/resources/laws/revisedlep.html*.)

3. Extension of the Transition Period for State External Review Processes

PHS Act section 2719(b) requires that a non-grandfathered group health plan that is not a self-insured plan that is not subject to State insurance regulations and a health insurance issuer offering non-grandfathered group or individual health insurance coverage comply with an applicable State external review process if that process includes, at a minimum, the consumer protections set forth in the Uniform Health Carrier External Review Model Act issued by the National Association of Insurance Commissioners (the NAIC Uniform Model Act). Paragraph (c)(2) of the 2010 interim final regulations under PHS Act section 2719, as amended, sets forth the minimum consumer protection standards that a State external review process must include to qualify as an applicable State external review process under PHS Act section 2719(b)(1) (NAIC-parallel external review process).

Under PHS Act section 2719(b)(2), if a State's external review process does not meet the minimum consumer protection standards set forth in the NAIC Uniform Model Act (or if a plan is self-insured and not subject to State insurance regulation), group health plans and health insurance issuers in the group and individual markets in that State are required to implement an effective external review process that meets minimum standards established by the Secretary of HHS through guidance. These standards must be similar to the standards established under PHS Act section 2719(b)(1) and must meet the requirements set forth in paragraph (d) of the 2010 interim final regulations, as amended.

In June 2011, the Departments amended the July 2010 interim final regulations and announced that plans and issuers could continue to participate in a State external review process that met Federal standards that were NAIC-similar for a limited time (the NAIC-similar external review

[75] Under the interim final regulations, the CLAS standard included a ''tagging and tracking requirement'' which required plans and issuers, to the extent individuals request a document in a non-English language, to ''tag'' and ''track'' such request so that any future notices would be provided automatically in the non-English language.

process), in anticipation that such an allowance would reduce market disruption during a transition period. Contemporaneous with the June 2011 amendment, the Departments issued guidance which, among other things, established the NAIC-similar external review process.

The Departments recognize that many States have done considerable work to bring their external review laws and processes into compliance with the NAIC Uniform Model Act and, because of those efforts, the Departments have extended the transition periods to allow States more time to meet the NAIC-parallel external review process standards. States continue to make changes to their laws through what have often proven to be complex and time consuming processes, often involving legislative changes; and it is apparent that more time is needed for some States to achieve NAIC-parallel external review processes. Therefore, the Departments are extending the NAIC-similar external review process transition period so that the last day of the transition period is December 31, 2017. Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2), if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act. During this transition period, the NAIC-similar external review process will continue to apply [76] for non-grandfathered group health plans and issuers of non-grandfathered group or individual coverage in the State.[77] This modification seeks to minimize cost and confusion for participants and enrollees, issuers, and plans alike. Furthermore, the extension will provide States that are currently in the process of making changes to external review laws time to implement NAIC-parallel external review processes. The Departments will continue to work with health insurance issuers, States, and other stakeholders to assist them in coming into compliance with the law. Once this transition period has ended, plans and issuers in a State that has not implemented the NAIC-parallel external review process will be required to comply with a Federal external review process.

4. Federal External Review

PHS Act section 2719(b)(2) provides that plans and issuers in States without an external review process that meets the requirements of PHS Act section 2719(b)(1) or that are self-insured plans not subject to State insurance regulation shall implement an effective external review process that meets minimum standards established by the Secretary of HHS through guidance and that is similar to a State external review process described in PHS Act section 2719(b)(1). The interim final regulations reiterated this statutory requirement, and also provided additional standards, including that the Federal external review process, like the State external review process, will provide for expedited external review and additional consumer protections with respect to external review for claims involving experimental or investigational treatment. The interim final regulations also set forth the scope of claims eligible for review under the Federal external review process. The interim final regulations also established the procedural standards that apply to claimants, plans, and issuers under this Federal external review process, as well as the substantive standards under this process. These final regulations incorporate both the procedural and substantive standards established in the interim final regulations and subsequent subregulatory guidance without substantial change and with minor clarifications.

a. Scope of Federal External Review Process

The 2010 interim final regulations set forth the original scope of claims eligible for external review under the Federal external review process. Specifically, any adverse benefit determination (including final internal adverse benefit determination) could be reviewed unless it related to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (for example, worker classification and similar issues were not within the scope of the Federal external review process). After considering comments received in response to the 2010 interim final regulations, the Departments suspended the original rule and temporarily narrowed its scope. The amended scope limited the Federal external review process to claims that involve (1) medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit, or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and (2) a rescission of coverage (whether or not the rescission has any effect on any particular benefit at the time). The amendments also provided two examples of claims involving medical judgment.

The Departments received mixed comments in response to the revised scope of Federal external review in the 2011 amendment to the July 2010 interim final regulations. Generally, comments supported narrowing the scope to decisions based on medical judgment and suggested permanently adopting the standards in the 2011 amendment. However, there were also commenters that objected to limiting the scope and favored the original scope as stated in the July 2010 interim final regulations. Some of these commenters stated that the description of medical judgment was ambiguous and that it was unclear how to determine whether a claim involved ''medical judgment.'' Other commenters disagreed with the description of medical judgment, finding either the explanation was too vague or that certain information in the examples did not fall within what was normally considered medical judgment.

Additionally, the Departments received comments requesting more clarity around the treatment of coding issues under the amended scope of Federal external review. The Departments recognize that there may be instances when a patient may have a procedure performed that is similar to another and a coding issue impacts whether coverage is provided. For example, a patient may need a stoma revision, and recent significant weight loss necessitates a procedure to remove the patient's excess skin and tissue prior to addressing the stoma. However, the skin removal procedure may be coded as a cosmetic surgery, such as an abdominoplasty or ''tummy tuck'', instead of as a panniculectomy, and is therefore not covered. In this case both procedures involve the removal of skin from the abdomen, but one procedure is an excluded cosmetic surgery while the other is covered so long as certain medical criteria are met. This dispute would likely be resolved via an internal appeal, but in the event that the initial decision to deny coverage was affirmed on an internal appeal, the claimant

[76] If a State enacts an NAIC-parallel law prior to January 1, 2018, coverage subject to that State law will be required to comply with the provisions of that State law, in accordance with ERISA section 731 and PHS Act section 2719 and 2724.

[77] See Technical Release 2011–02, Guidance on External Review for Group Health Plans and Health Insurance Issuers Offering Group and Individual Health Coverage, and Guidance for States on State External Review Processes, June 22, 2011. The temporary standards were extended in March 15, 2013 in Technical Release 2013–01, Extension of the Transition Period for the Temporary NAIC-Similar State External Review Process under the Affordable Care Act.

could have the claim reviewed in a Federal external review process. Medical judgment is necessary to determine whether the correct code was used in the patient's case. To the extent that a coding error such as this one involves medical judgment, the claim is within the scope of Federal external review under the July 2010 interim final regulations, as amended.

After consideration of comments, these final regulations make permanent the scope for Federal external review as set out in the 2011 amendments to the July 2010 interim final regulations, to include only an adverse benefit determination that involves medical judgment as determined by the external reviewer, or a rescission of coverage. The interim final regulations included a non-exhaustive list of adverse benefit determinations that involve medical judgment. The final regulations add two items to the list of adverse benefit determinations that involve medical judgment: (1) A plan's or issuer's determination of whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program, and (2) a plan's or issuer's determination of whether a plan is complying with the nonquantitative treatment limitation provisions of the Mental Health Parity and Addiction Equity Act and its implementing regulations, which generally require, among other things, parity in the application of medical management techniques. Both of these clarifications were included in preambles to regulations issued previously by the Departments.[78]

b. Federal External Review Process for Self-Insured Group Health Plans

The preamble to the 2010 interim final regulations stated that the Departments will address in sub-regulatory guidance how non-grandfathered self-insured group health plans may comply with the requirements of the new Federal external review process. The Department of Labor issued Technical Releases 2010–01 and 2011–02 regarding procedures for Federal external review.[79] The technical releases set forth these procedures for non-grandfathered self-insured group health plans not subject to a State external review process. Technical Release 2011–02 also provided non-grandfathered health insurance issuers subject to a Federally-administered external review process[80] and all non-grandfathered self-insured, non-Federal governmental plans with the option of using the external review process set out in Technical Release 2010–01.

In general, under these procedures, a group health plan must first allow a claimant to file a request for Federal external review with the plan. The group health plan must then complete a preliminary review of the request within five business days following the date of receipt of the external review request. Within one business day after completion of the preliminary review, the plan must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number for the Employee Benefits Security Administration (toll free number 866–444–EBSA (3272)). Upon its determination that a request is eligible for external review, the group health plan must then assign an independent review organization (IRO), accredited by URAC or by a similar nationally-recognized accrediting organization, to conduct the external review. The IRO must timely notify the claimant in writing of the external review and provide the claimant 10 business days to submit additional information that the IRO must consider. The group health plan must provide the IRO with any documents and information used in making the original determination within five business days after the date of the assignment and the IRO must forward any information submitted by the claimant to the group health plan within one business day after receipt of the information. The IRO must review all information and documents timely received and must provide written notice of the final external review decision to the claimant and the group health plan within 45 days after the request for the external review. After the final external review decision, the IRO must maintain records of all associated claims and notices for six years. If the IRO has decided to reverse the original determination, then, upon receipt of the IRO's notice of this decision, the group health plan must immediately provide coverage or payment for the claim.

The technical releases also provided that a group health plan must allow a claimant to make a request for expedited external review for benefit determinations involving a medical condition for which the timeframe for completion of an expedited internal appeal or standard external review under the interim final regulations would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function. The IRO must provide a notice of the final external review decision as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for expedited review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan.

These final regulations incorporate the guidance in Technical Releases 2010–01 and 2011–02 without substantial change. These final regulations also continue to permit non-grandfathered self-insured plans to comply with the external review process outlined in these final regulations or a State external review process if the State chooses to expand access to their State external review process to plans that are not subject to the applicable State laws.

Furthermore, these final regulations continue to provide issuers subject to a Federally-administered external review process and all self-insured, non-Federal governmental plans with the option of electing the private accredited IRO process for external review described in these final regulations or the Federally-administered external review process, which is administered by HHS (also referred to as the HHS-administered external review process).

Similar to the technical releases, these final regulations continue to provide that group health plans must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. Moreover, the plan must take action to protect against bias and to ensure independence. Accordingly, plans must contract with at least three IROs for assignments under the plan and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection). In addition, the IRO may not be eligible for any financial incentives based on the likelihood that the IRO

[78] *See* 78 FR 33158, 33164 (June 3, 2013); *see also* 78 FR 68240, 68247–8 (November 13, 2013).

[79] *See* Technical Release 2010–01, available at: *http://www.dol.gov/ebsa/pdf/ACATechnicalRelease2010-01.pdf* and Technical Release 2011–02, available at: *http://www.dol.gov/ebsa/pdf/tr11-02.pdf.*

[80] Where a State's external review process does not meet the Federal consumer protection standards, issuers and self-insured non-Federal governmental plans may choose to utilize either the Federal IRO external review process or an HHS -administered Federal external review process in which a designated Federal contractor will perform all functions of the external review.

will support the denial of benefits. (Of course, plans also may not terminate an IRO's contract in retaliation for granting claims.) For issuers and all self-insured, non-Federal governmental plans participating in the HHS-administered external review process, the requirement to take action to protect against bias and to ensure independence is satisfied without contracting with three IROs for assignment and rotating the claims assignments among them. Under the HHS-administered external review process, there are other unique factors that ensure independence and the absence of bias such as HHS oversight and lack of privity of contract between the issuer or self-insured non-Federal governmental plan and the IRO.

After issuance of the interim final regulations and technical releases, the Departments received questions relating to self-insured group health plans contracting directly with IROs. While such a group health plan must designate an IRO to conduct any external review, neither the interim final regulations nor the technical releases require a plan to contract directly with any IRO. As clarified in the FAQs about the Affordable Care Act implementation, issued on September 20, 2010, where a self-insured plan contracts with a third party administrator that, in turn, contracts with an IRO, the standards of the technical release can be satisfied in the same manner as if the plan had contracted directly. Such a contract does not automatically relieve the plan from responsibility if there is a failure to provide an individual with external review and fiduciaries of plans that are subject to ERISA have a duty to monitor the service providers to the plan. Furthermore, plans may contract with an IRO in another State, as these final regulations do not require the plan to be located in the same State as the IRO. If additional questions arise regarding the IRO external review process, the Departments may issue additional subregulatory guidance.

c. Filing Fees for External Review

The Departments also received comments related to the standard allowing consumers to be charged a filing fee when requesting external review. While the original 2004 NAIC model upon which the 2010 interim final regulations was based expressly permitted imposition of a nominal filing fee for a claimant requesting an external review, and a small number of States have adopted this approach, the 2010 NAIC model did not address this topic. Commenters on the 2010 interim final regulations indicated that the ability to charge a filing fee should be prohibited because such fees may dissuade consumers from filing an appeal, even in cases where the fee is not a financial hardship for the consumer.

The Departments find the change in the NAIC model to be important and are concerned that any fee may impose a financial hardship on some claimants or discourage them from seeking external review. Therefore, these final regulations generally prohibit the imposition of filing fees for external review on claimants. However, the Departments recognize that several States' external review processes currently applicable to group and individual coverage permit nominal filing fees. Therefore, in determining whether a State external review process provides the claimants with minimum consumer protections, these final regulations do not invalidate existing State external review processes because they permit a nominal filing fee, consistent with the 2004 NAIC model.[81] Therefore, plans and coverage subject to such laws may continue to impose nominal fees for as long as such laws continue to apply. For this purpose, consistent with the interim final regulations, to be considered nominal, the filing fee must not exceed $25, must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed $75. All other plans and coverage must pay the full cost of the IRO for conducting the external review, without imposing any nominal filing fee.

G. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138)

PHS Act section 2719A, as added by the Affordable Care Act provides, with respect to a non-grandfathered group health plan or health insurance issuer offering non-grandfathered group or individual health insurance coverage, rules regarding the designation of primary care providers, if a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider. In addition, the statute provides requirements relating to benefits for emergency services. On June 28, 2010, the Departments issued interim final regulations implementing PHS Act section 2719A.[82] The Departments also released Affordable Care Act Implementation FAQs Part I Q15 to address an issue with respect to emergency services.[83] These regulations adopt the 2010 interim final regulations without substantial change and incorporate the clarification issued in subregulatory guidance.

1. Choice of Healthcare Professional

The interim final regulations and these final regulations state that if a plan or issuer requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any primary care provider who is available to accept the participant, beneficiary, or enrollee and who participates in the network of the plan or issuer.

Commenters recommended clarifying that in instances where a participant, beneficiary, or enrollee is incapacitated, a family member may select the primary care provider on their behalf. Under existing State and Federal law, including ERISA, a duly authorized representative is permitted to act on behalf of a participant or beneficiary for all purposes, including the designation of a primary care provider as provided under these final regulations. The final regulations regarding the designation of a primary care provider do not include any new text to address cases of incapacity. However, as with all of the market reform provisions, a duly authorized representative may act on behalf of a participant or beneficiary to the extent permitted under other applicable Federal and State law.

Commenters recommended that participants, beneficiaries, and enrollees be allowed to designate a provider of any specialty or licensure as their primary care provider to improve access to care. For example, commenters recommended that enrollees have the option of designating a nurse practitioner as their primary care provider. The Departments do not define primary care provider for purposes of these final regulations. The classification of who is considered a primary care provider is determined under the terms of the plan or coverage

[81] Twelve States expressly authorize nominal fees: Connecticut, Hawaii, Kentucky, Massachusetts, Minnesota, New Jersey, New York, North Dakota, Rhode Island, South Dakota, Vermont, and Wyoming.

[82] 75 FR 37188 (June 28, 2010).

[83] Affordable Care Act Implementation FAQs Part I, Q&A–15, available at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html.*

and in accordance with applicable State law.

If a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusion with respect to coverage of pediatric care.

Some commenters recommended that participants, beneficiaries, or enrollees have the option to designate physicians of various pediatric sub-specialties as the child's primary care provider to improve access to specialty care without prior authorization from a primary care coordinator. For example, commenters suggested that a pediatric cancer patient with a serious chronic condition should have the option of designating a pediatric oncologist that can provide cancer treatment as well as other routine treatment as the child's primary care provider. The Departments interpret this provision to mean that if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of any physician (allopathic or osteopathic) who specializes in pediatrics, including pediatric subspecialties, based on the scope of that provider's license under applicable State law. The designated provider must also participate in the plan network and be available to accept the child. These final regulations incorporate this clarification.

The interim final regulations also established requirements for a plan or issuer that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. Specifically, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. Plans and issuers must also treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider. For this purpose, a health care professional specializing in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

Commenters sought clarification that women of all ages may receive obstetrical and gynecological care without prior authorization or referral by the plan, issuer, or any person (including a primary care provider), noting that the statutory provision contains no restrictions based on the age of a participant, beneficiary or enrollee. The Departments agree that all women regardless of age are ensured direct access to obstetrical and gynecological care under this provision.

Since the promulgation of the interim final regulations, it has come to the Departments' attention that some plans and issuers utilize plan designs where the delivery of care is coordinated through medical groups within the network based on the geographic location of the participant and the provider. Specifically, the Departments have encountered plan provisions in insured group health plan coverage that require participants to designate a primary care provider but restrict a participant's choice of provider based on the distance that the participant lives or works from the provider. Stakeholders requested that the Departments clarify in the final regulations that the choice of healthcare professional provision does not prohibit the application of such geographical limitations with respect to the selection of primary care providers. Stakeholders highlighted that prohibiting such geographical limitations would fundamentally disrupt these plan designs, as well as the underlying negotiated capitation arrangements (where payment is rendered on a per person rather than per service basis). Stakeholders also noted that the underlying provider contracts do not permit providers to accept participants that are not within the specified geographic limit, and, accordingly, such limitations should not violate these provisions of the regulations, as the providers are not available to accept such participants, based on the terms of the plan, and as required by the regulations.

The Departments recognize the importance of allowing plans and issuers the flexibility to deliver care in a cost-effective and efficient manner. Accordingly, these final regulations include a codification of the Departments' interpretation that plans and issuers are not prohibited under PHS Act section 2719A from applying reasonable and appropriate geographic limitations with respect to which participating primary care providers are considered available for purposes of selection as primary care providers, in accordance with the terms of the plan, the underlying provider contracts, and applicable State law. The Departments may provide additional guidance if questions persist or if the Departments become aware of geographic limitations that unduly restrict a participant's choice of provider.

2. Emergency Services

a. Additional Administrative Requirements

Under the interim final regulations and these final regulations, if a group health plan or issuer provides any benefits with respect to services in the emergency department of a hospital, then the plan or issuer must provide coverage for emergency services without the individual or the health care provider having to obtain prior authorization (even if the emergency services are provided out of network). For a plan or health insurance coverage with a network of providers that provide benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

b. Out-of-Network Cost-Sharing Requirements

Cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. The preamble to the interim final regulations explained that out-of-network providers may bill patients for the difference between the providers' billed charges and the amount collected from the plan or issuer and the amount collected from the patient in the form of a copayment or coinsurance amount (referred to as balance billing [84]). Section 1302(c)(3)(B) of the Affordable Care Act excludes such balance billing amounts from the definition of cost sharing, and the requirement in section 2719A(b)(1)(C)(ii)(II) that cost sharing for out-of-network services be limited to that imposed in network only applies to

[84] *See* Uniform Glossary of Health Coverage and Medical Terms at *http://www.dol.gov/ebsa/pdf/sbcuniformglossaryproposed.pdf* and *https://www.cms.gov/apps/glossary.*

cost sharing expressed as a copayment amount or coinsurance rate. Because the statute neither requires plans or issuers to cover balance billing amounts, nor prohibits balance billing, even where the protections in the statute apply, patients may still be subject to balance billing. In the preamble to the interim final regulations under PHS Act section 2719A, the Departments explained that it would defeat the purpose of the protections in the statute if a plan or issuer paid an unreasonably low amount to a provider, even while limiting the coinsurance or copayment associated with that amount to in-network amounts.[85]

To avoid the circumvention of the protections of PHS Act section 2719A, the Departments determined it necessary that a reasonable amount be paid before a patient becomes responsible for a balance billing amount. Therefore, as provided in the interim final regulations and these final regulations, a plan or issuer must pay a reasonable amount for emergency services by some objective standard. Specifically, a plan or issuer satisfies the copayment or coinsurance limitations in the statute if it provides benefits for out-of-network emergency services (prior to imposing in-network cost sharing) in an amount at least equal the greatest of: (1) The median amount negotiated with in-network providers for the emergency service; (2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount); or (3) the amount that would be paid under Medicare for the emergency service (minimum payment standards). The interim final regulations under PHS Act section 2719 clarified that the cost-sharing requirements create a minimum payment requirement. The cost-sharing requirements do not prohibit a group health plan or health insurance from providing benefits with respect to an emergency service that are greater than the amounts specified in the regulations.

Some commenters expressed concern about the level of payment for out-of-network emergency services and urged the Departments to require plans and issuers to use a transparent database to determine out-of-network amounts. The Departments believe that this concern is addressed by our requirement that the amount be the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

c. Clarifications Regarding Balance Billing

Some commenters sought clarification about the interaction of the minimum payment standards under the interim final regulations and State laws that prohibit balance billing for emergency services. Balance billing generally is the practice of billing by a provider that is not a preferred provider for the difference between the charge of a provider that is not a preferred provider and the allowed amount under the plan or coverage. Some stakeholders expressed their opposition to the use of balance billing because it creates a substantial financial burden and may discourage a participant, beneficiary, or enrollee from obtaining the care needed in an emergency situation. Other stakeholders suggested that plans and issuers should be required to negotiate contracts with hospitals and facility-based providers that avoid balance billing. However, the statute does not require plans or issuers to cover balance billed amounts, nor does it prohibit balance billing. Even where the protections in the statute apply, a participant, beneficiary, or enrollee may be subject to balance billing. In the future, the Departments will consider ways to prevent providers from billing a participant, beneficiary, or enrollee for emergency services from out-of-network providers at in-network hospitals and facilities. States may also consider ways to prevent balance billing in these circumstances.

The minimum payment standards are designed to reduce potential amounts of balance billing to patients. Stakeholders commented that in circumstances where patients will not be balance billed (because balance billing is prohibited or because the issuer, rather than the patient, is required to cover the balance bill), the minimum payment standards are not necessary. In response to these comments, the Departments issued an FAQ[86] stating that the minimum payment standards set forth in the interim final regulations were developed to protect patients from being financially penalized for obtaining emergency services on an out-of-network basis. If State law prohibits balance billing, plans and issuers are not required to satisfy the payment minimum set forth in the regulations. Similarly, if a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the plan or issuer is not required to satisfy the payment minimum. In both situations, however, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in-network. In addition, a plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balance billed in order to prevent inadvertent payment by an enrollee or beneficiary. These final regulations incorporate this clarification. The regulations do not preempt existing State consumer protection laws and do not prohibit States from enacting new laws with respect to balance billing that would provide consumer protections at least as strong as the Federal statute.

In response to the interim final regulations, commenters also requested that the Departments require plans and issuers to inform a participant, beneficiary, or enrollee using clear and understandable language of the consequences of using out-of-network emergency services, including the possibility of balance billing. Another commenter stated that the summary plan description (SPD) provides sufficient information to meet the notice requirements. The Departments agree that plans and issuers must disclose the terms of the coverage as part of plan documents and are not adding a new notice requirement at this time.

d. Definition of Emergency Services

In applying the rules relating to emergency services, the terms emergency medical condition, emergency services, and stabilize have the meaning given to those terms under the Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act. Under EMTALA, the term emergency services includes (1) ''an appropriate medical screening examination that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department, to determine whether an emergency medical condition exists''; and (2) ''such further medical examination and such treatment as may be required to stabilize the medical condition.''[87]

[85] 75 FR 37188, 37194 (June 28, 2010).

[86] See Affordable Care Act Implementation FAQ Part I Q15 at *http://www.dol.gov/ebsa/faqs/faq-aca.html* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs.html*.

[87] 42 U.S.C. 1395dd(a)–(b).

Some commenters recommended that the Departments define ''emergency services'' such that an enrollee or beneficiary may only receive emergency benefits if an enrollee or beneficiary seeks treatment within 24 hours of the onset of an emergency. These final regulations decline to adopt this comment. The term ''emergency services'' as defined by the interim final regulations and these final regulations is based on the statutory definition, which does not specify parameters with respect to time. Accordingly, a plan or issuer cannot set a time limit within which to seek emergency services and must provide coverage for any emergency services that meet the definition of emergency services under EMTALA.

Some commenters requested clarification as to whether air ambulance transport and other emergency transportation is within the scope of the term ''emergency services.'' The Departments decline to provide a rule addressing this issue. These final regulations continue to provide that the terms emergency medical condition, emergency services, and stabilize have the meaning given to those terms under EMTALA, section 1867 of the Social Security Act.[88]

H. Provisions No Longer Applicable

1. Special Rule Relating to Dependent Coverage of Children to Age 26 for Grandfathered Group Health Plans

The dependent coverage provision of PHS Act section 2714 applies to all group health plans and health insurance issuers offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after September 23, 2010, whether or not the plan or health insurance coverage qualifies as a grandfathered health plan. However, consistent with section 2714 of the PHS Act, for plan years beginning before January 1, 2014, the 2010 interim final regulations provided that a grandfathered health plan that is a group health plan that makes available dependent coverage of children may exclude from coverage an adult child who has not attained age 26 if the child is eligible to enroll in an employer-sponsored health plan (as defined in section 5000A(f)(2) of the Code) other than a group health plan of a parent. Because this special rule for grandfathered group health plans no longer applies, it is not incorporated into these final regulations.

2. Transitional Rules for Individuals Whose Coverage Ended by Reason of Reaching a Dependent Eligibility Threshold

The 2010 interim final regulations implementing PHS Act section 2714 provided transitional relief for a child whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26. The 2010 interim final regulations also required a plan or issuer to give such a child a special enrollment opportunity, which was required to be provided (including written notice) not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Because the transitional rule no longer applies, it is not incorporated into these final regulations.

3. Restricted Annual Limits and Transitional Rules for Individuals Whose Coverage or Benefits Ended by Reason of Reaching a Lifetime Dollar Limit

PHS Act section 2711 and its implementing interim final regulations generally prohibited lifetime or annual limits on the dollar value of EHBs (as defined in section 1302(b) of the Affordable Care Act). With respect to annual dollar limits, the statute and the interim final regulations allowed the imposition of ''restricted annual limits'' with respect to EHBs for plan years (in the individual market, policy years) beginning before January 1, 2014. The interim final regulations adopted a three-year phased approach to restricted annual limits. As set forth in the interim final regulations, the restricted annual limits on the dollar value of EHBs could not be lower than:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, $750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, $1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, $2 million.

With respect to plan or policy years beginning on or after January 1, 2014, no annual dollar limits are permitted on essential health benefits except in the case of grandfathered individual market coverage.

The interim final regulations also provided transitional rules for individuals who reached a lifetime dollar limit under a group health plan or health insurance coverage prior to the applicability date of the interim final regulations. The regulations required a plan or issuer to provide an individual whose coverage ended due to reaching a lifetime dollar limit with an enrollment opportunity (including written notice) that continues for at least 30 days. The notice and enrollment opportunity was required to be provided not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Because the provisions regarding restricted annual dollar limits and the transitional rules regarding lifetime dollar limits no longer apply, they are not incorporated into these final regulations.

I. Applicability

1. General Applicability

These final regulations apply to group health plans and health insurance issuers beginning on the first day of the first plan year (or, in the individual market, the first day of the first policy year) beginning on or after January 1, 2017. Until these final regulations become applicable, plans and issuers are required to continue to comply with the corresponding interim final regulations at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015, and 45 CFR parts 144, 146, and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015. In accordance with section 7805(e)(2) of the Code, the corresponding temporary regulations promulgated by the Department of the Treasury are inapplicable. Under section 104 of the Health Insurance Portability and Accountability Act (HIPAA), enacted on August 21, 1996, and subsequent amendments, the Departments must coordinate policies with respect to parallel provisions of ERISA, the PHS Act, and the Code (shared provisions). The Departments operate under a Memorandum of Understanding[89] implementing HIPAA section 104 which provides that the shared provisions must be administered so as to have the same effect at all times and the Departments must coordinate policies relating to enforcing the shared provisions in order to avoid duplication of enforcement efforts and to assign

[88] For a more detailed discussion of definitions and requirements under EMTALA, see CMS State Operations Manual, Appendix V, pg. 33–41, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf.*

[89] See 64 FR 70164 (December 15, 1999).

priorities in enforcement. Therefore, until these final regulations promulgated by the Department of the Treasury become applicable, compliance with corresponding interim final regulations at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015 shall satisfy corresponding requirements of the Code.

Section 1251 of the Affordable Care Act provides that grandfathered health plans are subject to only certain provisions of the Affordable Care Act. The final regulations under PHS Act section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136) and PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138) do not apply to grandfathered health plans. Final regulations under PHS Act section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108); PHS Act section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126); PHS Act section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128); and PHS Act section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120) apply to grandfathered health plans, except the prohibition of preexisting condition exclusions and prohibition on annual dollar limits do not apply to grandfathered health plans that are individual health insurance coverage. For a list of the market reform provisions under title XXVII of the PHS Act, as added or amended by the Affordable Care Act and incorporated into ERISA and the Code, applicable to grandfathered health plans, visit *http://www.dol.gov/ebsa/pdf/grandfatherregtable.pdf.*

2. Expatriate Plans

On December 16, 2014, Congress enacted the Expatriate Health Coverage Clarification Act of 2014 (EHCCA) as part of the Consolidated and Further Continuing Appropriations Act, 2015, Division M, Public Law 113–235. The EHCCA provides that the market reform requirements of the Affordable Care Act generally do not apply to expatriate health plans, expatriate health insurance issuers with respect to expatriate health plans, and employers in their capacity as plan sponsors of expatriate health plans. However, the plans, coverage, sponsors and issuers must still satisfy provisions of the PHS Act, ERISA and the Code that would otherwise apply if not for the enactment of the Affordable Care Act. The EHCCA exception from the market reform requirements applies to expatriate health plans that are issued or renewed on or after July 1, 2015.

Treasury and IRS issued Notice 2015–43, 2015–29 I.R.B. 73, to provide interim guidance on the EHCCA. The notice provides that until the issuance of further guidance and except as otherwise provided in the notice, issuers, employers, and plan sponsors generally may apply the requirements of EHCCA using a reasonable good faith interpretation of the statute. The notice also provides that until further guidance is issued, using the definition of expatriate health plan provided in Affordable Care Act Implementation FAQs [90] is treated as a reasonable good faith interpretation of the statute. As explained in the notice, the Departments intend to publish proposed regulations implementing and providing guidance on the EHCAA. Consequently, these final regulations do not address the application to expatriate health plans of the Affordable Care Act provisions under which these final regulations are promulgated.

III. Economic Impact Analysis—Departments of Labor and Health and Human Services

Executive Orders 12866 and 13563

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

Under Executive Order 12866 (58 FR 51735), ''significant'' regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. These final regulations have been designated ''significant regulatory actions'' under section 3(f) of Executive Order 12866. Accordingly, the regulations have been reviewed by the Office of Management and Budget.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year). The Departments have concluded that these final regulations would have economic impacts of $100 million or more in at least one year, thus meeting the definition of an ''economically significant rule'' under Executive Order 12866. Therefore, consistent with Executive Orders 12866 and 13563, the Departments have provided an assessment of the potential benefits and the costs associated with these final regulations.

The Departments expect these final regulations, when compared with the interim final regulations, to have marginal benefits and costs. This is because they primarily provide clarifications of the previous interim final regulations issued in 2010 and 2011 and incorporate subregulatory guidance, including frequently asked questions and safe harbors issued by the Departments. The Departments do not have sufficient data to quantify these costs and benefits, but they are qualitatively discussed throughout the remainder of this section and summarized in the Accounting Table.

[90] See FAQs about Affordable Care Act Implementation (Part XIII), Q&A–1, available at *http://www.dol.gov/ebsa/pdf/faq-aca13.pdf* and *http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ACA_implementation_faqs13.html.* See also FAQs about Affordable Care Act Implementation (Part XVIII), Q&A–6 and Q&A–7, available at *http://www.dol.gov/ebsa/pdf/faq-aca18.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ACA_implementation_faqs18.html.*

TABLE 1—ACCOUNTING TABLE

Category	Estimate	Year dollar	Discount rate	Period covered
Benefits—Qualitative: These final regulations help ensure the protections and benefits intended by Congress. Many of these benefits have a distributional component, and promote equity, in the sense that they will benefit those who are especially vulnerable as a result of health problems and financial status. Other benefits include increased access to care and to information needed to protect consumer's rights. These final regulations also lead to improved health outcomes for patients and increase certainty for issuers, plans and consumers by providing clarifications and guidance.				
Costs:				
Annualized Monetized	$169.9	2015	7%	2016–2025
($millions/year)	$169.9	2015	3%	2016–2025
Qualitative: The Departments have quantified where possible the costs associated with these final regulations. These costs include burden that will be incurred to prepare and distribute required disclosures and notices, and to bring plan and issuers' policies and procedures into compliance with the new requirements. The Departments have not been able to quantify cost related to increased access to care. To the extent these patient protections increase access to health care services, increased health care utilization and costs could result.				
Transfers:				
Annualized Monetized	$53.5	2015	7%	2016–2025
($millions/year)	$53.5	2015	3%	2016–2025
Qualitative: Due to the risk pooling nature of health insurance these patient protections and other requirements create a transfer from those paying premiums to those individuals and families now obtaining increased protections, coverage and services.				

1. Need for Regulatory Action

a. Preservation of Right To Maintain Existing Coverage

Section 1251 of the Affordable Care Act provides that grandfathered health plans are subject only to certain provisions of the Affordable Care Act. The statute, however, is silent regarding changes plan sponsors and issuers can make to plans and health insurance coverage while retaining grandfather status.

These final regulations are necessary in order to provide rules that group health plans and health insurance issuers can use to determine which changes they can make to the terms of the plan or health insurance coverage while retaining their grandfather status, thus exempting them from certain provisions of the Affordable Care Act and fulfilling a goal of the legislation, which is to allow those that like their coverage to keep it. These final regulations are designed to allow individuals to keep the coverage they had on March 23, 2010 (the date of enactment of the Affordable Care Act) to reduce short term disruptions in the market, and to ease the transition required by the market reforms.

In drafting this rule, the Departments attempted to balance a number of competing interests. For example, the Departments sought to provide adequate flexibility to group health plans and issuers to ease transition and mitigate potential premium increases while avoiding excessive flexibility that would unduly delay implementation of critical consumer protections in the Affordable Care Act. In addition, the Departments recognized that many group health plans and issuers make changes to the terms of plans or health insurance coverage on an annual basis: Premiums fluctuate, provider networks and drug formularies change, employer and employee contributions and cost-sharing change, and covered items and services may vary. Without some ability to make some adjustments while retaining grandfather status, the ability of individuals to maintain their current coverage would be frustrated, because most plans or health insurance coverage would quickly cease to be regarded as the same group health plan or health insurance coverage in existence on March 23, 2010. At the same time, allowing unfettered changes while retaining grandfather status would also be inconsistent with Congress's intent to provide a transition to the Affordable Care Act market reforms.

These final regulations regarding grandfather health plans are designed, among other things, to take into account reasonable changes routinely made by plan sponsors or issuers without the plan or health insurance coverage relinquishing its grandfather status. Thus, for example, these final regulations generally permit plans and issuers to make voluntary changes to increase benefits, to conform to required legal changes, and to voluntarily adopt other consumer protections in the Affordable Care Act without relinquishing grandfather status.

b. Prohibition of Preexisting Condition Exclusions

Section 2704 of the PHS Act, as added by the Affordable Care Act, generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing any preexisting condition exclusion.

Studies estimate that preexisting conditions affect approximately 129 million Americans [91] which includes a broad range of conditions, from heart disease—affecting an estimated 85.6 million American adults (with more than 1 in 3 having one or more types of cardiovascular disease [92])—to cancer—which in 2012 affected an estimated 14 million Americans and will affect an estimated 1.7 million additional people in 2015 [93]—to relatively minor conditions like hay fever, asthma, or previous sports injuries.[94] Denials of benefits or coverage based on a preexisting condition previously made adequate health insurance unavailable to millions of Americans. Before enactment of the Affordable Care Act, in 45 States, health insurance issuers in the individual market could deny coverage, charge higher premiums, and/

[91] ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011.

[92] Mozzafarian, D., *et al.* Heart Disease and Stroke Statistics—2015 Update: A Report From the American Heart Association. *Circulation.* 2015; 131(4):e29–322.

[93] National Cancer Institute: Surveillance, Epidemiology, and End Results Program (SEER) Stat Fact Sheet: All Cancer Types. *http://seer.cancer.gov/statfacts/html/all.html.*

[94] Pollitz, K., *et al.* How Accessible is Individual Health Insurance for Consumers in Less than Perfect Health? Kaiser Family Foundation, June 2001.

or deny benefits for a preexisting condition.[95]

These regulations finalize interim final regulations which were necessary to implement this statutory provision which Congress enacted to help ensure that quality health coverage is available to more Americans without the imposition of a preexisting condition exclusion.

c. Lifetime and Annual Limits

Section 2711 of the PHS Act, as added to the Affordable Care Act, generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing annual and lifetime limits on the dollar value of essential health benefits.

These protections ensure that patients are not confronted with devastating healthcare costs because they have exhausted their health coverage when faced with a serious medical condition.

These regulations finalize interim final regulations that were necessary to implement the statutory provisions with respect to annual and lifetime limits that Congress enacted to help ensure that more Americans with chronic, long-term, and/or expensive illnesses have access to quality health coverage.

d. Prohibition on Rescissions

Section 2712 of the PHS Act, as added by the Affordable Care Act, prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from rescinding coverage except in the case of fraud or intentional misrepresentation of material fact.

Prior to the Affordable Care Act, thousands of Americans lost health coverage each year due to rescission. When a coverage rescission occurs, an individual's health coverage is retroactively cancelled, which means that the insurance company is no longer responsible for medical care claims that had previously been accepted and paid. Rescissions can result in significant financial hardship for affected individuals, because, in most cases, the individuals have accumulated significant medical expenses.

These final regulations implement the statutory provision enacted by Congress to protect the most vulnerable Americans, those that incur substantial medical expenses due to a serious medical condition, from financial devastation by ensuring that such individuals do not unjustly lose health coverage by rescission.

[95] Levitt, L., *et al.* How Buying Insurance Will Change Under Obamacare. Kaiser Family Foundation, September 2013.

e. Coverage of Dependents to Age 26

PHS Act section 2714, as added by the Affordable Care Act, requires group health plans and health insurance issuers offering group or individual health insurance coverage that make dependent coverage available for children to continue to make coverage available to such children until the attainment of age 26. With respect to a child receiving dependent coverage, coverage does not have to be extended to a child or children of the child or a spouse of the child. Furthermore these final regulations clarify that for an individual not described in Code section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for health coverage, such as a condition that the individual be a dependent for income tax purposes, and the final regulations also clarify that distinctions based upon age that apply generally to all individuals covered under the plan (employees, spouses, dependent children) are not prohibited. These regulations finalize the interim final regulations, which were necessary to implement the statute.

f. Internal Claims and Appeals and External Review

Before the enactment of the Affordable Care Act, health plan sponsors and issuers were not uniformly required to implement claims and appeals processes. For example, ERISA-covered group health plan sponsors were required to implement internal claims and appeal processes that complied with the DOL claims procedure regulation,[96] while group health plans that were not covered by ERISA, such as plans sponsored by State and local governments were not. Health insurance issuers offering coverage in the individual insurance market were required to comply with various applicable State internal appeals laws but were not required to comply with the DOL claims procedure regulation.

With respect to external appeal processes, before the enactment of the Affordable Care Act, sponsors of fully insured ERISA-covered group health plans, fully-insured State and local governmental plans, and fully-insured church plans were required to comply with State external review laws, while self-insured ERISA-covered group health plans were not subject to such laws due to ERISA preemption. In the individual health insurance market, issuers in States with external review laws were required to comply with such laws. However, uniform external review standards did not apply, because State external review laws vary from State-to-State. Moreover, at least six States did not have external review laws when the Affordable Care Act was enacted; therefore, prior to the Affordable Care Act, issuers in those States were not required to implement an external review process.

[96] 29 CFR 2560.503–1.

Under this regulatory system, inconsistent claims and appeals processes applied to plan sponsors and issuers and a patchwork of consumer protections were provided to participants, beneficiaries, and enrollees. The applicable processes and protections depended on several factors including whether (1) plans were subject to ERISA, (2) benefits were self-funded or financed by the purchase of an insurance policy, (3) issuers were subject to State internal claims and appeals laws, and (4) issuers were subject to State external review laws, and if so, the scope of such laws (such as, whether the laws only apply to one segment of the health insurance market, *e.g.,* managed care or HMO coverage). These uneven protections created an appearance of unfairness, increased cost for issuers and plans operating in multiple States, and may have led to confusion among consumers about their rights.

Congress enacted PHS Act section 2719 to ensure that plans and issuers implemented more uniform internal and external claims and appeals processes and to set a minimum standard of consumer protections that are available to participants, beneficiaries, and enrollees. These final regulations are necessary to provide rules that plan sponsors and issuers can use to implement effective internal and external claims and appeals processes that meet the requirements of PHS Act section 2719.

These changes do not add any incremental costs to those associated with the 2010 interim final rules, because they simply incorporate sub-regulatory guidance that was already issued.

g. Patient Protections

Section 2719A of the PHS Act, as added by the Affordable Care Act, requires group health plans and health insurance issuers offering group or individual health insurance coverage to ensure choice of healthcare professionals (including pediatricians, obstetricians, and gynecologists) and greater access to benefits for emergency services. Provider choice is a strong predictor of patient trust in a provider, and patient-provider trust can increase

health promotion and therapeutic effects.[97] Studies have found that patients tend to experience better quality healthcare if they have long-term relationships with their healthcare provider.[98]

The emergency care provisions of PHS Act section 2719A require (1) non-grandfathered group health plans and health insurance issuers that cover emergency services to cover such services without prior authorization and without regard to whether the health care provider furnishing the services is a participating network provider, and (2) copayments and coinsurance for out-of-network emergency care do not exceed the cost-sharing requirements that would have been imposed if the services were provided in-network. These provisions will help to ensure that patients receive covered emergency care when they need it, especially in situations where prior authorization cannot be obtained due to exigent circumstances or an in-network provider is not available to provide the services. They also will protect patients from the substantial financial burden that can be imposed when differing copayment or coinsurance arrangements apply to in-network and out-of-network emergency care.

These regulations finalize the interim final regulations that were necessary to implement the statutory provision enacted by Congress to provide these essential patient protections.

A. Section 1251 of the Affordable Care Act, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251, 29 CFR 2590.715–1251, 45 CFR 147.140)

1. Affected Entities and Individuals

The Departments estimate that there are 2.3 million ERISA-covered plans with an estimated 66 million policy holders and 130.2 million participants and beneficiaries in those plans.[99] Similarly, the Departments estimate that there are 128,400 State and local governmental health plans [100] with an estimated 21.1 million policy holders and 41.1 million participants and beneficiaries in those plans.[101]

The 2014 Employer Health Benefits Survey reports that 37 percent of firms offer health benefits that have at least one health plan that is a grandfathered plan, and 26 percent of employees are enrolled in grandfathered plans.[102] Using the above estimates, there are 851,000 (2.3 million ERISA-covered plans* 0.37) ERISA-covered plans with 17.2 million policy holders (66 million policy holders *0.26) and 33.9 million participants and beneficiaries (130.2 million participants and beneficiaries * 0.26). There are approximately 47,500 grandfathered State and local governmental health plans (0.37*128,400 plans [103]) with approximately 5.5 million policyholders (21.1 million policy holders *0.26) and 10.7 million participants and beneficiaries (41.1 million participants and beneficiaries * 0.26).

There were an estimated 1.4 million policies with grandfathered coverage during 2013 with 2.2 million enrollees.[104]

2. Discussion of Economic Impacts of Retaining or Relinquishing Grandfather Status

The economic effects of these final regulations will depend on decisions by plan sponsors and issuers, as well as by those covered under these plans and health insurance coverage.

For a plan sponsor or issuer, the potential economic impact of the application of the provisions in the Affordable Care Act may be one consideration in making its decisions. To determine the value of retaining a health plan's grandfather status, each plan sponsor or issuer must determine whether the rules applicable to grandfathered health plans are more or less favorable than the rules applicable to non-grandfathered health plans. This determination will depend on such factors as the respective prices of grandfathered and non-grandfathered health plans, as well as the preferences of grandfathered health plans' covered populations and their willingness to pay for benefits and patient protections available under non-grandfathered health plans. In making its decision whether to maintain grandfather status, a plan sponsor or issuer is also likely to consider the market segment (because different rules apply to the large and small group market segments), and the utilization pattern of its covered population. Those costs and benefits of the various provisions of the Affordable Care Act and their interaction with the coverages' grandfathered status have been discussed in the impact analysis of those individual requirements and are not repeated here.

3. Impacts on the Individual Market

The market for individual insurance is significantly different than that for group coverage. As discussed in previous interim final regulations issued in 2010 and 2011, for many, the market is transitional, providing a bridge between other types of coverage. One study found a high percentage of individual insurance policies began and ended with employer-sponsored coverage.[105] More importantly, coverage on particular policies tends to be for short periods of time. As such, high turnover rates are likely the chief source of changes in grandfather status. Reliable data are scant, so there is no ability to update estimates as to how many people in the individual market are in non-grandfathered plans today.

1. Disclosure of Grandfather Status and Document Retention

To maintain grandfathered health plan status under these final regulations, a plan or issuer must maintain records that document the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain or clarify its status as a grandfathered health plan, disclose its status as a grandfathered health plan, and if switching issuers and intending to maintain its status as a grandfathered plan, it must provide to the new health insurance issuer with documentation of plan terms under the prior health coverage sufficient for it to determine whether a change causing a cessation of grandfathered health plan status has occurred.

The Departments estimate that the total cost for these requirements will be $1.8 million annually. For a detailed discussion of the grandfathered health plan document retention and disclosure requirements, see the Paperwork

[97] Piette, John, *et al.,* ''The Role of Patient-Physician Trust in Moderating Medication Nonadherence Due to Cost Pressures.'' *Archives of Internal Medicine* 165, August (2005) and Roberts, Kathleen J., ''Physician-Patient Relationships, Patient Satisfaction, and Antiretroviral Medication Adherence Among HIV-Infected Adults Attending a Public Health Clinic.'' *AIDS Patient Care and STDs* 16.1 (2002).

[98] Blewett, Lynn, *et al.,* ''When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services.'' *Journal of General Internal Medicine* 23.9 (2008).

[99] EBSA estimates based on the 2014 Medical Expenditure Survey—Insurance Component.

[100] The estimate of the total number of State and local governmental plans is based on the 2012 Census of Government.

[101] Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2014 Annual Social and Economic Supplement to the Current Population Survey, Table 3C *http://www.dol.gov/ebsa/pdf/coveragebulletin2014.pdf.*

[102] Kaiser Family Foundation, ''2014 Employer Health Benefits Survey.'' *http://kff.org/health-costs/report/2014-employer-health-benefits-survey/.*

[103] The estimate of the total number of State and local governmental plans is based on the 2012 Census of Government.

[104] Based on data from the McKinsey Center for U.S. Health System Reform and Medical Loss Ratio submissions for 2013 reporting year.

[105] Adele M. Kirk. The Individual Insurance Market: A Building Block for Health Care Reform? *Health Care Financing Organization Research Synthesis.* May 2008.

Reduction Act section later in this preamble.

B. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108)

1. Affected Entities and Individuals

In the individual market, those applying for insurance will no longer face exclusions or denials of coverage based on a preexisting condition while those covered by non-grandfathered individual coverage with a rider or exclusion period will gain coverage for any preexisting condition otherwise covered by the plan. In the group market, participants and beneficiaries that have experienced a lapse in coverage will no longer face up to a twelve-month exclusion for preexisting conditions.

There are two main categories of people who have most likely been directly affected by this provision: First, those who had a preexisting condition and who were uninsured; second, those who were covered by grandfathered individual policies containing riders excluding coverage for a preexisting condition or have an exclusion period. It is difficult to estimate precisely how many uninsured individuals had a preexisting condition as of when this provision went into effect, as information on whether individuals have a preexisting condition for the purpose of obtaining health insurance is not collected in any major population based survey and can include conditions from hay fever to HIV/AIDS, all which could result in a denial of coverage.[106] The Departments find it difficult to estimate the number of individuals that will be uniquely affected by these final regulations due to the interactions with other provisions of the Affordable Care Act; however, estimates indicate that 50–129 million non-elderly individuals with a preexisting condition, 25 million uninsured individuals—including the 3.7 million adults that fall into the ''coverage gap'' in States without Medicaid expansion, and the estimated 66.6–82 million with ESI with preexisting conditions could benefit from these final regulations.[107]

2. Benefits

These final regulations will expand and improve coverage for those Americans with preexisting conditions; those currently diagnosed, undiagnosed, or who will develop conditions as they age. This will likely increase access to health care, improve health outcomes, and reduce family financial strain and ''job lock.''

For many years insurance providers/issuers maintained risk pools that are equal to that of the general population, using various methodologies;[108] often to the detriment of those most in need. Passage of the Affordable Care Act on March 23, 2010, provided millions of Americans with a way to obtain, re-obtain, or keep their affordable health coverage without the fear of losing or not having it when they are at their most vulnerable.

Prior to enactment of the Affordable Care Act, an estimated 50–52 million non-elderly people lacked insurance and 50–129 million were diagnosed with a preexisting condition.[109] Numerous studies show that uninsured adults and children are 3 to 6 times more likely to go without or postpone receiving needed care, experience higher delays and incidences of unmet needs, have higher incidences in avoidable hospital stays, and have a higher risk of death after an accident or when hospitalized.[110] This provision benefits and protects the millions of non-elderly persons who currently have a preexisting condition and those that will develop some condition as they age—in one study of those reporting good or excellent health, 15–30 percent will develop a preexisting condition in the next eight years[111]—by providing them a means to obtain or keep health coverage. Without the protections of these final regulations, many more Americans could be faced with the fear and anxiety of trying to obtain health coverage or faced with insufficient coverage due to preexisting conditions.

As discussed previously, those with preexisting condition exclusions or those that were uninsured could have found themselves being charged 2.5 times more prior to the Affordable Care Act.[112] The higher cost faced by those with preexisting conditions, whether uninsured or containing riders, could have led families to encounter financial hardships, crisis, and emotional stress.

Reports show that those lacking coverage are more likely to have trouble paying bills while being more likely to take on additional credit card debt and spend down family assets and savings, often resulting in the loss of their homes and personal bankruptcy: In 1981 the foreclosure rate reported to be associated with medical issues was only 8 percent; by 2007 this rate had increased to 62.1 percent of all personal bankruptcies, and 49 percent of foreclosures.[113] These higher rates can in turn lead to many health care organizations providing uncompensated care: In 2008, the uninsured received $116 billion worth of hospital care—the primary source of which was federal funding.[114] In addition to their advantages with regard to access to care, health, and well-being these final regulations are likely to lower families' out-of-pocket health care spending and the level of uncompensated care; thus benefiting State and Federal

[106] Levitt, L., *et al.* How Buying Insurance Will Change Under Obamacare. *Kaiser Family Foundation,* September 2013.

[107] ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011 and Artiga, S. *et al.* The Impact of the Coverage Gap in States not Expanding Medicaid by Race and Ethnicity. *The Kaiser Family Foundation,* April 2015.

[108] Claxton, G. and Lundy, J. How Health Care Coverage Works: A Primer 2008 Update. *The Kaiser Family Foundation,* April 2008.

[109] ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011; Collins, S., *et al.* Help is on the Horizon: How the Recession Has Left Millions of Workers Without Health Insurance, and How Health Reform Will Bring Relief—Findings from The Commonwealth Fund Biennial Health Insurance Survey of 2010. *The Commonwealth Fund.* 2011. Studies utilized 2008 MEPS data and The Commonwealth Biennial Health Insurance Survey of 2010 and prior years to estimate the numbers of individuals with preexisting conditions.

[110] Collins, S., *et al.* Help is on the Horizon: How the Recession Has Left Millions of Workers Without Health Insurance, and How Health Reform Will Bring Relief—Findings from The Commonwealth Fund Biennial Health Insurance Survey of 2010. *The Commonwealth Fund.* 2011; Callahan, S., *et al.* Access to Health Care for Young Adults With Disabling Chronic Conditions. *Arch Pediatr Adolesc Med.* 2006;160:178–182; and Bernstein, J., *et al.* Issue Brief: How Does Insurance Coverage Improve Health Outcomes? *Mathematica Policy Research, Inc.* 2010:1.

[111] Bailey, K. Worry No More: Americans with Pre-Existing Conditions Are Protected by the Health Care Law, *Families USA;* 2012 and ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011.

[112] Bailey, K. Worry No More: Americans with Pre-Existing Conditions Are Protected by the Health Care Law, *Families USA;* 2012 and Anderson, G. From 'Soak The Rich' To 'Soak The Poor': Recent Trends In Hospital Pricing. *Health Affairs,*2007; 26(3), pp. 780–789.

[113] Himmelstein, D. *et al.* Medical Bankruptcy in the United States, 2007: Results of a National Study. *Am Jour of Med.* 2009; 122(8), pp. 741–746; Robertson, T., *et al.* ''Get sick, get out: The medical causes of home mortgage foreclosures.'' *Health Matrix: Journal of Law-Medicine.* 2008; 18(65), pp 65–105; Fact Sheet. Key Facts about the Uninsured Population. *The Kaiser Family Foundation.* October 2014; see also *https://www.medicare.gov/your-medicare-costs/help-paying-costs/medicaid/medicaid.html.*

[114] Stoll, K. and Bailey, K. Hidden Health Tax: Americans Pay a Premium. *Families USA, 2009* and Coughlin, T. *et al.* Uncompensated Care for Uninsured in 2013: A detailed Examination. *The Kaiser Family Foundation,* 2014.

governments and, by extension, taxpayers.

Finally, these final regulations may reduce instances of ''job lock''-situations in which workers are unable to change jobs due to concerns regarding health insurance coverage for them and/or their dependents. Due to the limitations and exclusions in individual health coverage, many people were forced into a position where they chose to remain in a job out of fear of losing their existing coverage or chose a job with sponsored coverage over a higher wage position.[115] Job lock leads to a number of labor market distortions resulting in workers in jobs that are a ''poor fit,'' with reduced satisfaction or skills that are not properly utilized, affecting their ability to start new businesses, retire, or reduce their work load.[116] One study indicates that 35 percent of those surveyed worried they will have to forego job opportunities or forego retirement to maintain coverage.[117]

Under the Affordable Care Act, the interim final regulations, and these final regulations, someone currently insured through the group market with less than 18 months of continuous coverage may be more willing to leave their job and become a self-employed entrepreneur if they or their dependents have a preexisting condition—resulting in potentially 2–4 million more self-employed individuals.[118] Similarly, even a worker with more than 18 months of continuous coverage who is already protected by HIPAA may be more likely to consider switching firms and changing policies because they will not have to worry that a preexisting condition could be excluded for up to 12 months.[119] While the total reduction in job-lock may be small, the impact on those families with members that have preexisting conditions may be significant.

Executive Order 12866 requires agencies to take account of ''distributive impacts'' and ''equity.'' Requiring health plans and issuers to provide coverage to adults and children with preexisting conditions will result in a small increase in premium for relatively healthy adults and children, and a large increase in health and financial security for individuals with preexisting conditions. This transfer is a meaningful increase in equity, and is a benefit of this final regulation.

3. Costs and Transfers

Although those that have preexisting condition exclusions have higher health care costs than healthier individuals, among individuals with preexisting conditions, those who are uninsured have expenditures that are somewhat lower than the average insured individual.[120] It is expected that when those individuals who are uninsured or have policies with preexisting condition exclusions gain coverage, there will be additional demand for and utilization of services, leading to a transfer from out-of-pocket spending to spending covered by insurance, which will partially be mitigated by a reduction in cost-shifting of uncompensated care to the insured population as coverage expands.

In evaluating the impact of this provision, it is important to remember that the full net effects of this provision cannot be estimated because of its interactions with other provisions in the Affordable Care Act. For example, under the current guaranteed availability and renewability protections in the individual market, children and young adults with a preexisting condition are now generally able to obtain and maintain coverage on a parental plan, where he or she can potentially stay on that plan until age 26. As another example, the Affordable Care Act requires that non-grandfathered health plans provide recommended preventive services at no cost-sharing. This will amplify the benefits of coverage for newly insured individuals with preexisting conditions. Moreover, the expansion of the preexisting condition exclusion policy occurred at the same time as other policies were implemented, such as the individual responsibility and premium tax credit provisions. Therefore, the Departments cannot provide a more precise estimation of either the benefits or the costs and transfers of this provision.

C. PHS Act Section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126)

1. Affected Entities and Individuals

Prior to the passage of the Affordable Care Act, both the incidence and amount of lifetime limits varied by market and plan type (*e.g.,* HMO, PPO, POS). In the RIA for the interim final regulations, it was estimated that only 8 percent of large employers, 14 percent of small employers and 19 percent of individual market policies imposed an annual limit at that time and thus would have been directly impacted by the interim final regulations, which were phased in.

Fear and anxiety about reaching annual or lifetime limits on coverage was a major concern among Americans who have health insurance, although while such limits were relatively common in health insurance, the numbers of people expected to exceed either an annual or lifetime limit was quite low.

2. Benefits

As discussed in the RIA for the interim final regulations, annual and lifetime limits function as caps on how much a group health plan or insurance company will spend on medical care for a given insured individual over the course of a year, or the individual's lifetime. Once a person reaches this limit or cap, the person is essentially uninsured: He or she must pay the remaining cost of medical care out-of-pocket. These limits particularly affect people with high-cost conditions,[121] which typically are very serious and can lead to financial hardship. Prohibiting lifetime limits and annual limits will benefit families and individuals experiencing financial burdens due to exceeding the benefit limits of their insurance policy. By ensuring and continuing coverage, the regulations also reduce uncompensated care, which would otherwise increase premiums of the insured population through cost-shifting.

These provisions will also improve access to care. Reaching a limit could interrupt or cause the termination of needed treatment, leading to worsening of medical conditions. The removal and restriction of benefit limits helps ensure continuity of care and the elimination of the extra costs that arise when an

[115] GAO, Private Health Insurance: Estimates of Individuals with Preexisting Conditions Range from 36 million to 122 million, GAO–12–439, 2012.

[116] Baker, D. Job Lock and Employer—Provided Health Insurance: Evidence from the Literature. *Public Policy Institute.* 2015;I–35; ASPE. At Risk: Pre-Existing Conditions Could Affect 1 in 2 Americans: 129 Million People Could Be Denied Affordable Coverage Without Health Reform, 2011; Fact Sheet. Key Facts about the Uninsured Population. *The Kaiser Family Foundation.* October 2014.

[117] Altman, D. Pre-X Redux. *The Kaiser Family Foundation,* June 2013.

[118] Baker, D. Job Lock and Employer—Provided Health Insurance: Evidence from the Literature. *Public Policy Institute.* 2015;I–35.

[119] Foronstin, P. Health Insurance Portability and Job Lock: Findings from the 1998 Health Confidence Survey. *Employee Benefit Research Institute Notes.* 1998: 19(8), pp. 4–6.

[120] Coughlin, T. *et al.* Uncompensated Care for Uninsured in 2013: A Detailed Examination. *The Kaiser Family Foundation,* 2014; GAO, Private Health Insurance: Estimates of Individuals with Preexisting Conditions Range from 36 million to 122 million, GAO–12–439, 2012.

[121] A December 2014 study by Milliman ''2014 U.S. organ and tissue transplant cost estimates and discussion'' found that the average 2014 billed charges related to a heart transplant is $1,242,200, a liver transplant averaged $739,100, while a heart-lung transplant averaged $2,313,600.

untreated or undertreated condition leads to the need for even more costly treatment, that could have been prevented if no loss of coverage had occurred. By ensuring continuation of coverage, the regulations benefit the health and the economic well-being of participants, beneficiaries, and enrollees.

Executive Order 12866 explicitly requires agencies to take account of ''distributive impacts'' and ''equity,'' and these considerations help to motivate the relevant statutory provisions and the interim final regulations and these regulations. Prohibiting lifetime and annual limits assures that insurance will perform the function for which it was designed—namely, protecting health and financial wellbeing for those most in need of care. This represents a meaningful improvement in equity, which is a benefit associated with the regulations.

3. Costs and Transfers

As discussed in the regulatory impact analysis for the interim final regulations, extending health insurance coverage for individuals who would otherwise hit a lifetime or annual limit will increase the demand for and utilization of health care services, thereby generating additional costs to the system. The three year phase-in of the elimination of annual limits and the immediate elimination of lifetime limits increased the actuarial value of the insurance coverage for affected plans and policies if no other changes were made to the plan or policy. Issuers and plans in the group market may have chosen to make changes to the plan or policy to maintain the pre-regulation actuarial value of the plan or policy, such as changing their provider networks or copayments in some manner. To the extent that higher premiums (or other plan or policy changes) are passed on to all employees, there is an explicit transfer from workers who would not incur high medical costs to those who do incur high medical costs. If, instead, the employers do not pass on the higher costs of insurance coverage to their workers, this can result in lower profits or higher prices for the employer's goods or services. In the individual market, when policies were individually underwritten with no rating bands in the majority of States, the Departments expected the added premium cost or other benefit changes to be largely borne by the individual policyholder. With the market reforms in place, along with single risk pool requirements, issuers can spread the increased costs across the entire individual market, leading to a transfer from those who do not incur high medical costs to those who do incur such costs. However, as with the group market, such a transfer was expected to be modest, given the small numbers of people who were expected to exceed their benefit limits. The Departments previously estimated that the transfer would be three-quarters of a percent or less for lifetime limits and one-tenth of a percent or less for annual limits, under a situation of pure community rating where all the costs get spread across the insured population. This impact does not apply to grandfathered individual market plans.

It is worth noting that these transfers are expected to have been significantly mitigated by the associated expansion of coverage created by the interim final regulations and other regulations implementing the Affordable Care Act. The Departments expect that, as a result of the gradual elimination of annual limits and the immediate elimination of lifetime limits, fewer people have been left without protection against high medical costs. This results in fewer individuals spending down resources and enrolling in Medicaid or receiving other State and locally funded medical support. Such an effect will likely be amplified due to the high-cost nature of people who exceed benefit limits.

D. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128)

1. Affected Entities and Individuals

PHS Act Section 2712 and these final regulations create a statutory Federal standard and enforcement power in the group and individual markets where it did not exist. Prior to this provision taking effect, varying Federal common laws existed for ERISA plans. State rules pertaining to rescission have been found to be preempted by ERISA by five circuit courts (5th, 6th, 7th, 9th and 11th as of 2008).

The Affordable Care Act and its implementing regulations should have a large effect on reducing the number of rescissions for two reasons. First, the Affordable Care Act raised the standard governing when coverage may be rescinded. Group health plans and health insurance issuers may now only rescind coverage based on fraud or intentional misrepresentation of a material fact which is a higher standard than most State laws required previously. Second, the interaction of these regulations with PHS Act sections 2704, prohibition of preexisting condition exclusions, and sections 2705, prohibiting discrimination against individual participants and beneficiaries based on health status, could significantly reduce the number of policies rescinded. Previously, the issues surrounding the reporting of pre-existing conditions to issuers and an individual's health status were primary causes of rescissions. With the main source of rescissions removed there would be a significant drop in rescissions even without these regulations.

The Departments assume that these final regulations will have their largest impact on the individual insurance market, because group health coverage rarely is rescinded.[122] By creating a new Federal standard governing when policies can be rescinded, the Departments expect these final regulations to potentially affect the approximately 6.7 million non-elderly individual health insurance policies covering 10.9 million policy holders and their dependents in the individual health insurance market.[123] In addition, approximately 430 health insurance issuers offering coverage in the individual health insurance market who currently could rescind health insurance coverage are expected to be affected.[124] That said, the actual incidence of individuals who are subject to rescissions each year is likely to be small. The NAIC Regulatory Framework Task Force collected data on 52 companies covering the period 2004–2008, and found that rescissions averaged 1.46 per thousand policies in force.[125] These pre-Affordable Care Act estimates are believed to be a significant over-statement of rescissions occurring now, however no new data is available. Using this estimate implies that when combined with the current numbers of policy holders in the individual market there could be approximately 9,900 rescissions per year.

2. Benefits

Because there is little pre-Affordable Care Act data available and no publicly available post-Affordable Care Act data, the Departments find it difficult to estimate the benefits associated with this provision. However, the Departments believe that the benefits of this provision would accrue to those individuals who without these regulations would have their policies rescinded.

[122] This statement is based on the Departments' conversations with industry experts.

[123] 2013 filings of the Medical Loss Ratio Report found at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Medical-Loss-Ratio.html*.

[124] 2013 filings of the Medical Loss Ratio Report.

[125] NAIC Rescission Data Call, December 17, 2009, p.1.

As noted, Executive Order 12866 requires consideration of ''distributive impacts'' and ''equity.'' To the extent that rescissions are arbitrary, or targeted at those most ill, and revoke the insurance that enrollees paid for and expected to cover the cost of expensive illnesses and conditions, preventing rescissions would prevent inequity and greatly increase health and economic well-being. Consumers would have greater confidence that purchasing insurance would be worthwhile, and policies would represent better value for money.

Individuals who otherwise would have had their policies rescinded are now able to retain their coverage; the maintenance of such coverage through severe illness helps to prevent financial hardship for the enrollee and their family, creating a substantial financial benefit.[126]

As discussed previously, uninsured individuals are less likely to receive needed care when they become ill, resulting in the worsening of their condition. The lack of insurance can lead to lost workplace productivity and additional mortality and morbidity. Additionally, this provision protects those individuals currently receiving treatment for a condition by eliminating the potential interruptions or terminations in care resulting from rescissions, resulting in higher losses in productivity.[127] Thus, this rule would contribute to increased worker productivity by reducing the burden associated with the loss of insurance coverage, and the concomitant financial and emotional stress.

3. Costs and Transfers

As with the benefits, the costs and transfers of these regulations are similar to those of the interim final regulations. The prohibition of rescissions except in cases of fraud or intentional misrepresentation of material fact could lead insurers to spend more resources checking applications before issuing policies than they did before the Affordable Care Act, which would increase administrative costs. However, under the final regulations, these costs could be partially offset by decreased costs associated with reduced post-claims underwriting.

To the extent that continuing coverage for these generally high-cost populations leads to additional demand for and utilization of health care services, there will be additional costs generated in the health care system. However, given the relatively low rate of rescissions (approximately 0.15 percent of individual policies in force) and the relative nature of those individuals who generally have policies rescinded (who would have difficulty going without treatment), the Departments estimate that these additional costs would be small.

For those policies or plans that are rescinded, the requirement for an advance notice prior to such a rescission imposes a total hour burden of approximately 250 hours and a cost burden of approximate $3,900. These costs are discussed in more detail in the Paperwork Reduction Act section later in this preamble.

A transfer likely will occur within the individual health insurance market from policyholders whose policies would not have been rescinded before the Affordable Care Act to some of those whose policies that would have been rescinded before the Affordable Care Act, depending on the market and the rules which apply to it. This transfer could result from higher overall premiums insurers will charge to recoup the costs associated with the health care costs of those individuals with chronic or serious conditions whose policies could previously be rescinded (the precise change in premiums depending on the competitive conditions in specific insurance markets). This transfer across the market would benefit those individuals with substantially higher medical costs, due to chronic or severe conditions, and would be attributable to insurers covering those costs associated with such individuals.

E. PHS Act Section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120)

1. Affected Entities and Individuals

Prior to implementation of the Affordable Care Act there were an estimated 6.6 million uninsured young adults age 19–26; with an estimated 3.3 million having parents with ESI and an additional 2.7 million with individual coverage, all of whom could potentially have been affected.[128] Implementation of this provision allowed 13.7 million young adults to either stay on or join their parents' health plans (from November 2010 until November 2011).[129] There was a rapid response to changes in the regulations leading to large number of employers enrolling young adults ,[130] with thirteen percent of small firms and 70 percent of large firms enrolling at least one young adult—small employers on average enrolled two young adults while large employers enrolled on average 492 young adults.[131]

Studies have shown that 2.3 million young adults were able to gain coverage since implementation of the Affordable Care Act and this provision in 2010 through the start of the open enrollment period in October 2013.[132] The number of affected young adults has continued to increase as more employers began covering young adult dependents and those on individual grandfathered plans began changing policies to include dependents up to age 26. This has resulted in an additional 3.4 million young adults gaining coverage since October 2013, resulting in a total of an estimated 5.7 million gaining coverage from 2010 through March 2015.[133]

2. Benefits

The benefits of these final regulations are expected to outweigh the costs to the regulated community. As of March 2015, an estimated 5.7 million additional young adults are now covered by their parents' health plans due to the implementation of this provision.[134] Expanding coverage options for the 19–26 year old population has resulted in a decline in the number of uninsured young adults, declining to an uninsured rate of 26.7 percent in the third quarter of 2013 (before the start of the October 2013 open enrollment period).[135]

Uninsured young adults are less likely to have access to care and thus delay seeking needed care,[136] leading to

[126] Girion, Lisa ''Health Net Ordered to Pay $9 million after Canceling Cancer Patient's Policy,'' *Los Angeles Times* (2008), available at: *http://www.latimes.com/business/la-fi-insure23feb23,1,5039339.story.*

[127] Collins et al. ''Gaps in Health Insurance: An All American Problem'' *Commonwealth Fund* (2006), available *http://www.commonwealthfund.org/usr_doc/Collins_gapshltins_920.pdf.*

[128] Collins, S. and Nicholson, J. Rite of Passage: Young Adults and the Affordable Care Act of 2010. *The Commonwealth Fund.* May 2010.

[129] Collins, S. *et al.* Young, Uninsured and in Debt: Why Young Adults Lack Health Insurance and How the Affordable Care Act is Helping. *The Commonwealth Fund.* June 2012.

[130] Cantor, J. *et al.* Early Impact of the Affordable Care Act on Health Insurance Coverage of Young Adults. *Health Services Research,* 47:5 (2012):pp. 1773–1790.

[131] Claxton, G. *et al.* Employer Health Benefits: 2011 Annual Survey. *Kaiser Family Foundation and Health Research & Education Trust.* 2011

[132] *ASPE Data Point,* Health Insurance Coverage and the Affordable Care Act, September 2015.

[133] ASPE. Health Insurance Coverage and the Affordable Care Act. May 2015 at *http://aspe.hhs.gov/sites/default/files/pdf/83966/ib_uninsured_change.pdf.*

[134] Id.

[135] Ibid and Sommers, B. Number of Young Adults Gaining Insurance Due to the Affordable Care Act Now Tops 3 Million. *ASPE Issue Brief,* June 2012.

[136] Newacheck, P. *et al.* Health Insurance and Access to Primary Care for Children. *N Engl J Med.*

higher costs when care is received. Further, expanded coverage provides young adults with security and protection from the financial consequences of serious medical emergencies. Recent studies have found that due to the implementation of this provision there has been a decline in the number of young adults facing higher out–of-pocket expenses (greater than $1,500);[137] benefiting them when many young adults are currently facing elevated debt burdens and low wages.[138]

Additionally, expanding coverage to those aged 19–26 should decrease the cost-shifting of uncompensated care onto those with coverage (including $147 million from emergency department care),[139] increase the receipt of preventive health care and provide more timely access to high quality care, resulting in a healthier population. In particular, children with chronic conditions or other serious health issues will be able to continue coverage through a parent's plan until age 26.

Extending dependent coverage of children to age 26 will also permit greater job mobility for this population as their health coverage will no longer be tied to their jobs, thus reducing the potential of ''job lock'',[140] or student status.

3. Costs and Transfers

Estimates for the incremental annual premium costs for the newly covered individuals were developed in the interim final regulations; estimating that for those enrolling in their parents' ESI, the expected annual premium cost would lead to an expected increase of 0.7 percent in 2011, 1.0 percent in 2012, and 1.0 percent in 2013. A recent study carried out by Depew and Bailey found that the requirement dependent coverage provision led to a 2.5–2.8 percent increase in premiums for plans that cover children, and that employers did not pass on the entire premium increase to employees in the form of higher required plan contributions.[141] To the extent that some of these increases are passed on to workers in the form of higher premiums for all workers purchasing family policies or in the form of lower wages for all workers, there will be a transfer from workers who do not have newly covered dependents to those who do. To the extent that these higher premiums result in lower profits or higher prices for the employer's product, the higher premiums will result in a transfer either from stockholders or consumers to workers who have newly covered dependents.

In addition, to the extent these final regulations result in a decrease in the number of uninsured, the Departments expect a reduction in uncompensated care, and a reduction in liability for those who fund uncompensated care, including public programs (primarily Medicaid and State and local general revenue support for public hospitals), as well as the portion of uncompensated care that is paid for by shifting costs from private payers. Such effects would lead to lower premiums for the insured population, both with or without newly covered children.

For the number of young adults enrolling in their parents' non-group (individual) insurance policy, the Departments estimated that, to a large extent, premiums in the individual market will be borne by the parents who are purchasing the coverage. If, instead, these costs are distributed over the entire individual market (as would be the case in a pure community rated market), the Departments estimated in the interim final regulations that the individual premiums would rise 0.7 percent in 2011, 1.0 percent in 2012, and 1.2 percent in 2013. However, the Departments expected the actual increase across the entire individual market, if any, to be much smaller than these estimates, because they expected the costs to be largely borne by the subscribers who are directly affected rather than distributed across the entire individual market.

F. PHS Act Section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136)

1. Estimated Number of Affected Entities

These provisions are applicable to non-grandfathered health plans and coverage. Using the estimates from the discussion of affected entities for the grandfathering provisions discussed in paragraph III.C, there are 96.3 million individuals covered by non-grandfathered ERISA-covered health plans, 30.4 million individuals covered by non-grandfathered State and local health plans, and 8.7 million individuals in non-grandfathered health coverage in the individual market.

Not all potentially affected individuals will be affected equally by these final regulations. Sponsors of ERISA-covered group health plans were required to implement an internal appeals process that complied with the DOL claims procedure regulation before the Affordable Care Act's enactment, and the Departments also understand that many non-Federal governmental plans and church plans that are not subject to ERISA had implemented internal claims and appeals processes that comply with the DOL claims procedure regulation. Therefore, participants and beneficiaries covered by such plans only will be affected by the internal claims and appeals standards that are provided by the Secretary of Labor in paragraph (b)(2)(ii) of these final regulations under PHS Act section 2719.

These final regulations will have the largest impact on individuals covered in the individual health insurance market, because with the issuance of the interim final regulation, these issuers were required to comply with the DOL claims procedure regulation for internal claims and appeals as well as the additional standards added by the Secretary of the Department of Health and Human Services in paragraph (b)(3) of these final regulations that are in some cases more protective than the ERISA standard.

On the external appeals side, before the enactment of the Affordable Care Act, issuers offering coverage in the group and individual health insurance market were already required to comply with State external review laws. At that time, all States except Alabama, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming had external review laws, and thirteen States had external review laws that apply only to certain market segments (for example, managed care or HMOs).

338:8 (1998) and Sommers, B. *et al.* The Affordable Care Act Has Led To Significant Gains in Health Insurance and Access to Care for Young Adults. *Health Affairs,* 32:1 (2013):pp. 165–174.

[137] Busch, S. *et al.* ACA Dependent Coverage Provision Reduced High Out-Of-Pocket Health Care Spending For Young Adults. *Health Affairs,* 33:8 (2014): pp. 1361–1366 and Mulcahy, A. *et al.* Insurance Coverage of Emergency Care for Young Adults under Health Reform. *N Engl J Med.* 368:22 (2013).

[138] Chua, K-P. and Sommers, B. Changes in Health and Medical Spending Among Young Adults Under Health Reform. *JAMA,* 311:23 (2014).

[139] Mulcahy, A. *et al.* Insurance Coverage of Emergency Care for Young Adults under Health Reform. *N Engl J Med.* 368:22 (2013).

[140] Sommers, B. *et al.* The Affordable Care Act Has Led To Significant Gains in Health Insurance and Access to Care for Young Adults. *Health Affairs,* 32:1 (2013):pp. 165–174.

[141] Depew, B. and Bailey, J. Did the Affordable Care Act's dependent coverage mandate increase premiums? *Journal of Health Economics,* 41 (2015):pp. 1–14

Currently, all States except, Alabama, Alaska, Florida, Georgia, Pennsylvania, and Wisconsin have State external review laws that satisfy the requirement to provide a NAIC-similar or NAIC-parallel external review process. These six States that do not meet the requirements, must use the HHS-administered process or must contract with accredited independent review organizations to review external appeals on their behalf until they meet the requirements.[142]

Individuals participating in ERISA-covered self-insured group health plans will be among those most affected by the external review requirements contained in these final regulations, because the preemption provisions of ERISA prevent a State's external review process from applying directly to an ERISA-covered self-insured plan. These plans will now be required to comply with the Federal external review process set forth under paragraph (d) of these final regulations.

In summary, the number of affected individuals depends on several factors, including whether (i) a health plan retains its grandfather status, (ii) the plan is subject to ERISA, (iii) benefits provided under the plan are self-funded or financed by the purchase of an insurance policy, (iii) the applicable State has enacted an internal claims and appeals law, and (iv) the applicable State has enacted an external review law, and if so the scope of such law, and (v) the number of new plans and enrollees in such plans.

The following, is a summary of the benefits and costs as discussed in the interim final regulations and that are still applicable to these final regulations.

2. Benefits

Because of data limitations and a lack of effective measures, the Departments did not attempt to quantify the expected benefits. Nonetheless, the Departments were able to identify several of the interim final regulation's major economic benefits.

The interim final regulations and these final regulations will help transform the current, highly variable health claims and appeals process into a more uniform and structured process. This will:

- Improve the extent to which employee benefit plans provide benefits consistent with the established terms of the plan;
- ensure greater certainty and consistency in the handling of benefit claims and appeals and improved access to information about the manner in which claims and appeals are adjudicated;
- increase efficiency in the operation of employee benefit plans and health care delivery as well as health insurance and labor markets;
- increase efficiency of health plans by enhancing their transparency and fostering participants' confidence in the plan's fairness;
- reduce delays and inappropriate denials;
- reduce the levels of error in the system and improve health outcomes;
- improve health care, health plan quality, and insurance market efficiency by serving as a communication channel, providing feedback from participants, beneficiaries, and providers to plans about quality issues; and
- enhance some insurers' and group health plans' abilities to effectively control costs by limiting access to inappropriate care.

3. Costs and Transfers

The Departments have quantified the primary source of costs associated with these final regulations that will be incurred to (i) administer and conduct the internal and external review process, and (ii) prepare and distribute required disclosures and notices. These costs and the methodology used to estimate them are discussed under the Paperwork Reduction Act section. The total cost related to the information collections is $160.1 million annually.

a. Additional Requirements for Group Health Plans

Paragraph (b)(2)(i) of these final regulations imposes additional requirements to the DOL claims procedure regulation that must be satisfied by group health plans and issuers offering group and individual coverage in the individual and group health insurance markets. The Departments believe that the additional requirements have modest costs associated with them, because they merely clarify provisions of the DOL claims procedure regulation.

As discussed in the impact analysis for the interim final regulations the Departments were not able to estimate the costs for some of the requirements, namely for: the definition of adverse determination, expedited notification of benefit determination involving urgent care, eliminating conflicts of interest, and deemed exhaustion of internal process. The Departments were able to quantify the costs for Full and fair review and Enhanced notice with culturally and linguistically appropriate notices. These costs are included in the Paperwork Reduction Act Section.

b. Additional Requirements for Issuers in the Individual Insurance Market

To address certain relevant differences in the group and individual markets, health insurance issuers offering individual health insurance coverage must comply with three additional requirements. First, these final regulations expand the scope of the group health coverage internal claims and appeals process to cover initial eligibility determinations.

This protection is important since eligibility determinations in the individual market are frequently based on the health status of the applicant, including preexisting conditions. The Departments do not have sufficient data to quantify the costs associated with this requirement.

Second, although the DOL claims procedure regulation permits group health plans to have a second level of internal appeals, these final regulations require health insurance issuers offering individual health insurance coverage to have only one level of internal appeals. This allows the claimant to seek either external review or judicial review immediately after an adverse determination is upheld in the first level of internal appeals. The Departments have factored this cost into their estimate of the cost for issuers offering coverage in the individual market to comply with this requirement.

Finally, these final regulations require health insurance issuers offering individual health insurance coverage to maintain records of all claims and notices associated with their internal claims and appeals processes. An issuer must make such records available for examination upon request. Accordingly, a claimant or State or Federal agency official generally would be able to request and receive such documents free of charge. The Departments believe that minimal costs are associated with this requirement, because most issuers retain the required information in the normal course of their business operations.

c. External Appeals

The analysis of the cost associated with implementing an external review process under the interim final regulations and these final regulations focuses on the cost incurred by the following three groups that were not required to implement an external review process before the enactment of the Affordable Care Act: Plans and participants in ERISA-covered self-

[142] Affordable Care Act: Working with States to Protect Consumers, available at *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html*.

insured plans; plans and participants in States with no external review laws; and plans and participants in States that have State laws only covering specific market segment (usually HMOs or managed care coverage).

The Departments estimate that there are approximately 78.7 million participants in self-insured ERISA-covered plans and approximately 15.5 million participants in self-insured State and local governmental plans. In the States which currently have no external review laws or whose laws do not meet the federal minimum requirements [143] there are an estimated 13.8 million participants (8.1 million participants in ERISA-covered plans, 3.7 million participants in governmental plans and 2 million individual covered by policies in the individual market). These estimates lead to a total of 108 million participants, however, only the 80.0 million participants in non-grandfathered plans will be required to be covered by the external review requirement.

The Departments assume that there are an estimated 1.3 external appeals for every 10,000 participants [144], and that there will be approximately 10,400 external appeals annually. As required by these final regulations or applicable State law, plans or issuers are required to pay for most of the cost of the external review while claimants may be charged a nominal filing fee in States that authorized such fees as of November 18, 2015. One study found that the average cost of a review was approximately $665.[145] The average cost per appeal in the HHS-administered External Review Program is approximately $625 for a standard case and $825 for an expedited case.[146]

The actual cost per review will vary by State and type of review (standard or expedited). Lacking data on the percent of appeals that are expedited, but with the majority of appeals being standard appeals, the higher cost per appeal of $665 for a standard appeal is used as an estimate for all appeals. These estimates lead to an estimated cost of the external review of $6.9 million (10,400 reviews * $665) annually.

On average, about 40 percent of denials are reversed on external appeal.[147] An estimate of the dollar amount per claim reversed is $12,500.[148] This leads to $53.5 million in additional claims being reversed by the external review process annually. While this amount is a cost to plans, it represents a payment of benefits that should have previously been paid to participants, but was denied. Part of this amount is a transfer from plans and issuers to those now receiving payment for denied benefits. Part of the amount could also be a cost if the reversal leads to services and hence resources being utilized now that had been denied previously. The Departments are not able to distinguish between the two types but believe that most reversals are associated with a transfer.

These final regulations also require claimants to receive a notice informing them of the outcome of an appeal and/or external review. The independent review organization that conducts the external review is required to prepare the notice; therefore, the cost of preparing and delivering this notice is included in the fee paid them by the insurer to conduct the review.

4. Summary

These final rules extend the protections of the DOL claims procedure regulation to non-Federal governmental plans, and the market for individual coverage. Additional protections are added that cover these two markets and in addition to the market for ERISA-covered plans. These final regulations also extend the requirement to provide an independent external review. The Departments estimate that the total costs for these final regulations is $169.9 million annually with a transfer from the plan and its participants to those whose claims are reversed of $53.5 million annually.

G. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138)

1. Designation of Primary Care Provider

The statute, the interim final regulations and these final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee based on his or her geographic location.

a. Affected Entities and Individuals

Choice or assignment of a primary care provider is typically required by Health Maintenance Organizations (HMOs) and Point of Service plans (POS). Recent data suggest that there are 316,000 HMOs in the United States, accounting for more than 11.3 million enrollees with ESI. There are also 558,000 POS plans accounting for almost 7 million enrollees with ESI. The individual market includes 130,700 HMO policies.[149] Similar data do not exist for POS policies in the individual market.

This provision only applies to non-grandfathered health plans. However, due to the lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number enrollees and plans that would be affected by this provision. Moreover, there is no data on the number of plans that auto-assigned patients to primary care physicians and did not already allow patients to make the final provider choice, as this would be the population to benefit maximally from the interim final rules and these regulations. From conversations with industry experts the Departments expect, however, that this number would be very small, and therefore the benefits and costs of this provision would be small as well.

b. Benefits, Costs, and Transfers

As discussed in the RIA for the interim final regulations, provider choice allows patients to take into account factors they may value when choosing their provider, such as provider credentials, office hours and location, advice from professionals, and information on the experience of other patients. Provider choice is a strong predictor of patient trust in their provider, which could lead to decreased

[143] These states are Alabama, Alaska, Florida, Georgia, Pennsylvania, and Wisconsin. *See* Affordable Care Act: Working with States to Protect Consumers, available at *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html*

[144] AHIP Center for Policy and Research, ''An Update on State External Review Programs, 2006,'' July 2008.

[145] North Carolina Department of Insurance ''Healthcare Review Program: Annual Report,'' 2013 Table 4. *http://www.ncdoi.com/smart/Documents/ExternalReviewReport16.pdf*

[146] The HHS-administered External Review Program is approximately $625 for a standard case and $825 for an expedited case.

[147] Of the 105 cases fully reviewed in the HHS-administered external review process so far, 28 have been overturned and 25 have been partially overturned.

[148] North Carolina Department of Insurance ''Healthcare Review Program: Annual Report,'' 2013. *http://www.ncdoi.com/smart/Documents/ExternalReviewReport16.pdf*

[149] Data for the group market (plan and participant counts) were calculated using the 2012 MEPS, 2012 Census of Government, 2014 Current Population Survey, and 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits. Data for the individual market were calculated using AHIP ''Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits,'' Table 10 and Medical Loss Ratio submissions for 2013 reporting year.

likelihood of malpractice claims, improved medication adherence and also improves health outcomes.

Although difficult to estimate given the data limitations described, the costs for this provision are likely to be minimal. As noted in the RIA for the interim final regulations, when enrollees like their providers, they are more likely to maintain appointments and comply with treatment, both of which could induce demand for services, but these services could then in turn reduce costs associated with treating more advanced conditions. However, the number of affected entities from this provision is very small, leading to small additional costs. There will likely be negligible transfers due to this provision given no changes in coverage or cost-sharing.

2. Designation of Pediatrician as Primary Care Provider

If a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics, including pediatric subspecialties (based on the scope of that provider's license under applicable State law), as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

a. Affected Entities and Individuals

Due to lack of data on enrollment in managed care organizations by age, as well as lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number of enrollees and plans that would be affected by these provisions. As a reference, there are an estimated 5.6 million individuals under age 19 with ESI who are in an HMO plan.[150]

b. Benefits, Costs, and Transfers

By expanding participating primary care provider options for children to include pediatricians, this provision benefits individuals who are making decisions about care for their children. As discussed in the previous section, research indicates that when doctors and patients have a strong, trusting relationship, patients often have improved medication adherence, health promotion, and other beneficial health outcomes.

In addition, allowing enrollees to select a physician specializing in pediatrics as their children's primary care provider has removed any referral related delays for individuals in plans that required referrals to pediatricians and did not allow physicians specializing in pediatrics to serve as primary care providers. The American Academy of Pediatrics (AAP) strongly supports the idea that the choice of primary care clinicians for children should include pediatricians.[151] Regular pediatric care, including care by physicians specializing in pediatrics, can improve child health outcomes and avert preventable health care costs.

Giving enrollees in covered plans (that require the designation of a primary care provider) the ability to select a participating pediatrician as the child's primary care provider benefits those individuals who would not otherwise have been given this choice. Again, the extent of these benefits will depend on the number of enrollees with children that are covered by plans that do not allow the selection of a pediatrician as the primary care provider, which industry experts suggest would be small.

Although difficult to estimate given the data limitations described, the costs for this provision are likely to be small. Giving enrollees a greater choice of primary care providers by allowing them to select participating physicians who specialize in pediatrics as their child's primary care provider could lead to increased health care costs by increasing the take-up of primary care services, assuming they would not have utilized appropriate services as frequently if they had not been given this choice.

Any transfers associated with the interim final regulations and these final regulations are expected to be minimal. To the extent that pediatricians acting as primary care providers would receive higher payment rates for services provided than would other primary care physicians, there may be some transfer of wealth from policy holders of non-grandfathered group plans to those enrollees that choose the former providers. However, the Departments do not believe that this is likely given the similarity in income for primary care providers that care for children.

3. Patient Access to Obstetrical and Gynecological Care

The statute, the interim final regulations and these final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. Specifically, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology (OB/GYN). These plans and issuers must also treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the OB/GYN as the authorization of the primary care provider. For this purpose, an OB/GYN is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

a. Affected Entities and Individuals

Requiring referrals or authorizations to OB/GYNs is typically required by HMOs and POS plans.

This provision applies to non-grandfathered health plans. However, due to the lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number enrollees and plans that would be affected by this provision. As a reference, there are an estimated 7.3 million females between ages 21 to 65 with ESI who are in HMO plans.[152]

b. Benefits, Costs, and Transfers

This provision gives women in covered plans easier access to their OB/GYNs, where they can receive preventive services such as pelvic and breast exams, without the added time, expense, and inconvenience of needing permission first from their primary care providers. Moreover, this provision may also save time and reduce administrative burden since participating OB/GYNs do not need to

[150] Estimate based on data from the 2012 MEPS, 2012 Census of Government, 2014 Current Population Survey, and 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits.

[151] See AAP Policy Statement, ''Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults'', available at: *http://pediatrics.aappublications.org/content/132/5/e1452.full.pdf+html.*

[152] Estimate based on data from the 2012 MEPS, 2012 Census of Government, 2014 Current Population Survey, and 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits.

get an authorization from a primary care provider to provide care and order obstetrical and gynecological items and services. To the extent that primary care providers spend less time seeing women who need a referral to an OB/GYN, access to primary care providers will be improved. To the extent that the items and services are critical and would have been delayed while getting an authorization from the primary care provider, this provision will improve the treatment and health outcomes of female patients. Access to such care can have substantial benefits in women's lives.

To the extent that direct access to OB/GYN services results in increased utilization of recommended and appropriate care, this provision may result in benefits associated with improved health status for the women affected. Potential cost savings also exist since women in affected plans will not need to visit their primary care provider in order to get a referral for routine obstetrical and gynecological care, items, and services, thereby reducing unnecessary time and administrative burden, and decreasing the number of office visits paid by her and by her health plan.

One potential area of additional costs associated with this provision would be induced demand, as women who no longer need a referral to see an OB/GYN may be more likely to receive preventive screenings and other care. Data is limited to provide an estimate of this induced demand, but the Departments believe it to be small.

To the extent this provision results in a shift in services to higher cost providers, it will result in a transfer of wealth from enrollees in non-grandfathered group plans to those individuals using the services affected. However, such an effect is expected to be small.

4. Emergency Services

PHS Act section 2719A, the interim final regulations, and these final regulations provide that a group health plan and a health insurance issuer covering emergency services must do so without the individual or the health care provider having to obtain prior authorization (even if the emergency services are provided out-of-network). For a plan or health insurance coverage with a network of providers that provide benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

Finally, the interim final regulations and these final regulations provide that cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. The regulations also provide that a plan or health insurance issuer provide benefits for out-of-network emergency services (prior to imposing in-network cost sharing) in an amount at least equal the greatest of: (1) The median amount negotiated with in-network providers for the emergency service; (2) the amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount); or (3) the amount that would be paid under Medicare for the emergency service. In applying the rules relating to emergency services, the statute and the regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act.

The statute and the regulations relating to emergency services do not apply to grandfathered health plans; however, other Federal or State laws related to emergency services may apply regardless of grandfather status.

a. Affected Entities and Individuals

The interim final regulations and these regulations directly affect out-of-pocket expenditures for individuals enrolled in non-grandfathered private health plans (group or individual) whose copayment or coinsurance arrangements for emergency services differ between in-network and out-of-network providers. These regulations may also require some health plans to change the amount they pay to out-of-network providers compared to their pre-Affordable Care Act contractual arrangements. There are no available data, however, that allow for national estimates of the number of plans (or number of enrollees in plans) that have different payment arrangements for out-of-network than in-network providers, or differences between in- and out-of-network copayment and coinsurance arrangements, in order to more precisely estimate the number of enrollees affected.

Prior to the issuance of the interim final regulations, the Departments conducted an informal survey of benefits plans for large insurers in order to assess the landscape with regard to copayment and coinsurance for emergency department services, but found that a variety of arrangements existed in the marketplace prior to the issuance of the interim final regulations. Many of the large insurers maintained identical copayment and/or coinsurance arrangements between in- and out-of-network providers. Others had differing arrangements based on copayments, coinsurance rates, or a combination of the two. While useful for examining the types of arrangement that exist in the market place, these data do not contain enrollment information and therefore cannot be used to make impact estimates.

It was estimated in the interim final regulations that a maximum of 2.1 to 4.2 million individuals would be potentially affected by differing out-of-pocket requirements. Based on an informal survey, some proportion, possibly a large portion, of these individuals were covered by plans that had identical in- and out-of-network requirements. Therefore, the number of individuals affected by this regulatory provision was expected to be smaller.

b. Benefits, Costs, and Transfers

Insurers maintained differing copayment and coinsurance arrangements between in- and out-of-network providers as a cost containment mechanism. Implementing reduced cost sharing for the use of in-network providers provides financial incentive for enrollees to use these providers, with whom plans often have lower-cost contractual arrangements. In emergency situations, however, the choice of an in-network provider may not be available—for example, when a patient is some distance from his or her local provider networks or when an ambulance transports a patient to the nearest hospital which may not have contractual arrangements with the person's insurer. In these situations, the differing copayment or coinsurance arrangements could place a substantial financial burden on the patient. This provision eliminates this disparity in out-of-pocket burden for enrollees, leading to potentially substantial financial benefit.

The regulations also provide for potentially higher payments to out-of-network providers, if usual customary rates or Medicare rates are higher than median in-network rates. This can have a direct economic benefit to providers and patients, as the remaining differential between provider charge and plan payment will be smaller,

leading to a smaller balance-bill for patients.

To the extent that expectations about such financial burden with out-of-network emergency department usage would cause individuals to delay or avoid seeking necessary medical treatment when they cannot access a network provider, this provision may result in more timely use of necessary medical care. It may therefore result in health and economic benefits associated with improved health status; and fewer complications and hospitalizations due to delayed and possibly reduced mortality. The Departments expect that this effect would be small, however, because insured individuals are less likely to delay care in emergency situations.

The economic costs associated with the emergency services provisions are likely to be minimal. These costs will occur to the extent that any lower cost-sharing will induce new utilization of out-of-network emergency services. Given the nature of these services as emergency services, this effect is likely to be small for insured individuals. In addition, the demand for emergency services in truly emergency situations can result in health care cost savings and population health improvements due to the timely treatment of conditions that could otherwise rapidly worsen.

As discussed in the RIA for the interim final regulations, the emergency services provisions are likely to result in some transfers from the general membership of non-grandfathered group health plans that have differing copayment and coinsurance arrangements to those policy holders that use the out-of-network emergency services. The precise amount of the transfer which would occur through an increase in premiums is impossible to quantify due to lack of data, but only applies to non-grandfathered health plans.

5. Application to Grandfathered Plans

The provisions relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

6. Patient Protection Disclosure Requirement

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization.

Accordingly, as was provided in the interim final regulations, these final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

The Departments estimate that the cost to plans and insurance issuers to prepare and distribute the disclosure is $940,000 in 2015. For a discussion of the Patient Protection Disclosure Requirement, see the Paperwork Reduction Act section later in this preamble.

IV. Paperwork Reduction Act

A. Departments of Labor and the Treasury

These final regulations contain a notice of grandfather status and third party disclosure, rescissions notice, and patient protection disclosures requirement for issuers and notice requirements related to internal claims and appeals and external review that are information collection requests (ICRs) subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)).

In accordance with the requirements of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)), the Departments submitted an ICR to OMB in accordance with 44 U.S.C. 3507(d), contemporaneously with the publication of the interim final regulations, for OMB's review under the emergency PRA Procedures.[153] OMB subsequently approved the ICRs. Contemporaneously with the publications of the emergency ICRs, the Departments published a separate **Federal Register** notice informing the public that it intended to request OMB to extend the approval for three years and soliciting comments on the ICRs. OMB approved the ICR extensions.

No public comments were received in response to the ICRs contained in the interim final regulations that specifically addressed the paperwork burden analysis of the information collections. The comments that were submitted contained information relevant to the costs and administrative burdens attendant to the proposals. The Departments took into account the public comments when analyzing the economic impact of the proposals, and developing the revised paperwork burden analysis, which is summarized in the following sections.

A copy of the ICRs may be obtained by contacting the following PRA addressee or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers. Email: *ebsa.opr@dol.gov*.

1. ICR Regarding Affordable Care Act Notice of Grandfather Status and Third Party Disclosure

As discussed earlier in this preamble, to maintain grandfathered health plan status under these final regulations, a plan or issuer must maintain records that document the plan or policy terms in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan, disclose its status as a grandfathered health plan, and if switching issuers and intending to maintain its status as a grandfathered plan it must provide to the new health insurance issuer documentation of plan terms under the prior health coverage sufficient for it to determine whether a change causing a cessation of grandfathered health plan status has occurred.

a. Grandfathered Health Plan Disclosure

The final regulations provide that the plan or issuer of a grandfathered plan must disclose to participants and beneficiaries its status as a grandfathered health plan. Model language is provided by the Departments. Using data from the 2014 Employer Health Benefits Survey it is estimated that 37 percent of plans are grandfathered plans and 26 percent of employees in ERISA-covered plans are in a grandfathered plans.[154]

The Departments estimate that there are 850,700 (2.3 million ERISA-covered plans * 0.37) ERISA-covered plans[155]—with an estimated 17.2 million policy holders (66 million policy holders *0.26)—that will need to include the

[153] 5 CFR 1320.13.

[154] Kaiser Family Foundation, ''2014 Employer Health Benefits Survey.'' *http://kff.org/health-costs/report/2014-employer-health-benefits-survey/*.

[155] EBSA estimates based on the 2014 Medical Expenditure Survey—Insurance Component.

notice in plan documents.[156] After plans satisfied the grandfathered health plan disclosure requirement in 2011, any additional burden should be de minimis if a plan wants to maintain its grandfathered status in future years. The Departments also expect the cost of removing the notice from plan documents as plans relinquish their grandfathered status to be de minimis and therefore it is not estimated. Based on the foregoing, the Departments estimate that plans will incur no additional burden to maintain or remove the notice from plan documents.

The Departments estimate that the notice will require one-half of a page and five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a total cost burden of approximately $266,000 ($0.05 per page*1/2 pages per notice * 17.2 million notices*0.62).

b. Record Keeping Requirement

Plans were required to maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010.

The Departments assume that most of the documents required to be retained to satisfy the recordkeeping requirement of these final regulations are already retained by plans for tax purposes, to satisfy ERISA's record retention and statute of limitations requirements, and for other business reasons. The Departments estimated this as a one-time cost incurred in 2011, because after the first year, the Departments anticipate that any future costs to retain the records will be de minimis.

c. Documentation of Plan Terms

These final regulations contain a disclosure requirement that requires that a group health plan that is changing health insurance coverage to provide to the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph (g)(1) under the Affordable Care Act section 1251 regulations are exceeded. The number of plans that might be effected (133,200) is estimated by multiplying the number of grandfathered plans (850,700) by the percent of plans shopping for a new carrier (58 percent) and the number of plans shopping for a new carrier that switched (27 percent). Each of these plans would need to transmit to the carrier documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of paragraph (g)(1) of the final regulations under Affordable Care Act section 1251 are exceeded. It is estimated that the electronic transmission of the already retained documents would require 2 minutes of a clerical staff's time with a labor rate of $30.42 per hour.[157] These estimate result in an hour burden of 4,440 hours (133,200*2/60) with an equivalent cost of $135,100 (133,200*2/60*$30.42). Each of these plans would need to transmit to the carrier documentation of plan terms. If half of the plans transmit the required documents electronically then 66,600 plans will be sent via mail resulting in a materials and postage costs of $467,600 ((66,600*(90 pages *5 cents per page + $2.52 postage)).

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with an ICR unless the ICR has a valid OMB control number.

The paperwork burden estimates are summarized as follows:

Type of Review: Revision.

Agency: Employee Benefit Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Disclosure and Recordkeeping Requirements for Grandfathered Plans under the Affordable Care Act.

OMB Control Number: 1210–0140; 1545–2178.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 850,700.

Total Responses: 18,143,923.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours (three year average): 2,200 (Employee Benefits Security Administration); 2,200 (Internal Revenue Service).

Estimated Total Annual Cost Burden (three year average): $366,800 (Employee Benefits Security Administration); $366,800 (Internal Revenue Service).

2. ICR Regarding Affordable Care Act Notice Relating to Rescissions

As discussed earlier in this preamble, PHS Act Section 2712 and these final regulations provide rules regarding rescissions for group health plans and health insurance issuers that offer group or individual health insurance coverage. A plan or issuer must not rescind coverage under the plan, policy, certificate, or contract of insurance except in the case of fraud or intentional misrepresentation of a material fact. These final regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 calendar days advance notice to an individual before coverage may be rescinded. This rescission notice requirement is an information collection request (ICR) subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)).

The Departments assume that rescissions are rare in the group market and that small group health plans are affected by rescissions. The Departments are not aware of a data source on the number of group plans whose policy is rescinded; therefore, the Departments assume that 100 small group health plan policies are rescinded in a year. The Departments estimate that there is an average of 15.33 participants in small, insured plans.[158] Based on these numbers the Departments estimate that approximately 100 policies are rescinded during a year, which would result in 1,533 notices being sent to affected participants with 38 percent transmitted electronically and 62 percent mailed. The Departments estimate that 15 minutes of legal professional time at $129.94 per hour would be required by the insurers of the 100 plans to prepare the notice and one minute per notice of clerical professional time at $30.42 per hour would be required to distribute the paper notices. The Departments believe

[156] Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2014 Annual Social and Economic Supplement to the Current Population Survey, Table 3C.

[157] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/pdf/ocwage.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/ecec.t02.htm*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/eci.nr0.htm*). Secretaries, Except Legal, Medical, and Executive (43–6014): $16.35(2013 BLS Wage rate)/0.675(ECEC ratio) *1.2(Overhead Load Factor) *1.023(Inflation rate) −2(Inflated 2 years from base year) = $30.42.

[158] U.S. Department of Labor, EBSA calculations using the March 2014 Current Population Survey Annual Social and Economic Supplement and the 2012 Medical Expenditure Panel Survey.

the costs of electronic transmission would be de minimis. This results in an hour burden of approximately 41 hours with an equivalent cost of approximately $3,700.[159]

The Departments estimate that the cost burden associated with distributing the paper notices via mail will be approximately $500. This results from distributing 950 paper notices at a cost of $0.54 per notice.[160]

These paperwork burden estimates are summarized as follows:

Type of Review: Revision of existing collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Required Notice of Rescission of Coverage under the Patient Protection and Affordable Care Act Disclosures.

OMB Number: 1210–0141; 1545–2180.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 100.

Total Responses: 1,533.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 20.5 hours (Employee Benefits Security Administration); 20.5 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $250 (Employee Benefits Security Administration); $250 (Internal Revenue Service).

3. ICR Regarding Affordable Care Act Patient Protection Disclosure Requirement

a. Patient Protection Disclosure

As discussed earlier in this preamble, PHS Act section 2719A imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of health care professionals. When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) Choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; (2) obtain obstetrical or gynecological care without prior authorization; or (3) coverage of emergency services. Accordingly, these final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscriber) of these rights when applicable. Model language is provided in these final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance. The Affordable Care Act patient protection disclosure requirement is an ICR subject to the PRA.

In order to satisfy these final regulations' patient protection disclosure requirement, the Departments estimate that 41,000 ERISA-covered plans will need to notify an estimated 693,000 policy holders annually of their plans policy in regards to designating a primary care physician and for obstetrical or gynecological visits.[161] The Departments believe that plans would only incur costs associated with this notice during the first year after relinquishing grandfather status. In subsequent years, this notice would remain unchanged and its costs are factored into the burden estimates associated with the Summary Plan Description information collection request (OMB Control Number 1210–0039).

The following estimates are based on the assumption that five percent of group health plans will relinquish grandfathered health plan status annually. Because the final regulations provide model language for this purpose, the Departments estimate that five minutes of clerical time (with a labor rate of $30.42/hour) will be required to incorporate the required language into the plan document and ten minutes of a human resource professional's time (with a labor rate of $110.30/hour) will be required to review the modified language. Therefore, the Departments estimate that plans relinquishing grandfathered health plan status will incur an annual hour burden of 10,000 hours with an equivalent cost of $866,000.[162]

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically at de minimis cost. This results in a cost burden of $11,000.[163]

b. Out-of-Network Emergency Services Disclosure

The final regulations require that a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is more restrictive than the copayment or coinsurance requirement that would apply if the services were provided in network. If State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by an enrollee or beneficiary. This information should already be routinely included in the Explanation of Benefit documents

[159] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/pdf/ocwage.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/ecec.t02.htm*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/eci.nr0.htm*).

[160] This estimate is based on an average document size of one page, $.05 cents per page material and printing costs, and $0.49 postage costs.

[161] The Departments' estimate of the number of ERISA-covered health plans was obtained from the 2014 Medical Expenditure Survey—Insurance Component and the number of policy holders was obtained from the Health Insurance Coverage Bulletin: Abstract of Auxiliary Data for the March 2014 Annual Social and Economic Supplement to the Current Population Survey, Table 3C *http://www.dol.gov/ebsa/pdf/coveragebulletin2014.pdf*. Information on HMO and POS plans and enrollment in such plans was obtained from the Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2014. The Department assumes that five percent of group health plans will relinquish grandfathered health plan status annually.

[162] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/pdf/ocwage.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/ecec.t02.htm*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/eci.nr0.htm*).

[163] This estimate is based on an average document size of ½ page, $.05 cents per page material and printing costs, and $0.49 postage costs for paper notices and de minimis costs for electronically distributed notices. The Departments assume 62 percent of notices will be on paper and 38 percent will be distributed electronically.

sent by plans and issuers to enrollees and beneficiaries. Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe this is a usual and customary business practice. Plans and issues routinely provide enrollees and beneficiaries with the Explanation of Benefit documents.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number. These paperwork burden estimates are summarized as follows:

Type of Review: Revision of an existing collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of Treasury.

Title: Disclosure Requirement for Patient Protections under the Affordable Care Act.

OMB Number: 1210–0142; 1545–2181.

Affected Public: Business or other for profit; not-for-profit institutions.

Total Respondents: 41,000.

Total Responses: 693,000.

Frequency of Response: One time.

Estimated Total Annual Burden Hours: 5,000 (Employee Benefits Security Administration); 5,000 (Internal Revenue Service).

Estimated Total Annual Burden Cost: $5,500 (Employee Benefits Security Administration); $5,500 (Internal Revenue Service).

4. ICR Regarding Affordable Care Act Internal Claims and Appeals and External Review

PHS Act section 2719 and these final regulations, require that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1 (the DOL claims procedure regulation) and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations under PHS Act section 2719.

The burden to comply with the DOL claims procedure regulations is accounted for under OMB control number 1210–0053, therefore it is not included here.

Paragraph (b)(2)(ii)(C) of the final regulations under PHS Act section 2719 adds an additional requirement that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered to be relied upon, or generated by the plan or issuer in connection with the claim. The related hour burden is 1,100 hours and the related cost burden is $1.1 million.

The June 2011 amendment to the interim final regulations required that plans and issuers must provide participants and beneficiaries who reside in a county where ten percent or more of the population residing in the county is literate only in the same non-English language with a one-sentence statement in all notices written in the applicable non-English language about the availability of language services. In addition to including the statement, plans and issuers are required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request. Providing notice of the services and the translation services is estimated to have a cost burden of $1 million annually.

Also, PHS Act section 2719 and these final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. Plans and issuers must provide to those conducting the external reviews required documents. There is an estimated 8,400 external appeals conducted annually. The related hour burden is 3,500 hours with an equivalent cost of $193,700 and a cost burden of $80,000 annually.

In total, the hour burden associated with claims, appeals, and external review is approximately 4,500 hours at an equivalent cost of $244,800 annually. Because the burden is shared equally between the Department of Labor and the Department of the Treasury, each Department's share is 2,300 hours at an equivalent cost of $122,400 annually.

In total, the cost burden is approximately $2.2 million annually. Because the burden is shared equally between the Department of Labor and the Department of the Treasury, each Department's share is $1.1 million annually.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

The paperwork burden estimates are summarized as follows:

Type of Review: Revision.

Agency: Employee Benefit Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Affordable Care Act Internal Claims and Appeals and External Review Disclosures for Non-Grandfathered Plans.

OMB Control Number: 1210–0144; 1545–2182.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 1,769,264.

Total Responses: 275,430.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours (three year average): 2,300 (Employee Benefits Security Administration); 2,300 (Internal Revenue Service).

Estimated Total Annual Cost Burden (three year average): $1,143,000 (Employee Benefits Security Administration); $1,143,000 (Internal Revenue Service).

B. Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. These final regulations contain ICRs that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized below in the Table below. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

As discussed above in the Department of Labor and Department of the Treasury PRA section, these final regulations contain a notice of grandfather status, rescissions notice, and patient protection disclosures requirement for issuers, and notice requirements related to internal claims and appeals and external review. These requirements are ICRs under the Paperwork Reduction Act. Each of these requirements is discussed in detail in the following sections. Estimated hourly labor rates are calculated using data from the 2013

National Occupational Employment Survey.[164]

1. ICRs Regarding Affordable Care Act Notice of Grandfather Status (§§ 147.140(a)(2), 147.140(a)(3)(i), 147.140(a)(3)(ii))

a. Grandfathered Health Plan Disclosure

The final regulations provide model language for the grandfathered health plan disclosure that can be incorporated into existing plan documents. After plans first satisfied the grandfathered health plan disclosure requirement in 2011, any additional burden is expected to be negligible if a plan wants to maintain its grandfathered status in future years. It is also expected that the cost of removing the notice from plan documents as plans relinquish their grandfathered status would be minimal and therefore it is not estimated.

Issuers and multi-employer plans must also add a prominent disclosure in their group policies, certificates, or contracts of insurance that plan sponsors are required to notify the issuer if the contribution rate changes at any point during the plan year. This only affects issuers of fully insured group health plans and multi-employer plans and after this requirement is first satisfied, any additional burden in future years is expected to be negligible and is therefore not estimated.

Grandfathered plans will incur printing and material costs associated with the disclosure requirements. It is estimated that there will be approximately 47,500 grandfathered State and local governmental health plans with approximately 5.5 million policyholders [165] and approximately 1.4 million policyholders in the individual market with grandfathered coverage [166] issued by 430 issuers during 2015. Therefore, grandfathered plans and issuers in the individual markets will need to send approximately 6.9 million disclosures notifying plan participants and beneficiaries of their plans' status as a grandfathered health plan. We anticipate that the notice will require one-half of a page and five cents per page printing and material cost will be incurred. We also assume that 38 percent of the notices will be delivered electronically. This results in a total annual cost burden of approximately $106,000. The number of notices and cost burden are likely to be lower in subsequent years as more plans relinquish their grandfathered status. In the absence of data regarding how many plans will retain grandfathered status in subsequent years, we consider this estimate to be the upper limit for the number of notices and cost burden in future years.

b. Recordkeeping Requirement

It is assumed that most of the documents required to be retained to satisfy the recordkeeping requirement of these final regulations are already retained by plans for tax purposes, to satisfy ERISA's record retention and statute of limitations requirements, and for other business reasons. It was previously estimated that after the one-time cost related to record keeping requirement was incurred in 2011, costs in subsequent years will be negligible and, therefore, not estimated.

c. Grandfathered Plan Change in Carrier Disclosure

A group health plan that is changing health insurance issuers must provide to the succeeding health insurance issuer (and the succeeding health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health insurance coverage sufficient to make a determination whether the standards of § 147.140(g)(1) are exceeded.

The number of plans that might change carriers and thus be affected (7,400) is estimated by multiplying the estimated number of grandfathered plans (47,500) by the percent of plans shopping for a new carrier (58 percent) and the number of plans shopping for a new carrier that switched (27 percent).[167]

Each employer will require about 2 minutes of clerical labor (at an hourly cost of approximately $30) to send the information required for the disclosure (which is already retained under the recordkeeping requirement) electronically to the succeeding issuer. The total annual labor burden for all employers is estimated to be approximately 248 hours with an equivalent annual cost of approximately $7,500. The cost of transmitting the information electronically to the succeeding issuer is negligible and, therefore, not estimated. The number of disclosures and cost burden may be lower in subsequent years as more plans relinquish their grandfathered status. In the absence of data regarding how many plans will retain grandfathered status in subsequent years, we consider this estimate to be the upper limit for the burden in future years.

2. ICR Regarding Affordable Care Act Notice Relating to Rescissions (§ 147.128(a)(1))

This analysis assumes that rescissions only occur in the individual health insurance market, because rescissions in the group market are rare. It is estimated that there are approximately 430 issuers issuing 6.77 million policies in the individual market during a year. A report on rescissions found that 0.15 percent of policies were rescinded during the 2004 to 2008 time period. Based on these numbers, it is estimated that approximately 10,200 policies are rescinded during a year, which would result in approximately 10,200 notices being sent to affected policyholders, with 38 percent transmitted electronically and 62 percent mailed. It is estimated that each issuer will require 15 minutes of legal professional time (at approximately $129.94 per hour) to prepare the notice and one minute per notice of clerical professional time (at approximately $30.42 per hour) to distribute the notice to each policyholder. Assuming that the cost of electronic distribution is minimal, this results in an annual hour burden of approximately 212 hours with an equivalent annual cost of approximately $17,160.

Issuers will incur cost to print and send the notices. We assume that the notice will require one page printing and material cost will be $0.05 per page, mailing cost will be $0.49 per notice, and 38 percent of the notices will be delivered electronically at minimal cost. Therefore, it is estimated that the cost burden associated with mailing the notices to approximately 6,300 affected policy holders will be approximately $3,400.

3. ICR Regarding Affordable Care Act Patient Protection Disclosure Requirement (§ 147.138(a)(4))

b. Patient Protection Disclosure

In order to satisfy the patient protection disclosure requirement, State and local government plans and issuers in individual markets will need to notify policy holders of their plans policy in regards to designating a primary care physician and for obstetrical or gynecological visits and

[164] 2013 National Occupational Employment Survey, April 2014, Bureau of Labor Statistics, *http://www.bls.gov/news.release/pdf/ocwage.pdf.*

[165] The Department lacks data on the number of State and local plans that are grandfathered plans. The Kaiser ''Employer Health Benefits Survey'' has estimates for private employer plans. Those estimates are used here as a proxy. They report that 37 percent of plans are grandfather plans and 26 percent of covered employees are in those plans. *http://kff.org/health-costs/report/2014-employer-health-benefits-survey/.*

[166] Estimate based on data from the McKinsey Center for US Health System Reform and Medical Loss Ratio submissions for 2013 reporting year.

[167] See Section 14.*http://kff.org/health-costs/report/2014-employer-health-benefits-survey/.*

will incur a one-time burden and cost to incorporate the notice into plan documents. State and local government plans that are currently not grandfathered and issuers in the individual market have already incurred the one-time cost to prepare and incorporate this notice in their existing plan documents. Only State and local government plans and individual market plans that relinquish their grandfathered status in subsequent years will become subject to this notice requirement and incur the one-time costs to prepare the notice.

There are an estimated 128,400 non-federal governmental plans and 430 health insurance issuers in the individual market. We estimate that five percent of non-federal governmental plans will relinquish their grandfathered status annually over the next three years and will therefore incur one-time costs to prepare the notice. Health insurance issuers in the individual market will also have five percent of their policies relinquish grandfathered status annually over the next three years. Data obtained from the 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 13 percent of plans have an HMO option and that 23 percent of plans offer a POS option. Thus, approximately 2,740 plans and issuers will produce notices each year.[168] While not all HMO and POS options require the designation of a primary care physician or a prior authorization or referral before a woman can visit an OB/GYN, the Department is unable to estimate this number. Therefore, this estimate should be considered an overestimate of the number of affected entities.

Each of these 2,740 plans and issuers will require a compensation and benefits manager to spend 10 minutes individualizing the model notice to fit the plan's specifications at an hourly rate of $110.30. This results in approximately 457 hours of burden at an equivalent cost of $50,400. Each plan will also require clerical staff to spend 5 minutes adding the notice to the plan's documents at an hourly rate of $30.42. This results in approximately 228 hours of burden at an equivalent cost of $7,000. The total annual burden associated with this requirement is 685 hours at an equivalent cost of $57,000.

The Department assumes that only printing and material costs are associated with the disclosure requirement, because the final regulations provide model language that can be incorporated into existing plan documents. The Department estimates that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically.

It is estimated that there are 27.9 million non-federal government plan policyholders and individual policyholders. As stated in the previous section, it is estimated that 5 percent of plans will relinquish their grandfathered status annually in the next three years. Data obtained from the 2014 Kaiser/HRET Survey of Employer Sponsored Health Benefits finds that 13 percent of covered workers in Government plans have an HMO option and that 8 percent of covered workers have a POS option. Data obtained from AHIP in 2009 finds that 1.93 percent of individual policyholders have an HMO options. Thus, it is estimated that plans will produce 228,000 notices each year, 38 percent of which will be sent electronically.[169] This results in a cost burden of approximately $3,500.[170]

c. Out-of-Network Emergency Services Disclosure

The final regulations require that a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is more restrictive than the copayment or coinsurance requirement that would apply if the services were provided in network. If State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, the a plan or issuer must provide an enrollee or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by an enrollee or beneficiary. This information should already be routinely included in the Explanation of Benefit documents sent by plans and issuers to enrollees and beneficiaries. Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), we believe this is a usual and customary business practice. Plans and issues routinely provide enrollees and beneficiaries with the Explanation of Benefit documents.

4. ICRs Regarding Affordable Care Act Internal Claims and Appeals and External Review (§§ 14.136 (b)(2)(ii), 147.136 (b)(2)(ii)(C), 147.136 (b)(3)(ii), 147.136 (b)(3)(ii)(C))

Paragraph (b)(2)(ii)(C) of the final regulations implementing PHS Act section 2719 provides that non-grandfathered ERISA-covered group health plans provide to the claimant, free of charge, any new or additional evidence considered relied upon, or generated by the plan or issuer in connection with the claim. The related hour burden is 773,800 hours and the related cost burden is $115.2 million.

The June 2011 amendment to the interim final regulations under PHS Act section 2719 required that plans and issuers must provide participants and beneficiaries who reside in a county where ten percent or more of the population residing in the county is literate only in the same non-English language with a one-sentence statement in all notices written in the applicable non-English language, about the availability of language services. In addition to including the statement, plans and issuers are required to provide a customer assistance process (such as a telephone hotline) with oral language services in the non-English language and provide written notices in the non-English language upon request. Providing notice of the services and the translation services is estimated to have a cost burden of $633,000 annually.

Also, PHS Act section 2719 and the final regulations provide that group health plans and issuers offering group health insurance coverage must comply either with a State external review process or a Federal review process. Plans and issuers must provide to those conducting the external reviews required documents. There is an estimated 2,100 external appeals conducted annually. The related hour burden is 150 hours with an equivalent cost of $4,600 and a cost burden of $5,400 annually.

In total, the burden associated with claims, appeals, and external review is approximately 774,000 hours at an equivalent cost of $41,601,000 annually. The cost burden associated with claims, appeals, language translation, and external review is approximately $115.8 million annually.

[168] 128,400 Governmental plans × 5% newly non-grandfathered plans × (13% HMOs + 23% POSs) + 430 issuers = approximately 2,700 affected plans and issuers.

[169] [21.1 million Government policyholders × 5% newly non-grandfathered plans × (13% in HMOs + 8% in POSs)] + [6.77 million individual policy holders × 5% newly non-grandfathered plans × 1.93% in HMOs] = approximately 228,000 notices.

[170] $0.05 per page * 1/2 pages per notice * 228,000 notices * 62% = approximately $3,500.

TABLE 2—ANNUAL REPORTING, RECORDKEEPING AND DISCLOSURE BURDEN (HHS)

	OMB Control No.	Number of respondents	Responses	Total annual burden (hours)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total costs ($)
Grandfathered Plans Disclosure (§ 147.140(a)(2))	0938–1093	47,932	6,850,695	0	$0	$106,186	$106,186
Grandfathered Plans Change in Carrier Disclosure (§ 147.140(a)(3)(i))	0938–1093	7,440	7,440	248	$7,544	$0	$7,544
Rescissions Notice (§ 147.128(a)(1))	0938–1094	430	10,200	212	$17,160	$3,400	$20,560
Patient Protection Disclosures (§ 147.138(a)(4))	0938–1094	2,741	228,086	685	$57,341	$3,535	$60,876
Claims and Appeals External Review ((§§ 147.136 (b)(2)(ii), 147.136 (b)(2)(ii)(C), 147.136 (b)(3)(ii), 147.136 (b)(3)(ii)(C))	0938–1098	95,500	399,151,000	773,996	$41,601,000	$115,827,000	$157,428,000
Total		154,043	406,247,421	775,141			$157,623,166

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 *et seq.*) and which are likely to have a significant economic impact on a substantial number of small entities.

The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. (States and individuals are not included in the definition of ''small entity.'') The Departments use as their measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

As discussed in detail in the ''Need for Regulatory Action'' section of this Regulatory Impact Analysis, these regulations are necessary to implement the following provisions: Affordable Care Act section 1251 (preservation of right to maintain existing coverage), and PHS Act sections 2704 (prohibition of preexisting condition exclusions), 2711 (no lifetime or annual limits), 2712 (prohibition on certain rescissions), 2714 (extension of dependent coverage), 2719 (internal appeals and external review process), and 2719A (patient protections). In response to the 2010 interim final regulations, the Departments received many comments that relate to early implementation issues and addressed many of these issues through sub-regulatory guidance. The Departments also held meetings with stakeholders, including small entities affected by the rules. After consideration of comments and stakeholder input received in response to the interim final regulations, the Departments are issuing these final regulations.

The Regulatory Flexibility Act requires agencies to assess and consider the direct economic impacts that regulations impose on small entities. The primary economic effects of these final regulations are indirect, because they result in transfers between individuals covered by health insurance. While these transfers could be significant, they do not impose direct effects on the regulated small entities for purposes of the RFA.

Most of the direct effects of the final regulations are associated with their disclosure requirements. As discussed below and in the Paperwork Reduction Act section above, these disclosure requirements do not have a significant economic impact. Therefore, pursuant to section 605(b) of the RFA, the Departments hereby certify that these final regulations are not likely to have a significant economic impact on a substantial number of small entities. The Departments' basis for this determination and their estimate of small entities affected by these final regulations is discussed below.

A. Affected Small Entities

There are several different types of small entities affected by these final regulations. For issuers and third party administrators, a small business is one that has total premium revenue of $38.5 million or less. The Departments continue to consider a small plan to be an employee benefit plan with fewer than 100 participants.[171] Further, while some large employers may have small plans, in general small employers maintain most small plans. Thus, the Departments believe that assessing the impact of this final rule on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR 121.201) pursuant to the Small Business Act (15 U.S.C. 631 *et seq.*).

Based on data from MLR annual report submissions for the 2013 MLR reporting year, approximately 141 out of 500 issuers of health insurance coverage nationwide had total premium revenue of $38.5 million or less.[172] This estimate may overstate the actual number of small health insurance companies that may be affected, since 77 percent of these small companies belong to larger holding groups, and many if not all of these small companies are likely to have non-health lines of business that would result in their revenues exceeding $38.5 million.

As discussed previously in the RIA, there are an estimated 2.3 million ERISA-covered plans and 128,400 State and local governmental health plans that may have experienced an increase in costs related to the provisions of these final rules. Ninety-seven percent of these plans are provided by small entities and have incurred costs related to the provisions of these final regulations.

[171] The basis for this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for pension plans that cover fewer than 100 participants.

[172] U. S. Small Business Administration, ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes'', July 14, 2014.

B. Direct Impacts of Final Rules on Small Entities

1. Affordable Care Act Section 1251, Preservation of Right To Maintain Existing Coverage (26 CFR 54.9815–1251, 29 CFR 2590.715–1251, 45 CFR 147.140)

The direct impacts of this provision on affected small entities are primarily associated with notices requirements. Specifically, the final regulations require affected plans to maintain records documenting the terms of the plan in effect on March 23, 2010, and any other documents that are necessary to verify, explain or clarify status as a grandfathered health plan (the ''recordkeeping requirement''). The plan must make such records available for examination upon request by participants, beneficiaries, individual policy subscribers, or a State or Federal agency official. The Departments believe this requirement imposes a minimal burden on small entities, because they should maintain such records in the usual and customary course of their business operations following standard business procedures.

To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act and must provide contact information for questions and complaints, in any summary of benefits provided under the plan to consumers. The Departments believe the costs associated with this disclosure are minimal, because a model statement is provided in the final rule and that statement can be provided in any summary of benefits that already is being provided to consumers.

Finally, if a grandfathered group health plan switches issuers and intends to maintain its status as a grandfathered plan, it must provide to the new health insurance issuer with documentation of plan terms under the prior health coverage sufficient for it to determine whether a change causing a cessation of grandfathered health plan status has occurred. This requirement also imposes a minimal burden on affected small entities, because the documents should be maintain in the ordinary course of the plan's business operations, and the only additional cost would be incurred to prepare the documentation for mailing and associated material and printing cost, which are estimated to total approximately $8.

1. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704, 29 CFR 2590.715–2704, 45 CFR 147.108)

The direct impacts of this rule on the regulated small entities is limited as the removal of preexisting condition exclusions primarily operates through the pricing of insurance products, which are paid by plan participants. Small businesses will be impacted when they pay for part of the health insurance premium. The Departments have not been able to estimate this effect separately from the effect on premiums brought about by the other the Affordable Care Act changes.

2. PHS Act Section 2711, Prohibition on Lifetime and Annual Limits (26 CFR 54.9815–2711, 29 CFR 2590.715–2711, 45 CFR 147.126)

The direct impacts of this rule on the regulated small entities were primarily limited to an initial notice sent shortly after the issuance of the interim final regulations requiring plans to notify participants that had lost coverage due to reaching the lifetime limit of the new coverage option. This notice requirement is no longer in effect as the statute now bans all annual and life time limits, so there are no individuals losing coverage that need to be notified. To the extent premiums increase and employers contribute part of the premiums, or plans are self-insured with payments from the employers general assets there could be direct effects on employers, but for most employers those effects are small.

3. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712, 29 CFR 2590.715–2712, 45 CFR 147.128)

PHS Act Section 2712 and the final regulations prohibit group health plans and health insurance issuers that offer group or individual health insurance coverage generally from rescinding coverage under the plan, policy, certificate, or contract of insurance from the individual covered under the plan or coverage unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. The final regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 days advance notice to an individual before coverage may be rescinded. The Departments believe that rescissions are rare in the group market and that small group health plans are affected by rescissions more than large group health plans.

The Departments estimate [173] that 15 minutes of legal professional time at $129.94 per hour [174] would be required by the insurers of the policies to prepare the notice, and one minute per notice of clerical professional time at $30.42 per hour [175] would be required to distribute the paper notices. The Departments believe the costs of electronic transmission would be de minimis. This leads to an estimate of less than $40 per rescission notice, which the Departments do not believe is significant.

4. PHS Act Section 2714, Coverage of Dependents to Age 26 (26 CFR 54.9815–2714, 29 CFR 2590.715–2714, 45 CFR 147.120)

The direct impacts of this rule on the regulated small entities were primarily limited to an initial notice sent shortly after the issuance of the interim final regulations requiring plans to notify participants of the new coverage option. To the extent premiums increase and employers contribute part of the premiums, or plans are self-insured with payments from the employers general assets there could be direct effects on employers, but for most employers those effects are small.

5. PHS Act Section 2719, Internal Claims and Appeals and External Review (26 CFR 54.9815–2719, 29 CFR 2590.715–2719, 45 CFR 147.136)

Not all potentially affected individuals will be affected equally by these final regulations. Sponsors of ERISA-covered group health plans were required to implement an internal

[173] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: Mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/pdf/ocwage.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/ecec.t02.htm*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/eci.nr0.htm*).

[174] Legal Professional (23–1011): $63.46 (2013 BLS Wage rate)/0.69 (ECEC ratio) *1.35 (Overhead Load Factor) *1.023 (Inflation rate) ^2 (Inflated 2 years from base year) = $129.94.

[175] Secretaries, Except Legal, Medical, and Executive (43–6014): $16.35 (2013 BLS Wage rate)/0.675 (ECEC ratio) *1.2 (Overhead Load Factor) *1.023 (Inflation rate) ^2 (Inflated 2 years from base year) = $30.42

appeals process that complied with the DOL claims procedure regulation before the Affordable Care Act's enactment, and the Departments also understand that many non-Federal governmental plans and church plans that are not subject to ERISA implement internal claims and appeals processes that comply with the DOL claims procedure regulation.

These final regulations will have the largest impact on individuals covered in the individual health insurance market, because with the issuance of the final regulation, these issuers were required to comply with the DOL claims procedure regulation for internal claims and appeals as well as the additional standards added by the Secretary of the Department of Health and Human Services in paragraph (b)(3) of the final regulations under PHS Act section 2719 that are in some cases more protective than the ERISA standard.

Using estimates calculated for the Paperwork Reduction Act it is estimated that there will be an average costs of 40 cents per notice that is required to be sent related to the internal claims and appeals.

On the external appeals side, before the enactment of the Affordable Care Act, issuers offering coverage in the group and individual health insurance market were already required to comply with State external review laws. At that time, all States except Alabama, Mississippi, Nebraska, North Dakota, South Dakota, and Wyoming had external review laws, and thirteen States had external review laws that apply only to certain market segments (for example, managed care or HMOs). Currently, all States except, Alabama, Alaska, Florida, Georgia, Pennsylvania, and Wisconsin have State external review laws that satisfy these requirements. These six states that do not meet the requirements, must use the HHS administered process or must contract with accredited independent review organizations to review external appeals on their behalf.[176]

Individuals participating in ERISA-covered self-insured group health plans will be among those most affected by the external review requirements contained in these final regulations, because the preemption provisions of ERISA prevent a State's external review process from applying directly to an ERISA-covered self-insured plan. These plans will now be required to comply with the Federal external review process set forth in these final regulations.

As discussed in the Regulatory Impact Section above an estimate for the average cost for an external appeal is $665. This cost would be incurred by plans or issuers. It is also estimated above that there is on average only 1.3 external appeals per 10,000 covered lives. The Departments believe such costs are minimal for purpose of the RFA, because most small entities will have no external appeals in a given year.

6. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719A, 29 CFR 2590.715–2719A, 45 CFR 147.138)

PHS Act section 2719A imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of health care professionals. When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; (2) obtain obstetrical or gynecological care without prior authorization; or (3) coverage of emergency services. Accordingly, these final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscriber) of these rights when applicable. Model language is provided in these final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

The Departments assume that this provision will primarily affect Health Maintenance Organizations and Point-of-Service type arrangements. The Department believes that insignificant costs are associated with this notice, because a model notice is provided in the final rule, and it can be distributed with existing plan documents,

The Departments estimate that each plan or issuer would require a compensation and benefits manager[177] to spend 10 minutes individualizing the model notice provided by the Departments to fit the plan's specifications at an hourly rate of $110.30.[178] This results in a cost of approximately $21 in the first year. The cost per participant to receive the notice would be less than five cents per paper notice as the notice would be included in existing documents.

VI. Unfunded Mandates Reform Act—Department of Labor and Department of Health and Human Services

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any final rule that includes a Federal mandate that could result in expenditure in any one year by State, local or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars updated annually for inflation. In 2015, that threshold level is approximately $144 million. These final regulations include a Federal mandate that may result in expenditures by State, local, or Tribal governments. Specifically, these final regulations include requirements regarding minimum consumer protection standards that a State external review process must include to qualify as an applicable State external review process under PHS Act section 2719(b)(1). However, we conclude that these costs would not exceed the $144 million threshold. Thus, the Departments of Labor and HHS conclude that these final regulations would not impose an unfunded mandate on State, local or Tribal governments or the private sector. Regardless, consistent with the policy embodied in UMRA, the final requirements described in this notice of final rulemaking has been designed to be the least burdensome alternative for State, Local and Tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

VII. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific

[176] *https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html.*

[177] The Department's estimated 2015 hourly labor rates include wages, other benefits, and overhead are calculated as follows: Mean wage from the 2013 National Occupational Employment Survey (April 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/pdf/ocwage.pdf*); wages as a percent of total compensation from the Employer Cost for Employee Compensation (June 2014, Bureau of Labor Statistics *http://www.bls.gov/news.release/ecec.t02.htm*); overhead as a multiple of compensation is assumed to be 25 percent of total compensation for paraprofessionals, 20 percent of compensation for clerical, and 35 percent of compensation for professional; annual inflation assumed to be 2.3 percent annual growth of total labor cost since 2013 (Employment Costs Index data for private industry, September 2014 *http://www.bls.gov/news.release/eci.nr0.htm*).

[178] Compensation and Benefits Manager (11–3041): $53.87 (2013 BLS Wage rate)/0.69 (ECEC ratio) *1.35 (Overhead Load Factor) *1.023 (Inflation rate) ^2 (Inflated 2 years from base year) = $110.30.

criteria by Federal agencies in the process of their formulation and implementation of policies that have ''substantial direct effects'' on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments of Labor's and HHS' view, these final regulations have federalism implications because they would have direct effects on the States, the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. Under these final regulations, group health plans and health insurance issuers offering group or individual health insurance coverage, including non-federal governmental plans as defined in section 2791 of the PHS Act, would be required to follow the Federal standards developed under Affordable Care Act section 1251 and PHS Act sections 2704, 2711, 2712, 2714, 2719 and 2719A, as added by the Affordable Care Act. However, in the Departments' view, the federalism implications of these final regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements in title XXVII of the PHS Act (including those added by the Affordable Care Act) are not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the ''narrowest'' preemption of State laws (See House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018).

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments of Labor and HHS have engaged in efforts to consult with and work cooperatively with affected States, including consulting with, and attending conferences of, the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments of Labor and HHS will act in a similar fashion in enforcing the Affordable Care Act.

Throughout the process of developing these final regulations, to the extent feasible within the applicable preemption provisions, the Departments of Labor and HHS have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments of Labor's and HHS' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this final rule, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached final rules in a meaningful and timely manner.

VIII. Special Analyses—Department of the Treasury

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these final regulations. For a discussion of the impact of this final rule on small entities, please see section V.B. of this preamble. Pursuant to section 7805(f) of the Code, this notice of final rulemaking has been submitted to the Small Business Administration for comment on its impact on small business.

IX. Congressional Review Act

These final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information, and has been transmitted to Congress and the Comptroller General for review.

X. Statutory Authority

The Department of the Treasury final regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1135, and 1191c; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144 and 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

requirements, and State regulation of health insurance.

John Dalrymple,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: October 27, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 6 day of November 2015.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 15, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 22, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

For the reasons stated in the preamble, the Internal Revenue Service amends Part 54 as set forth below:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding entries for §§ 54.9815–1251, 54.9815–2704, 54.9815–2711, 54.9815–2712, 54.9815–2714, 54.9815–2719, and 54.9815–2719A in numerical order to read in part as follows:

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

Section 54.9815–1251 also issued under 26 U.S.C. 9833.

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Section 54.9815–2704 also issued under 26 U.S.C. 9833.

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Section 54.9815–2711 also issued under 26 U.S.C. 9833.

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Section 54.9815–2712 also issued under 26 U.S.C. 9833.

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Section 54.9815–2714 also issued under 26 U.S.C. 9833.

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Section 54.9815–2719 also issued under 26 U.S.C. 9833.

Section 54.9815–2719A also issued under 26 U.S.C. 9833.

■ **Par. 2.** Section 54.9801–2 is amended by revising the introductory text and the definition of ''preexisting condition exclusion'' to read as follows:

§ 54.9801–2 Definitions.

Unless otherwise provided, the definitions in this section govern in applying the provisions of sections 9801 through 9815 and 9831 through 9833.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

■ **Par. 3.** Section 54.9801–3 is amended by revising the section heading and paragraph (a)(1) to read as follows:

§ 54.9801–3 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion defined*—(1) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning of § 54.9801–2.

* * * * *

■ **Par. 4.** Section 54.9815–1251 is added to read as follows:

§ 54.9815–1251 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage* means coverage provided by a group health plan, or a health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage. Accordingly, if any benefit package relinquishes grandfather status, it will not affect the grandfather status of the other benefit packages.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status*—(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act, and must provide contact information for questions and complaints, in any summary of benefits provided under the plan.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a ''grandfathered health plan'' under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must

comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime dollar limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or *www.dol.gov/ebsa/healthreform*. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at *www.healthcare.gov*.]

(3)(i) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual dollar limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan*— (1) *In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010. Further, the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfather status.

(2) *Anti-abuse rules*— (i) *Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(iii) *Illustrative list of bona fide employment-based reasons.* For purposes of paragraph (b)(2)(ii)(C) of this section, bona fide employment-based reasons include—

(A) When a benefit package is being eliminated because the issuer is exiting the market;

(B) When a benefit package is being eliminated because the issuer no longer offers the product to the employer;

(C) When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

(D) When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

(E) When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G*. During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G*.

(ii) *Conclusion.* In this *Example 1,* the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I*. On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option *H* and the employees that are moved are transferred to Option *I*. If instead of transferring employees from Option *H* to Option *I*, Option *H* was amended to match the terms of Option *I*, then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2,* the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I*. Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. (In addition, *see* 45 CFR 147.140(c), which provides that the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual dollar limits, do not apply to grandfathered health plans that are individual health insurance coverage.)

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime dollar limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. A plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that results in a change described in this paragraph (g)(1) becomes effective, regardless of when the amendment was adopted. Once grandfather status is lost, it cannot be regained.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. Whether or not a plan or coverage has eliminated substantially all benefits to diagnose or treat a particular condition must be determined based on all the facts and circumstances, taking into account the items and services provided for a particular condition under the plan on March 23, 2010, as compared to the benefits offered at the time the plan or coverage makes the benefit change effective.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, and determined for each copayment level if a plan has different copayment levels for different categories of services, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the

employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 54.9802(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(C) *Special rules regarding decreases in contribution rates.* An insured group health plan (or a multiemployer plan) that is a grandfathered health plan will not cease to be a grandfathered health plan based on a change in the employer contribution rate unless the issuer (or multiemployer plan) knows, or should know, of the change, provided:

(*1*) Upon renewal (or, in the case of a multiemployer plan, before the start of a new plan year), the issuer (or multiemployer plan) requires relevant employers, employee organizations, or plan sponsors, as applicable, to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer, or multiemployer plan, does not already have it); and

(*2*) The relevant policies, certificates, contracts of insurance, or plan documents disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year.

(D) *Application to plans with multi-tiered coverage structures.* The standards for employer contributions in this paragraph (g)(1)(v) apply on a tier-by-tier basis. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.,* self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.,* at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage would not cause the plan to lose grandfather status.

(E) *Group health plans with fixed-dollar employee contributions or no employee contributions.* A group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan solely because the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. (But see § 54.9815–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. (But see § 54.9815–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits). (But see § 54.9815–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted)

published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(4) *Examples.* The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1,* the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2,* the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except the grandfathered health plan subsequently increases the $40 copayment requirement to $45 for a later plan year. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 ($5 × 0.2527 = $1.26; $1.26 + $5 = $6.26).

Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5,* the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.–858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv)this section, which would permit an increase in the copayment of up to $5.36.

Example 6. (i) *Facts.* The same facts as *Example 5,* except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to $5.

(ii) *Conclusion.* In this *Example 6,* medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1000 for self-only coverage and $4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5000 − 1000)/5000) for self-only coverage and 67% ((12,000 − 4000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1200 for self-only coverage and $5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6000 − 1200)/6000) for self-only coverage and 67% ((15,000 − 5000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 8,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) Conclusion. In this *Example 9,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the (rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

§ 54.9815–1251T [Removed]

■ **Par. 5.** Section 54.9815–1251T is removed.

■ **Par. 6.** Section 54.9815–2704 is added to read as follows:

§ 54.9815–2704 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions.* A group health plan, or a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 54.9801–2).

(b) *Examples.* The rules of paragraph (a) of this section are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* § 54.9801–3(a)(2)):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N. N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. Therefore, such an exclusion is prohibited.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M. M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion. See Example 2* in 45 CFR 147.108(a)(2) for a conclusion that *M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. Therefore, such an exclusion is prohibited.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2704T [Removed]

■ Par. 7. Section 54.9815–2704T is removed.

■ Par. 8 Section 54.9815–2711 is added to read as follows:

§ 54.9815–2711 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any lifetime limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii) and (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any annual limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) offered through a cafeteria plan pursuant to section 125 of the Internal Revenue Code is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term ''essential health benefits'' means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations. For this purpose, a group health plan or a health insurance issuer that is not required to provide essential health benefits under section 1302(b) must define ''essential health benefits'' in a manner consistent with one of the three Federal Employees Health Benefit Program (FEHBP) options as defined by 45 CFR 156.100(a)(3) or one of the base-benchmark plans selected by a State or applied by default pursuant to 45 CFR 156.100.

(d) *Special rule for health reimbursement arrangements (HRAs) and other account-based plans*—(1) *In general.* If an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based plan are limited does not mean that the HRA or other account-based plan fails to meet the requirements of paragraph (a)(2) of this section. Similarly, if an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in PHS Act section 2713 and section 54.9815–2713(a)(1), the HRA or other account-based plan will not fail to meet the requirements of PHS Act section 2713 and § 54.9815–2713(a)(1).

(2) *Integration requirements.* An HRA or other account-based plan is integrated with a group health plan for purposes of paragraph (a)(2) of this section if it meets the requirements under either the integration method set forth in paragraph (d)(2)(i) of this section or the integration method set forth in paragraph (d)(2)(ii) of this section. Integration does not require that the HRA (or other account-based plan) and the group health plan with which it is integrated share the same plan sponsor, the same plan document, or governing instruments, or file a single Form 5500, if applicable. The term ''excepted benefits'' is used throughout the integration methods; for a definition of the term ''excepted benefits'' see Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).

(i) *Integration Method: Minimum value not required.* An HRA or other

account-based plan is integrated with another group health plan for purposes of this paragraph if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based plan) to the employee that does not consist solely of excepted benefits;

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan (other than the HRA or other account-based plan) that does not consist solely of excepted benefits, regardless of whether the plan is offered by the same plan sponsor (referred to as non-HRA group coverage);

(C) The HRA or other account-based plan is available only to employees who are enrolled in non-HRA group coverage, regardless of whether the non-HRA group coverage is offered by the plan sponsor of the HRA or other account-based plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA group coverage, such as a group health plan maintained by the employer of the employee's spouse);

(D) The benefits under the HRA or other account-based plan are limited to reimbursement of one or more of the following—co-payments, co-insurance, deductibles, and premiums under the non-HRA group coverage, as well as medical care (as defined under section 213(d) of the Code) that does not constitute essential health benefits as defined in paragraph (c) of this section; and

(E) Under the terms of the HRA or other account-based plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(ii) *Integration Method: Minimum value required.* An HRA or other account-based plan is integrated with another group health plan for purposes of this paragraph if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based plan) to the employee that provides minimum value pursuant to Code section 36B(c)(2)(C)(ii) (and its implementing regulations and applicable guidance);

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based plan is available only to employees who are actually enrolled in non-HRA MV group coverage, regardless of whether the non-HRA MV group coverage is offered by the plan sponsor of the HRA or other account-based plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA MV group coverage, such as a group health plan maintained by an employer of the employee's spouse); and

(D) Under the terms of the HRA or other account-based plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(3) *Forfeiture.* For purpose of integration under paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section, forfeiture or waiver occurs even if the forfeited or waived amounts may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For this purpose coverage under an HRA or other account-based plan is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election and through the date of the reinstatement event, the participant and the participant's beneficiaries have no access to amounts credited to the HRA or other account-based plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based plan may not be used to reimburse or pay medical expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *No integration with individual market coverage.* A group health plan, including an HRA or other account-based plan, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of paragraph (a)(2) of this section (or for purposes of the requirements of PHS Act section 2713).

(5) *Integration with Medicare parts B and D.* For employers that are not required to offer their non-HRA group health plan coverage to employees who are Medicare beneficiaries, an HRA or other account-based plan that may be used to reimburse premiums under Medicare part B or D may be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713) if the following requirements are satisfied with respect to employees who would be eligible for the employer's non-HRA group health plan but for their eligibility for Medicare (and the integration rules under paragraphs (d)(2)(i) and (ii) of this section continue to apply to employees who are not eligible for Medicare):

(i) The plan sponsor offers a group health plan (other than the HRA or other account-based plan and that does not consist solely of excepted benefits) to employees who are not eligible for Medicare;

(ii) The employee receiving the HRA or other account-based plan is actually enrolled Medicare part B or D;

(iii) The HRA or other account-based plan is available only to employees who are enrolled in Medicare part B or D; and

(iv) The HRA or other account-based plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Account-based plan.* An account-based plan for purposes of this section is an employer-provided group health plan that provides reimbursements of medical expenses other than individual market policy premiums with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based plan.

(e) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2711T [Removed]

■ **Par. 9.** Section 54.9815–2711T is removed.

■ **Par. 10.** Section 54.9815–2712 is added to read as follows:

§ 54.9815–2712 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance written notice to each participant who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if—

(i) The cancellation or discontinuance of coverage has only a prospective effect;

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions (including COBRA premiums) towards the cost of coverage;

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's authorized representative) and the sponsor, employer, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or

(iv) The cancellation or discontinuance of coverage is initiated by the Exchange pursuant to 45 CFR 155.430 (other than under paragraph (b)(2)(iii)).

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. The questionnaire includes the following question: ''Is there anything else relevant to your health that we should know?'' *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A*'s visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1,* the plan cannot rescind *A*'s coverage because *A*'s failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B.* After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B*'s coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2,* the plan cannot rescind *B*'s coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2712T [Removed]

■ **Par. 11.** Section 54.9815–2712T is removed.

■ **Par. 12.** Section 54.9815–2714 is added to read as follows:

§ 54.9815–2714 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example,* the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent*—(1) *In general.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant. Thus, for example, a plan or issuer may not deny or restrict dependent coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or any other person); residency with the participant or with any other person; whether the child lives, works, or resides in an HMO's service area or other network service area; marital status; student status; employment; eligibility for other coverage; or any combination of those factors. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may require coverage of certain children.)

(2) *Construction.* A plan or issuer will not fail to satisfy the requirements of this section if the plan or issuer limits dependent child coverage to children under age 26 who are described in section 152(f)(1) . For an individual not described in section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for dependent child health coverage, such

as a condition that the individual be a dependent for income tax purposes.

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1,* the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: Self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3,* the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

Example 4. (i) *Facts.* A group health plan sponsored by a large employer normally charges a copayment for physician visits that do not constitute preventive services. The plan charges this copayment to individuals age 19 and over, including employees, spouses, and dependent children, but waives it for those under age 19.

(ii) *Conclusion.* In this *Example 4,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. While the requirement of paragraph (d) of this section generally prohibits distinctions based upon age in dependent coverage of children, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this *Example 4,* the copayments charged to dependent children are the same as those charged to employees and spouses. Accordingly, the arrangement described in this *Example 4* (including waiver, for individuals under age 19, of the generally applicable copayment) does not violate the requirement of paragraph (d) of this section.

(f) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2714T [Removed]

■ **Par. 13.** Section 54.9815–2714T is removed.

■ **Par. 14.** Section 54.9815–2719 is added to read as follows:

§ 54.9815–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions*–(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 54.9815–1251. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 54.9815–2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health

insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 54.9815–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of

this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25; it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a

notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in

connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d)); and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1,* the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2,* the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2), if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.,* worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour

period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records

available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ **Par. 15.** Section 54.9815–2719A is added to read as follows:

§ 54.9815–2719A Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage

regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A's* child. *B* is a participating provider in the HMO's network and is available to accept the child.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A's* designation of *B* as the primary care provider for *A's* child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *A* takes *A's* child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A's* child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A's* coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A,* a female, requests a gynecological exam with Physician *B,* an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A's* designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1,* the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A's* primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C,* an out-of-network provider.

(ii) *Conclusion.* In this *Example 2,* the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A's* designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3,* the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care

physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4,* the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* The notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants or beneficiaries, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant or beneficiary for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-network. However, a participant or beneficiary may be required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount at least equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (B), and (C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. The amount in this

paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Special rules regarding out-of-network minimum payment standards*—(A) The minimum payment standards set forth under paragraph (b)(3) of this section do not apply in cases where State law prohibits a participant or beneficiary from being required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer provides in benefits, or where a group health plan or health insurance issuer is contractually responsible for such amounts. Nonetheless, in such cases, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in network.

(B) A group health plan and health insurance issuer must provide a participant or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to the amounts described under this paragraph (b)(3)(iii), to prevent inadvertent payment by the participant or beneficiary.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2,* by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3,* the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3.* Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4,* the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5,* the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5.* The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6,* the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the interim final regulations promulgated by the Department of Labor at 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

§ 54.9815–2719AT [Removed]

■ **Par. 16.** Section 54.9815–2719AT is removed.

§ 54.9815–2719T [Removed]

■ **Par. 17.** Section 54.9815–2719T is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons stated in the preamble, the Employee Benefits Security Administration adopts as final the interim final rules amending 29 CFR part 2590, which were published in the **Federal Register** on May 13, 2010 (75 FR 27122), June 17, 2010 (75 FR 34538), June 28, 2010 (75 FR 37188), and November 17, 2010 (75 FR 70114) with the following changes as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 18. The authority citation for Part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 19. Section 2590.701–2 is amended by revising the definition of ''preexisting condition exclusion'' to read as follows:

§ 2590.701–2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

■ 20. Section 2590.701–3 is amended by revising paragraph (a)(1) to read as follows:

§ 2590.701–3 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion defined*—(1) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning of § 2590.701–2.

* * * * *

■ 21. Section 2590.715–1251 revised to read as follows:

§ 2590.715–1251 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage* means coverage provided by a group health plan, or a health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage. Accordingly, if any benefit package relinquishes grandfather status, it will not affect the grandfather status of the other benefit packages.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status*—(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act, and must provide contact information for questions and complaints, in any summary of benefits provided under the plan.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a ''grandfathered health plan'' under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime dollar limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or *www.dol.gov/ebsa/healthreform.* This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at *www.healthcare.gov.*]

(3)(i) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual dollar limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan*—(1) *In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010. Further, the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfather status.

(2) *Anti-abuse rules*—(i) *Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(iii) *Illustrative list of bona fide employment-based reasons.* For purposes of this paragraph (b)(2)(ii)(C), bona fide employment-based reasons include—

(A) When a benefit package is being eliminated because the issuer is exiting the market;

(B) When a benefit package is being eliminated because the issuer no longer offers the product to the employer;

(C) When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

(D) When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

(E) When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G.* During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G.*

(ii) *Conclusion.* In this *Example 1,* the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I.* On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option *H* and the employees that are moved are transferred to Option *I.* If instead of transferring employees from Option *H* to

Option *I,* Option *H* was amended to match the terms of Option *I,* then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2,* the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I.* Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. (In addition, *see* 45 CFR 147.140(c), which provides that the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual dollar limits, do not apply to grandfathered health plans that are individual health insurance coverage.)

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime dollar limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. A plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that results in a change described in this paragraph (g)(1) becomes effective, regardless of when the amendment was adopted. Once grandfather status is lost, it cannot be regained.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. Whether or not a plan or coverage has eliminated substantially all benefits to diagnose or treat a particular condition must be determined based on all the facts and circumstances, taking into account the items and services provided for a particular condition under the plan on March 23, 2010, as compared to the benefits offered at the time the plan or coverage makes the benefit change effective.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, and determined for each copayment level if a plan has different copayment levels for different categories of services, causes a group health plan or health

insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d)) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 2590.702(d)) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(C) *Special rules regarding decreases in contribution rates.* An insured group health plan (or a multiemployer plan) that is a grandfathered health plan will not cease to be a grandfathered health plan based on a change in the employer contribution rate unless the issuer (or multiemployer plan) knows, or should know, of the change, provided:

(*1*) Upon renewal (or, in the case of a multiemployer plan, before the start of a new plan year), the issuer (or multiemployer plan) requires relevant employers, employee organizations, or plan sponsors, as applicable, to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer, or multiemployer plan, does not already have it); and

(*2*) The relevant policies, certificates, contracts of insurance, or plan documents disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year.

(D) *Application to plans with multi-tiered coverage structures.* The standards for employer contributions in this paragraph (g)(1)(v) apply on a tier-by-tier basis. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.,* self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.,* at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage would not cause the plan to lose grandfather status.

(E) *Group health plans with fixed-dollar employee contributions or no employee contributions.* A group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan solely because the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. (But see § 2590.715–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. (But see § 2590.715–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits). (But see § 2590.715–2711, which prohibits all annual dollar limits on essential health benefits for plan years beginning on or after January 1, 2014).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to

cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(4) *Examples.* The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1,* the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2,* the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except the grandfathered health plan subsequently increases the $40 copayment requirement to $45 for a later plan year. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 ($5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5,* the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv)this section, which would permit an increase in the copayment of up to $5.36.

Example 6. (i) *Facts.* The same facts as *Example 5,* except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to $5.

(ii) *Conclusion.* In this *Example 6,* medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5,000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1,000 for self-only coverage and $4,000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5,000 − 1,000)/5,000) for self-only coverage and 67% ((12,000 − 4,000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6,000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1,200 for self-only coverage and $5,000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6,000 − 1,200)/6,000) for self-only coverage and 67% ((15,000 − 5,000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 8,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion.* In this *Example 9,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the (rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

■ 22. Section 2590.715–2704 is revised to read as follows:

§ 2590.715–2704 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions.* A group health plan, or a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701–2).

(b) *Examples.* The rules of paragraph (a) of this section are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* § 2590.701–3(a)(2)):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N. N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. Therefore, such an exclusion is prohibited.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M. M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion. See Example 2* in 45 CFR 147.108(a)(2) for a conclusion that *M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition. Therefore, such an exclusion is prohibited.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 23. Section 2590.715–2711 is revised to read as follows:

§ 2590.715–2711 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any lifetime limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii) and (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any annual limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) offered through a cafeteria plan pursuant to section 125 of the Internal Revenue Code is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term ''essential health benefits'' means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations. For this purpose, a group health plan or a health insurance issuer that is not required to provide essential health benefits under section 1302(b) must define ''essential health benefits'' in a manner consistent with one of the three Federal Employees Health Benefit Program (FEHBP) options as defined by 45 CFR 156.100(a)(3) or one of the base-benchmark plans selected by a State or applied by default pursuant to 45 CFR 156.100.

(d) *Special rule for health reimbursement arrangements (HRAs) and other account-based plans*—(1) *In general.* If an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based plan are limited does not mean that the HRA or other account-based plan fails to meet the requirements of paragraph (a)(2) of this section. Similarly, if an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in PHS Act section 2713 and § 2590.715–2713(a)(1), the HRA or other account-based plan will not fail to meet the requirements of PHS Act section 2713 and § 2590.715–2713(a)(1).

(2) *Integration requirements.* An HRA or other account-based plan is integrated with a group health plan for purposes of paragraph (a)(2) of this section if it meets the requirements under either the integration method set forth in paragraph (d)(2)(i) of this section or the integration method set forth in paragraph (d)(2)(ii) of this section. Integration does not require that the HRA (or other account-based plan) and the group health plan with which it is integrated share the same plan sponsor, the same plan document, or governing instruments, or file a single Form 5500, if applicable. The term ''excepted benefits'' is used throughout the integration methods; for a definition of the term ''excepted benefits'' see Internal Revenue Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).

(i) *Integration Method: Minimum value not required.* An HRA or other account-based plan is integrated with another group health plan for purposes of this paragraph if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based plan) to the employee that does not consist solely of excepted benefits;

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan (other than the HRA or other account-based plan) that does not consist solely of excepted benefits, regardless of whether the plan is offered by the same plan sponsor (referred to as non-HRA group coverage);

(C) The HRA or other account-based plan is available only to employees who are enrolled in non-HRA group coverage, regardless of whether the non-HRA group coverage is offered by the plan sponsor of the HRA or other account-based plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA group coverage, such as a group health plan maintained by the employer of the employee's spouse);

(D) The benefits under the HRA or other account-based plan are limited to reimbursement of one or more of the following—co-payments, co-insurance, deductibles, and premiums under the non-HRA group coverage, as well as medical care (as defined under section 213(d) of the Internal Revenue Code) that does not constitute essential health benefits as defined in paragraph (c) of this section; and

(E) Under the terms of the HRA or other account-based plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(ii) *Integration Method: Minimum value required.* An HRA or other account-based plan is integrated with another group health plan for purposes of this paragraph if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based plan) to the employee that provides minimum value pursuant to Code section 36B(c)(2)(C)(ii) (and its implementing regulations and applicable guidance);

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Internal Revenue Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based plan is available only to employees who are actually enrolled in non-HRA MV group coverage, regardless of whether the non-HRA MV group coverage is offered by the plan sponsor of the HRA or other account-based plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA MV group coverage, such as a group health plan maintained by an employer of the employee's spouse); and

(D) Under the terms of the HRA or other account-based plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(3) *Forfeiture.* For purpose of integration under paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section, forfeiture or waiver occurs even if the forfeited or waived amounts may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For this purpose coverage under an HRA or other account-based plan is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election and through the date of the reinstatement event, the participant and the participant's beneficiaries have no access to amounts credited to the HRA or other account-based plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based plan may not be used to reimburse or pay medical expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *No integration with individual market coverage.* A group health plan, including an HRA or other account-based plan, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of paragraph (a)(2) of this section (or for purposes of the requirements of PHS Act section 2713).

(5) *Integration with Medicare parts B and D.* For employers that are not required to offer their non-HRA group health plan coverage to employees who are Medicare beneficiaries, an HRA or other account-based plan that may be used to reimburse premiums under Medicare part B or D may be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713) if the following requirements are satisfied with respect to employees who would be eligible for the employer's non-HRA group health plan but for their eligibility for Medicare (and the integration rules under paragraphs (d)(2)(i) and (d)(2)(ii) of this section continue to apply to employees who are not eligible for Medicare):

(i) The plan sponsor offers a group health plan (other than the HRA or other account-based plan and that does not consist solely of excepted benefits) to employees who are not eligible for Medicare;

(ii) The employee receiving the HRA or other account-based plan is actually enrolled Medicare part B or D;

(iii) The HRA or other account-based plan is available only to employees who are enrolled in Medicare part B or D; and

(iv) The HRA or other account-based plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Account-based plan.* An account-based plan for purposes of this section is an employer-provided group health plan that provides reimbursements of medical expenses other than individual market policy premiums with the

reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based plan.

(e) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

24. Section 2590.715–2712 is revised to read as follows:

§ 2590.715–2712 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance written notice to each participant who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if—

(i) The cancellation or discontinuance of coverage has only a prospective effect;

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions (including COBRA premiums) towards the cost of coverage;

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's authorized representative) and the sponsor, employer, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or

(iv) The cancellation or discontinuance of coverage is initiated by the Exchange pursuant to 45 CFR 155.430 (other than under paragraph (b)(2)(iii)).

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A's* prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. The questionnaire includes the following question: ''Is there anything else relevant to your health that we should know?'' *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A's* visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1,* the plan cannot rescind *A's* coverage because *A's* failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B.* After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B's* coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2,* the plan cannot rescind *B's* coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 25. Section 2590.715–2714 is revised to read as follows:

§ 2590.715–2714 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example,* the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent*—(1) *In general.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant. Thus, for example, a plan or issuer may not deny or restrict dependent coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or any other person); residency with the participant or with any other person; whether the child lives, works, or resides in an HMO's service area or other network service area; marital status; student status; employment; eligibility for other coverage; or any combination of those factors. (Other requirements of Federal

or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may require coverage of certain children.)

(2) *Construction.* A plan or issuer will not fail to satisfy the requirements of this section if the plan or issuer limits dependent child coverage to children under age 26 who are described in section 152(f)(1) of the Code. For an individual not described in Code section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for dependent child health coverage, such as a condition that the individual be a dependent for income tax purposes.

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1,* the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: Self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3,* the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

Example 4. (i) *Facts.* A group health plan sponsored by a large employer normally charges a copayment for physician visits that do not constitute preventive services. The plan charges this copayment to individuals age 19 and over, including employees, spouses, and dependent children, but waives it for those under age 19.

(ii) *Conclusion.* In this *Example 4,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. While the requirement of paragraph (d) of this section generally prohibits distinctions based upon age in dependent coverage of children, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this *Example 4,* the copayments charged to dependent children are the same as those charged to employees and spouses. Accordingly, the arrangement described in this *Example 4* (including waiver, for individuals under age 19, of the generally applicable copayment) does not violate the requirement of paragraph (d) of this section.

(f) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 26. Section 2590.715–2719 is revised to read as follows:

§ 2590.715–2719 Internal claims and appeals and external review processes.

(a) *Scope and definitions*–(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 2590.715–1251. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 2590.715–2712(a)(2) (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group health insurance

coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 2590.715–2712.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact

information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25; it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review; it must be waived if payment of the fee would impose an undue financial hardship; and the annual limit on filing

fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process

under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d)); and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1,* the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2,* the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2)) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.,* worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone

number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete, and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization.* (A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance

consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements*—(i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

■ 27. Section 2590.715–2719A is revised to read as follows:

§ 2590.715–2719A Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who

is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A's* child. *B* is a participating provider in the HMO's network and is available to accept the child.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A's* designation of *B* as the primary care provider for *A's* child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *A* takes *A's* child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A's* child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A's* coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A,* a female, requests a gynecological exam with Physician *B,* an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A's* designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1,* the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A's* primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C,* an out-of-network provider.

(ii) *Conclusion.* In this *Example 2,* the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A's* designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3,* the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4,* the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* The notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants or beneficiaries, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant or beneficiary for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-network. However, a participant or beneficiary may be required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount at least equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (B), and (C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to

determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Special rules regarding out-of-network minimum payment standards*—(A) The minimum payment standards set forth under paragraph (b)(3) of this section do not apply in cases where State law prohibits a participant or beneficiary from being required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer provides in benefits, or where a group health plan or health insurance issuer is contractually responsible for such amounts. Nonetheless, in such cases, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in network.

(B) A group health plan and health insurance issuer must provide a participant or beneficiary adequate and prominent notice of their lack of financial responsibility with respect to the amounts described under this paragraph (b)(3)(iii), to prevent inadvertent payment by the participant or beneficiary.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2,* by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3,* the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3.* Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4,* the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5,* the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5.* The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6,* the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the

higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 29 CFR part 2590, contained in the 29 CFR, parts 1927 to end, edition revised as of July 1, 2015.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Chapter I

For the reasons stated in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR parts 144, 146 and 147, which were published in the **Federal Register** on May 13, 2010 (75 FR 27122), June 17, 2010 (75 FR 34538), June 28, 2010 (75 FR 37188), and November 17, 2010 (75 FR 70114) with the following changes as set forth below:

PART 144—REQUIREMENTS RELATED TO HEALTH INSURANCE

■ 28. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 29. Section 144.103 is amended by revising the definition of ''preexisting condition exclusion'' to read as follows:

§ 144.103 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 30. The authority citation for part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

■ 31. Section 146.111(a)(1) is revised to read as follows:

§ 146.111 Preexisting condition exclusions.

(a) *Preexisting condition exclusion defined*—(1) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning of § 144.103 of this subchapter.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 32. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791 and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 33. Section 147.108 is revised to read as follows:

§ 147.108 Prohibition of preexisting condition exclusions.

(a) *In general.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103 of this subchapter).

(b) *Examples.* The rules of paragraph (a) of this section are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* § 146.111(a)(2) of this subchapter):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N. N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. Therefore, such an exclusion is prohibited.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M. M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion. See Example 2* in § 146.111(a)(2) of this subchapter for a conclusion that *M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(c) *Allowable screenings to determine eligibility for alternative coverage in the individual market*—(1) *In general.* (i) A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage options before offering a child-only policy if—

(A) The practice is permitted under State law;

(B) The screening applies to all child-only applicants, regardless of health status; and

(C) The alternative coverage options include options for which healthy children would potentially be eligible (*e.g.,* Children's Health Insurance Program (CHIP) or group health insurance).

(ii) An issuer must provide such coverage to an applicant effective on the first date that a child-only policy would have been effective had the applicant not been screened for an alternative coverage option, as provided by State law. A State may impose a reasonable time limit by when an issuer would have to enroll a child regardless of pending applications for other coverage.

(2) *Restrictions.* A health insurance issuer offering individual health insurance coverage may screen applicants for eligibility for alternative coverage provided that:

(i) The screening process does not by its operation significantly delay enrollment or artificially engineer eligibility of a child for a program targeted to individuals with a pre-existing condition;

(ii) The screening process is not applied to offers of dependent coverage for children; or

(ii) The issuer does not consider whether an applicant is eligible for, or is provided medical assistance under, Medicaid in making enrollment decisions, as provided under 42 U.S.C. 1396a (25)(G).

(d) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 34. Section 147.120 is revised to read as follows:

§ 147.120 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example,* the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent*—(1) *In general.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict dependent coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or primary subscriber, or any other person); residency with the participant (in the individual market, the primary subscriber) or with any other person; whether the child lives, works, or resides in an HMO's service area or other network service area; marital status; student status; employment; eligibility for other coverage; or any combination of those factors. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may require coverage of certain children.)

(2) *Construction.* A plan or issuer will not fail to satisfy the requirements of this section if the plan or issuer limits dependent child coverage to children under age 26 who are described in section 152(f)(1) of the Code. For an individual not described in Code section 152(f)(1), such as a grandchild or niece, a plan may impose additional conditions on eligibility for dependent child health coverage, such as a condition that the individual be a dependent for income tax purposes.

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1,* the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3,* the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

Example 4. (i) *Facts.* A group health plan sponsored by a large employer normally charges a copayment for physician visits that do not constitute preventive services. The plan charges this copayment to individuals age 19 and over, including employees, spouses, and dependent children, but waives it for those under age 19.

(ii) *Conclusion.* In this *Example 4,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age.

While the requirement of paragraph (d) of this section generally prohibits distinctions based upon age in dependent coverage of children, it does not prohibit distinctions based upon age that apply to all coverage under the plan, including coverage for employees and spouses as well as dependent children. In this *Example 4,* the copayments charged to dependent children are the same as those charged to employees and spouses. Accordingly, the arrangement described in this *Example 4* (including waiver, for individuals under age 19, of the generally applicable copayment) does not violate the requirement of paragraph (d) of this section.

(f) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 35. Section 147.126 is revised to read as follows:

§ 147.126 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii) and (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of essential health benefits for any individual, whether provided in-network or out-of-network.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) offered through a cafeteria plan pursuant to section 125 of the Internal Revenue Code is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term ''essential health benefits'' means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations. For this purpose, a group health plan or a health insurance issuer that is not required to provide essential health benefits under section 1302(b) must define ''essential health benefits'' in a manner consistent with one of the three Federal Employees Health Benefit Program (FEHBP) options as defined by 45 CFR 156.100(a)(3)or one of the base-benchmark plans selected by a State or applied by default pursuant to 45 CFR 156.100.

(d) *Special rule for health reimbursement arrangements (HRAs) and other account-based plans*—(1) *In general.* If an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in paragraph (a)(2) of this section, the fact that the benefits under the HRA or other account-based plan are limited does not mean that the HRA or other account-based plan fails to meet the requirements of paragraph (a)(2) of this section. Similarly, if an HRA or other account-based plan is integrated with other coverage under a group health plan and the other group health plan coverage alone satisfies the requirements in PHS Act section 2713 and § 147.130(a)(1), the HRA or other account-based plan will not fail to meet the requirements of PHS Act 2713 and § 147.130(a)(1).

(2) *Integration requirements.* An HRA or other account-based plan is integrated with a group health plan for purposes of paragraph (a)(2) of this section if it meets the requirements under either the integration method set forth in paragraph (d)(2)(i) of this section or the integration method set forth in paragraph (d)(2)(ii) of this section. Integration does not require that the HRA (or other account-based plan) and the group health plan with which it is integrated share the same plan sponsor, the same plan document, or governing instruments, or file a single Form 5500, if applicable. The term ''excepted benefits'' is used throughout the integration methods; for a definition of the term ''excepted benefits'' see Internal Revenue Code section 9832(c), ERISA section 733(c), and PHS Act section 2791(c).

(i) *Integration Method: Minimum value not required.* An HRA or other account-based plan is integrated with another group health plan for purposes of this paragraph if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based plan) to the employee that does not consist solely of excepted benefits;

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan (other than the HRA or other account-based plan) that does not consist solely of excepted benefits, regardless of whether the plan is offered by the same plan sponsor (referred to as non-HRA group coverage);

(C) The HRA or other account-based plan is available only to employees who are enrolled in non-HRA group coverage, regardless of whether the non-HRA group coverage is offered by the plan sponsor of the HRA or other account-based plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA group coverage, such as a group health plan maintained by the employer of the employee's spouse);

(D) The benefits under the HRA or other account-based plan are limited to reimbursement of one or more of the following—co-payments, co-insurance, deductibles, and premiums under the non-HRA group coverage, as well as medical care (as defined under section 213(d) of the Internal Revenue Code) that does not constitute essential health benefits as defined in paragraph (c) of this section; and

(E) Under the terms of the HRA or other account-based plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(ii) *Integration Method: Minimum value required.* An HRA or other account-based plan is integrated with

another group health plan for purposes of this paragraph if:

(A) The plan sponsor offers a group health plan (other than the HRA or other account-based plan) to the employee that provides minimum value pursuant to Code section 36B(c)(2)(C)(ii) (and its implementing regulations and applicable guidance);

(B) The employee receiving the HRA or other account-based plan is actually enrolled in a group health plan that provides minimum value pursuant to section 36B(c)(2)(C)(ii) of the Internal Revenue Code (and applicable guidance), regardless of whether the plan is offered by the plan sponsor of the HRA or other account-based plan (referred to as non-HRA MV group coverage);

(C) The HRA or other account-based plan is available only to employees who are actually enrolled in non-HRA MV group coverage, regardless of whether the non-HRA MV group coverage is offered by the plan sponsor of the HRA or other account-based plan (for example, the HRA may be offered only to employees who do not enroll in an employer's group health plan but are enrolled in other non-HRA MV group coverage, such as a group health plan maintained by an employer of the employee's spouse); and

(D) Under the terms of the HRA or other account-based plan, an employee (or former employee) is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan at least annually, and, upon termination of employment, either the remaining amounts in the HRA or other account-based plan are forfeited or the employee is permitted to permanently opt out of and waive future reimbursements from the HRA or other account-based plan.

(3) *Forfeiture.* For purpose of integration under paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section, forfeiture or waiver occurs even if the forfeited or waived amounts may be reinstated upon a fixed date, a participant's death, or the earlier of the two events (the reinstatement event). For this purpose coverage under an HRA or other account-based plan is considered forfeited or waived prior to a reinstatement event only if the participant's election to forfeit or waive is irrevocable, meaning that, beginning on the effective date of the election and through the date of the reinstatement event, the participant and the participant's beneficiaries have no access to amounts credited to the HRA or other account-based plan. This means that upon and after reinstatement, the reinstated amounts under the HRA or other account-based plan may not be used to reimburse or pay medical expenses incurred during the period after forfeiture and prior to reinstatement.

(4) *No integration with individual market coverage.* A group health plan, including an HRA or other account-based plan, used to purchase coverage on the individual market is not integrated with that individual market coverage for purposes of paragraph (a)(2) of this section (or for purposes of the requirements of PHS Act section 2713).

(5) *Integration with Medicare parts B and D.* For employers that are not required to offer their non-HRA group health plan coverage to employees who are Medicare beneficiaries, an HRA or other account-based plan that may be used to reimburse premiums under Medicare part B or D may be integrated with Medicare (and deemed to comply with PHS Act sections 2711 and 2713) if the following requirements are satisfied with respect to employees who would be eligible for the employer's non-HRA group health plan but for their eligibility for Medicare (and the integration rules under paragraphs (d)(2)(i) and (ii) of this section continue to apply to employees who are not eligible for Medicare):

(i) The plan sponsor offers a group health plan (other than the HRA or other account-based plan and that does not consist solely of excepted benefits) to employees who are not eligible for Medicare;

(ii) The employee receiving the HRA or other account-based plan is actually enrolled Medicare part B or D;

(iii) The HRA or other account-based plan is available only to employees who are enrolled in Medicare part B or D; and

(iv) The HRA or other account-based plan complies with paragraphs (d)(2)(i)(E) and (d)(2)(ii)(D) of this section.

(6) *Account-based plan.* An account-based plan for purposes of this section is an employer-provided group health plan that provides reimbursements of medical expenses other than individual market policy premiums with the reimbursement subject to a maximum fixed dollar amount for a period. An HRA is a type of account-based plan.

(e) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 36. Section 147.128 is revised to read as follows:

§ 147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if —

(i) The cancellation or discontinuance of coverage has only a prospective effect;

(ii) The cancellation or discontinuance of coverage is effective retroactively, to the extent it is attributable to a failure to timely pay required premiums or contributions (including COBRA premiums) towards the cost of coverage;

(iii) The cancellation or discontinuance of coverage is initiated by the individual (or by the individual's

authorized representative) and the sponsor, employer, plan, or issuer does not, directly or indirectly, take action to influence the individual's decision to cancel or discontinue coverage retroactively or otherwise take any adverse action or retaliate against, interfere with, coerce, intimidate, or threaten the individual; or

(iv) The cancellation or discontinuance of coverage is initiated by the Exchange pursuant to § 155.430 of this subchapter (other than under paragraph (b)(2)(iii) of this section).

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A's* prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146 of this subchapter. The questionnaire includes the following question: ''Is there anything else relevant to your health that we should know?'' *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A's* visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1,* the plan cannot rescind *A's* coverage because *A's* failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B.* After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B's* coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2,* the plan cannot rescind *B's* coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 37. Section 147.136 is revised to read as follows:

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*–(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 147.140. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must

comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants, beneficiaries and enrollees, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as

applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503–1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503–1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the issuer shall notify the claimant of the issuer's determination as soon as an issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) Avoiding conflicts of interest. In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(3)(ii)(E).

(*1*) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the name of the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(3)(ii)(F)(*2*) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(*2*) Notwithstanding paragraph (b)(3)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(*1*) of this section on the basis that the issuer met the standards for the exception under this paragraph (b)(3)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29 CFR 2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then

the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans)

include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment limitation provisions of Code section 9812 and § 54.9812, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (A denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan or health insurance coverage is not eligible for the Federal external review process under this paragraph (d)); and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1,* the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2,* the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model

Act and, therefore satisfies the requirements of paragraph (d)(2)) if such process provides the following.

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a preliminary review of the request to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan or health insurance coverage (*e.g.,* worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization.* (A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer at the time the claimant receives:

(A) An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph (d)(2)(iii)(B) of this section, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section and a self-insured nonfederal governmental plan may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the

applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements*—(i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language.* With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 38. Section 147.138 is revised to read as follows:

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic limitations with respect to the selection of primary care providers, in accordance with the terms of the plan or coverage, the underlying provider contracts, and applicable State law.

(iii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics (including pediatric subspecialties, based on the scope of that provider's license under applicable State law) as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network and is available to accept the child.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a

health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A,* a female, requests a gynecological exam with Physician *B,* an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A's* designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1,* the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A's* primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C,* an out-of-network provider.

(ii) *Conclusion.* In this *Example 2,* the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A's* designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3,* the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4,* the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for

emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount at least equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A),(B), and (C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Special rules regarding out-of-network minimum payment standards*—(A) The minimum payment standards set forth under paragraph (b)(3) of this section do not apply in cases where State law prohibits a participant, beneficiary, or enrollee from being required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer provides in benefits, or where a group health plan or health insurance issuer is contractually responsible for such amounts. Nonetheless, in such cases, a plan or issuer may not impose any copayment or coinsurance requirement for out-of-network emergency services that is higher than the copayment or coinsurance requirement that would apply if the services were provided in network.

(B) A group health plan and health insurance issuer must provide a participant, beneficiary, or enrollee adequate and prominent notice of their lack of financial responsibility with respect to the amounts described under this paragraph (b)(3)(iii), to prevent inadvertent payment by the participant, beneficiary, or enrollee.

(iv) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2,* by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates

the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3,* the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3.* Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4,* the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5,* the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5.* The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6,* the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

■ 39. Section 147.140 is revised to read as follows:

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan or group health insurance coverage has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage. Accordingly, if any benefit package relinquishes grandfather status, it will not affect the

grandfather status of the other benefit packages.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status*—(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act, and must provide contact information for questions and complaints, in any summary of benefits provided under the plan.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a ''grandfathered health plan'' under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime dollar limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or *www.dol.gov/ebsa/healthreform.* This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at *www.healthcare.gov.*]

(3)(i) *Documentation of plan or policy terms on March 23, 2010.* To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage.* To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual dollar limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010.* With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan*—(1) *In general.* Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010. Further, the addition of a new contributing employer or new group of employees of an existing contributing employer to a grandfathered multiemployer health plan will not affect the plan's grandfather status.

(2) *Anti-abuse rules*—(i) *Mergers and acquisitions.* If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility.* A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(iii) *Illustrative list of bona fide employment-based reasons.* For purposes of this paragraph (b)(2)(ii)(C), bona fide employment-based reasons include—

(A) When a benefit package is being eliminated because the issuer is exiting the market;

(B) When a benefit package is being eliminated because the issuer no longer offers the product to the employer;

(C) When low or declining participation by plan participants in the benefit package makes it impractical for the plan sponsor to continue to offer the benefit package;

(D) When a benefit package is eliminated from a multiemployer plan as agreed upon as part of the collective bargaining process; or

(E) When a benefit package is eliminated for any reason and multiple benefit packages covering a significant portion of other employees remain available to the employees being transferred.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G.* During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G.*

(ii) *Conclusion.* In this *Example 1,* the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I.* On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates

Option *H* and the employees that are moved are transferred to Option *I.* If instead of transferring employees from Option *H* to Option *I,* Option *H* was amended to match the terms of Option *I,* then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2,* the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I.* Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual dollar limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime dollar limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual dollar limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans—In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan. A plan or coverage will cease to be a grandfathered health plan when an amendment to plan terms that results in a change described in this paragraph (g)(1) becomes effective, regardless of when the amendment was adopted. Once grandfather status is lost, it cannot be regained.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition. Whether or not a plan or coverage has eliminated substantially all benefits to diagnose or treat a particular condition must be determined based on all the facts and circumstances, taking into account the items and services provided for a particular condition under the plan on March 23, 2010, as compared to the benefits offered at the time the plan or coverage makes the benefit change effective.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, and determined for each copayment level if

a plan has different copayment levels for different categories of services, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in § 146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(C) *Special rules regarding decreases in contribution rates.* An insured group health plan (or a multiemployer plan) that is a grandfathered health plan will not cease to be a grandfathered health plan based on a change in the employer contribution rate unless the issuer (or multiemployer plan) knows, or should know, of the change, provided:

(*1*) Upon renewal (or, in the case of a multiemployer plan, before the start of a new plan year), the issuer (or multiemployer plan) requires relevant employers, employee organizations, or plan sponsors, as applicable, to make a representation regarding its contribution rate for the plan year covered by the renewal, as well as its contribution rate on March 23, 2010 (if the issuer, or multiemployer plan, does not already have it); and

(*2*) The relevant policies, certificates, contracts of insurance, or plan documents disclose in a prominent and effective manner that employers, employee organizations, or plan sponsors, as applicable, are required to notify the issuer (or multiemployer plan) if the contribution rate changes at any point during the plan year.

(D) *Application to plans with multi-tiered coverage structures.* The standards for employer contributions in this paragraph (g)(1)(v) apply on a tier-by-tier basis. Therefore, if a group health plan modifies the tiers of coverage it had on March 23, 2010 (for example, from self-only and family to a multi-tiered structure of self-only, self-plus-one, self-plus-two, and self-plus-three-or-more), the employer contribution for any new tier would be tested by comparison to the contribution rate for the corresponding tier on March 23, 2010. For example, if the employer contribution rate for family coverage was 50 percent on March 23, 2010, the employer contribution rate for any new tier of coverage other than self-only (*i.e.,* self-plus-one, self-plus-two, self-plus-three or more) must be within 5 percentage points of 50 percent (*i.e.,* at least 45 percent). If, however, the plan adds one or more new coverage tiers without eliminating or modifying any previous tiers and those new coverage tiers cover classes of individuals that were not covered previously under the plan, the new tiers would not be analyzed under the standards for changes in employer contributions. For example, if a plan with self-only as the sole coverage tier added a family coverage tier, the level of employer contributions toward the family coverage would not cause the plan to lose grandfather status.

(E) *Group health plans with fixed-dollar employee contributions or no employee contributions.* A group health plan that requires either fixed-dollar employee contributions or no employee contributions will not cease to be a grandfathered health plan solely because the employer contribution rate changes so long as there continues to be no employee contributions or no increase in the fixed-dollar employee contributions towards the cost of coverage.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group or individual health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits. (But see § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* Grandfathered individual health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010. (*But see* § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits). (*But see* § 147.126, which generally prohibits all annual dollar limits on essential health benefits for plan years (in the individual market, policy years) beginning on or after January 1, 2014).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined.* For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined.* For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined.* For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage.* The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula.* The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(4) *Examples.* The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion.* In this *Example 1,* the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts.* Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion.* In this *Example 2,* the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion.* In this *Example 3,* the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts.* Same facts as *Example 3,* except the grandfathered health plan subsequently increases the $40 copayment requirement to $45 for a later plan year. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion.* In this *Example 4,* the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30 = 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 ($5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts.* On March 23, 2010, a grandfathered health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion.* In this *Example 5,* the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv)this section, which would permit an increase in the copayment of up to $5.36.

Example 6. (i) *Facts.* The same facts as *Example 5,* except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to $5.

(ii) *Conclusion.* In this *Example 6,* medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 x 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase

in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts.* On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion.* In this *Example 7,* the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts.* On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1000 for self-only coverage and $4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5000 − 1000)/5000) for self-only coverage and 67% ((12,000 − 4000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1200 for self-only coverage and $5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6000 − 1200)/6000) for self-only coverage and 67% ((15,000 − 5000)/15,000) for family coverage.

(ii) *Conclusion.* In this *Example 8,* because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts.* A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) Conclusion. In this *Example 9,* the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the (rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

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Part IV

Department of Labor

Office of Workers' Compensation Programs

20 CFR Part 30

Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act; Proposed Rules

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Part 30

RIN 1240–AA08

Claims for Compensation Under the Energy Employees Occupational Illness Compensation Program Act

AGENCY: Office of Workers' Compensation Programs, Department of Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains the changes to the regulations governing the administration of the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA or Act), being proposed by the Department of Labor (Department or DOL). Part B of the Act provides uniform lump-sum payments and medical benefits to covered employees and, where applicable, to survivors of such employees, of the Department of Energy (DOE), its predecessor agencies and certain of its vendors, contractors and subcontractors. Part B of the Act also provides smaller uniform lump-sum payments and medical benefits to individuals found eligible by the Department of Justice (DOJ) for benefits under section 5 of the Radiation Exposure Compensation Act (RECA) and, where applicable, to their survivors. Part E of the Act provides variable lump-sum payments (based on a worker's permanent impairment and/or qualifying calendar years of established wage-loss) and medical benefits for covered DOE contractor employees and, where applicable, provides variable lump-sum payments to survivors of such employees (based on a worker's death due to a covered illness and any qualifying calendar years of established wage-loss). Part E of the Act also provides these same payments and benefits to uranium miners, millers and ore transporters covered by section 5 of RECA and, where applicable, to survivors of such employees. The Office of Workers' Compensation Programs (OWCP) administers the adjudication of claims and the payment of benefits under EEOICPA, with National Institute for Occupational Safety and Health (NIOSH) within the Department of Health and Human Services (HHS) estimating the amounts of radiation received by employees alleged to have sustained cancer as a result of such exposure and establishing guidelines to be followed by OWCP in determining whether such cancers are at least as likely as not related to employment. Both DOE and DOJ are responsible for notifying potential claimants and for submitting evidence necessary for OWCP's adjudication of claims under EEOICPA.

DATES: Comments on the regulations in this proposed rule must be submitted on or before January 19, 2016. Written comments on the information collection requirements in this proposed rule must be received on or before December 18, 2015.

ADDRESSES: You may submit comments on the regulations in this proposed rule, identified by Regulatory Information Number (RIN) 1240–AA08, by any ONE of the following methods:

Federal e-Rulemaking Portal: The Internet address to submit comments on the regulations in the proposed rule is *www.regulations.gov.* Follow the Web site instructions for submitting comments. Comments will also be available for public inspection on the Web site.

Mail or Hand Delivery: Submit written comments to Rachel P. Leiton, Director, Division of Energy Employees Occupational Illness Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C–3321, 200 Constitution Avenue NW., Washington, DC 20210. The Department will only consider mailed comments that have been postmarked by the U.S. Postal Service or other delivery service on or before the deadline for comments.

Instructions: All comments must cite RIN 1240–AA08 that has been assigned to this rulemaking. Receipt of any comments, whether by Internet, mail or hand delivery, will not be acknowledged. Because the Department continues to experience significant delays in receiving postal mail in the Washington, DC area, commenters are encouraged to submit any mailed comments early.

In addition to having an opportunity to file comments on the regulations in this proposed rule, interested parties may file comments on the information collection requirements in this proposed rule with the Office of Management and Budget by mail, at Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of their comments to the Department by mail to Vincent Alvarez, U.S. Department of Labor, 200 Constitution Avenue NW., Room S–3201, Washington, DC 20210; by Fax to 202–693–1447; or by email to *alvarez.vincent@dol.gov.* In order to help ensure appropriate consideration, comments should mention at least one of the OMB control numbers mentioned in this preamble.

FOR FURTHER INFORMATION CONTACT: Rachel P. Leiton, Director, Division of Energy Employees Occupational Illness Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Room C–3321, 200 Constitution Avenue NW., Washington, DC 20210, Telephone: 202–693–0081 (this is not a toll-free number).

Individuals with hearing or speech impairments may access this telephone number via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA or Act), 42 U.S.C. 7384 *et seq.,* was originally enacted on October 30, 2000. The initial version of EEOICPA established a compensation program (known as Part B of the Act) to provide a uniform lump-sum payment of $150,000 and medical benefits as compensation to covered employees who had sustained designated illnesses due to their exposure to radiation, beryllium or silica while in the performance of duty for DOE and certain of its vendors, contractors and subcontractors. Part B of the Act also provides for payment of compensation to certain survivors of these covered employees, and for payment of a smaller uniform lump-sum ($50,000) to individuals (who would also receive medical benefits), or their survivors, who were determined to be eligible for compensation under section 5 of the Radiation Exposure Compensation Act (RECA), 42 U.S.C. 2210 note, by DOJ. Primary responsibility for the administration of Part B of the Act was assigned to DOL by Executive Order 13179 (''Providing Compensation to America's Nuclear Weapons Workers'') of December 7, 2000 (65 FR 77487). On May 25, 2001, the Department issued interim final regulations (66 FR 28948) governing its administration of Part B of the Act, and issued final regulations on December 26, 2002 (67 FR 78874) that went into effect on February 24, 2003.

The initial version of EEOICPA also created a second program (known as

Part D of the Act) that required DOE to establish a system by which DOE contractor employees (and their eligible survivors) could seek assistance from DOE in obtaining state workers' compensation benefits if a Physicians Panel determined that the employee in question had sustained a covered illness as a result of work-related exposure to a toxic substance at a DOE facility. A positive panel finding that was accepted by DOE required DOE, to the extent permitted by law, to order its contractor not to contest the claim for state workers' compensation benefits. However, Congress amended EEOICPA in Subtitle E of Title XXXI of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Public Law 108–375, 118 Stat. 1811, 2178 (October 28, 2004), by abolishing Part D of the Act and creating a new Part E (codified at 42 U.S.C. 7385s through 7385s-15) that it assigned to DOL for administration. Part E established a new system of variable federal payments for DOE contractor employees, uranium workers covered by section 5 of RECA, and eligible survivors of such employees. On June 8, 2005, the Department issued interim final regulations (70 FR 33590) governing its administration of Part E of the Act, and issued final regulations on December 29, 2006 (71 FR 78520) that went into effect on February 27, 2007.

II. Discussion of Proposed Changes to the Regulations

A. Stakeholder Engagement

As part of the development of the proposed rule, the Department hosted a telephonic listening session during which interested parties provided their views, ideas and concerns to Departmental leadership on the provisions of the existing regulations. The Department found the listening session to be helpful and considered relevant information raised during the session in developing the proposed regulations.

B. Overview of the Proposed Rule

The Department is proposing to amend certain of the existing regulations governing its administration of Parts B and E of EEOICPA to conform them to current administrative practice, based on its experience administering the Act since 2001, and to bring further clarity to the regulatory description of the claims adjudication process, and to improve the administration of the Act. The following discussion describes the proposed changes to the existing regulations that currently appear in 20 CFR part 30. Since some of these proposed changes involve moving existing text to new sections, please refer to those new sections when submitting comments on the proposed changes.

Subpart A—General Provisions

The proposed changes to the regulations in this subpart involve updating the language used in certain regulations in the introduction portion of subpart A, and both expanding upon existing definitional regulations and adding new definitions that memorialize programmatic determinations.

Introduction

The Department proposes to modify § 30.1 to update the Secretary's Order reference and delete the reference to the Assistant Secretary for Employment Standards, since that position, as well as the Employment Standards Administration, no longer exists. The proposed change to § 30.2 memorializes that HHS delegated its dose reconstruction responsibilities to NIOSH in 42 CFR 82.1. Consistent with this proposed change, the Department proposes to modify several other sections of the regulations, not otherwise discussed specifically below, to replace references to ''HHS'' in those sections with ''NIOSH.''

Definitions

The Department proposes to remove the language in the definition of a *beryllium vendor* in § 30.5(i) that references DOE's periodically published list of beryllium vendors in the **Federal Register**, since DOE no longer updates that list, and replace it with a reference to the final list of beryllium vendors that DOE published in the **Federal Register** on December 27, 2002. Based on the language of sections 7384l(7)(A) and 7384n(a)(2) of EEOICPA, the Department seeks to define a *beryllium vendor facility* in proposed § 30.5(j) as ''a facility owned and operated by a beryllium vendor.'' Proposed § 30.5(k) replaces the term ''medical doctor'' with ''licensed physician.''

The Department also proposes to update the existing definition of the *Department of Energy* or *DOE* in proposed § 30.5(w) to clarify that DOE's predecessor agencies date back to August 13, 1942, which is the date that the Manhattan Engineer District was established. In proposed § 30.5(x)(2)(iii), the Department adds language to bring this provision in line with programmatic policy, which states that a civilian employee of a state or federal government agency qualifies as a *Department of Energy contractor employee* if the agency employing that individual is found to have entered into a contract with DOE for the provision of one or more services it was not statutorily obligated to perform and DOE compensated the agency for those services, and also that the delivery or removal of goods from the premises of a DOE facility does not constitute a service for the purposes of determining a worker's coverage under the Act. Proposed § 30.5(ee) removes an ambiguity in the statute by more clearly defining the term *physician,* while proposed § 30.5(gg) simplifies the definition of a *specified cancer* by deleting the unnecessary references to ''RECA'' and ''EEOICPA.''

Further, the Department proposes to expand upon the existing definition of *time of injury* in new § 30.5(ii) by adding text explaining that the *time of injury* in a survivor's claim is the date of the employee's death. Finally, the Department proposes to add a definition for *time of payment* or *payment* in proposed § 30.5(jj) to define those terms as the date that a paper check issued by the Department of the Treasury is received by the payee or by someone who was legally able to act for the payee, or the date the Department of the Treasury made an Electronic Funds Transfer to the payee's financial institution.

Subpart B—Filing Claims; Evidence and Burden of Proof; Special Procedures for Certain Cancer Claims

The Department proposes revisions to subpart B, including changes in §§ 30.100 and 30.101 to require claimants to sign their own written claims, and in §§ 30.112 and 30.113 to codify the Department's current policy for evaluating affidavits and statements submitted by claimants as proof of an employee's work history or medical condition. In addition, the Department proposes other revisions that are described below, which update references and language used in the regulations that have changed since these regulations were last revised.

Filing Claims for Benefits Under EEOICPA

The Department proposes to amend § 30.100 to remove language in paragraphs (a) and (c)(1) allowing someone other than the employee to sign a written claim with the Department on the employee's behalf, and instead require that the employee sign his or her own claim. The same amendments are proposed in paragraphs (a) and (d)(1) in § 30.101 to require survivors to sign their own written claims. The Department believes that

this requirement will improve its communications with claimants. Also in §§ 30.100 and 30.101, the Department seeks to add the words ''or other carrier's date marking'' to the current language ''by postmark'' to reflect changes in delivery options, and to make that same change in several other sections of the regulations not otherwise discussed specifically below. In § 30.102(a), the Department proposes to remove the superfluous term ''minimum impairment rating'' and replace it with ''impairment rating.'' The term ''minimum impairment rating'' is an artifact left over from an early draft of what later was enacted as Part E of EEOICPA and has no intrinsic meaning in the scheme that Congress eventually passed. Due to the level of confusion its retention by Congress has caused, coupled with the fact that it serves no actual purpose because there is no ''minimum'' rating that is presumed, the Department seeks to remove that word when describing an employee's impairment rating.

Evidence and Burden of Proof

Proposed § 30.110 updates cross-references in that section. The Department proposes to amend §§ 30.112(b)(3) and 30.113(c) to remove the term ''self-serving'' when referring to affidavits and documents submitted to establish either covered employment or a covered medical condition. In its place, the proposed language codifies the program's practice of evaluating all employment and medical evidence in a claim when it decides if the claimant has met his or her burden of proof under § 30.111. The Department also proposes to amend § 30.114(b) to clarify that current paragraphs (b)(1) and (b)(2) pertain to Part B, and to add paragraph (b)(3) to provide that additional medical evidence, as described in other sections of the regulations, is required to establish claims for benefits under Part E.

Special Procedures for Certain Radiogenic Cancer Claims

Proposed § 30.115(a) deletes reference to HHS's regulation at 42 CFR 81.30, since HHS published a final rule in the **Federal Register** on February 6, 2012 to remove 42 CFR 81.30 from part 81. The proposed change to § 30.115(a)(2) deletes language stating that HHS may complete further development of the employee's work history and that it will provide DOE with a copy of the final dose reconstruction report for an employee, since HHS does not perform either of these actions.

Subpart C—Eligibility Criteria

The proposed changes in subpart C involve revising the existing regulations to better explain how the Department evaluates medical evidence submitted to establish a claim for chronic beryllium disease under Part B, and to provide the Department's current requirements for establishing work-related toxic exposure and a covered illness under Part E. In addition to those changes, the Department proposes minor updates to the language in this subpart, as explained below.

Eligibility Criteria for Claims Relating to Covered Beryllium Illness Under Part B of EEOICPA

Proposed § 30.205 updates cross-references in that section. The Department further proposes to amend § 30.206(a) to remove the language ''a facility owned, operated, or occupied by a beryllium vendor'' and to instead reference proposed § 30.5(j), which defines a *beryllium vendor facility.* Also, the Department proposes to add paragraph (d) in § 30.207 to memorialize its current practices for determining whether to evaluate an employee's medical evidence under either the pre- or post-1993 criteria outlined in section 7384l(13) of EEOICPA.

Eligibility Criteria for Claims Relating to Radiogenic Cancer Under Parts B and E of EEOICPA

Proposed §§ 30.210 and 30.211 update the cross-references in that section. Also, the proposed change in § 30.213(a) replaces the language ''the employee's radiation dose reconstruction'' with ''the employee's final dose reconstruction report.''

Eligibility Criteria for Claims Relating to Chronic Silicosis Under Part B of EEOICPA

Proposed § 30.220 updates the cross-references in that section. Proposed § 30.222 also updates the cross-reference in that section, and replaces the term ''medical doctor'' with ''licensed physician.''

Eligibility Criteria for Other Claims Under Part E of EEOICPA

Proposed § 30.230 updates the cross-references in that section. In addition, the Department proposes to amend § 30.231(a) to explain its current practice of evaluating affidavit evidence submitted by a claimant as proof of employment in conjunction with all evidence of employment to determine if the claimant has met his or her burden of proof under § 30.111. Proposed § 30.231(b) describes sources, in addition to the Site Exposure Matrices that are currently listed in that paragraph, that the Department considers to be reliable sources of information to establish whether an employee was exposed to a toxic substance at a DOE facility or a RECA section 5 facility. Proposed § 30.232(a) deletes the former Part D requirements for establishing a covered illness, as Congress abolished Part D and those requirements are now irrelevant. In its place, the Department seeks to add language to describe its current requirements for establishing a covered illness under Part E. Proposed § 30.232(b) updates the cross-reference in that paragraph.

Subpart D—Adjudicatory Process

The Department proposes to update the regulations in subpart D with policies that it has developed and followed since the last time these regulations were updated, and to increase both clarity and transparency in the claim adjudication process for radiogenic cancer claims filed under Part B of EEOICPA.

General Provisions

In § 30.300, the Department proposes to add language to explain that a claimant may seek judicial review of a final decision issued by FAB by filing an action in federal district court, since the current regulations do not provide this explanation.

Recommended Decisions on Claims

The Department proposes to modify § 30.306 to make recommended decisions more understandable by mandating that they include a narrative discussion of the district office's findings of fact and conclusions of law. The Department also proposes to move the provisions in current § 30.307 to § 30.308. Proposed § 30.307(a) describes the Department's longstanding general policy of issuing a single recommended decision to all of the survivors who filed claims under Part B and/or Part E of EEOICPA relating to the same deceased employee. Proposed § 30.307(b) explains the exception to the policy, which is that if another individual subsequently files a survivor claim for the same award referenced in proposed § 30.307(a), the recommended decision on that claim will not address the entitlement of the earlier claimants if the district office recommended that the later survivor claim be denied. No changes were made to the language in proposed § 30.308.

Hearings and Final Decisions on Claims

The Department proposes amending § 30.314(a), which currently provides a

FAB reviewer with the discretion to conduct hearings by telephone or teleconference, to also allow the FAB reviewer to conduct hearings by videoconference or other electronic means. Proposed § 30.314(b) includes new language to provide the FAB reviewer with the discretion to mail a hearing notice less than 30 days prior to the hearing if the claimant and/or representative waives the 30-day notice period in writing. The Department believes this will provide FAB with more flexibility when it comes to scheduling oral hearings. Proposed § 30.315(a) adds a provision that prohibits a claimant or representative from making more than one request to reschedule a hearing, since repeated requests to cancel and reschedule hearings have resulted in an undue burden on the claim adjudication process.

Since the beginning of OWCP's administration of Part B of EEOICPA, FAB reviewers have struggled with their regulatory obligation in existing § 30.318 to consider objections to final dose reconstruction reports that have been prepared by NIOSH during its portion of the adjudication process for radiogenic cancer claims. Currently, a FAB reviewer must decide if an objection to a final dose reconstruction report concerns the ''methodology'' that NIOSH used to calculate the estimated doses in the report, which cannot be considered by the FAB reviewer because it is binding on FAB, or if the objection concerns the ''application'' of that methodology to the individual facts of the claim, in which case it *can* be considered by the FAB reviewer. Because it can be difficult to understand the differences between these two possibilities, FAB reviewers have had varying levels of success in making these distinctions. This experience has also been frustrating for claimants, and has convinced the Department that FAB reviewers are ill-suited to address objections that concern matters within the particular scientific expertise of NIOSH.

As part of its dose reconstruction process described in 42 CFR part 82, NIOSH confers with claimants prior to finalizing a dose reconstruction report; however, information regarding those discussions is not always included in the final dose reconstruction report. NIOSH has agreed to include information regarding how it considered and addressed claimant concerns in the final dose reconstruction report it sends to OWCP, and has also agreed to make personnel available to help FAB reviewers address any objections raised while the claim is pending before FAB. Therefore, the Department proposes to modify § 30.318(a) to describe the potential for NIOSH to be more explicitly involved in FAB's consideration of objections to final dose reconstruction reports. By making these changes, the Department will be doing away with the current limitation on the scope of objections that can be raised before FAB. The Department also proposes to clarify its obligation to consider objections to how OWCP calculates the probability of causation in new § 30.318(b). All of the proposed changes to current § 30.318 are being proposed in an effort to be responsive to concerns expressed by claimants.

Lastly, the Department proposes to change §§ 30.310(b) and 30.319(b) to reflect recent changes in how the program receives and processes mail.

Reopening Claims

Proposed § 30.320(b)(2) allows claimants to request a reopening based on new medical evidence diagnosing a medical condition. The Department believes that this will afford claimants a greater opportunity to obtain additional review of their denied claim based on new medical evidence.

Subpart E—Medical and Related Benefits

The changes to subpart E consist of clarifying the Department's policies regarding paying for the treatment of covered medical conditions. Also in subpart E, the Department seeks to make changes relating to its payment for non-physician services, and to its ability to administratively close claims when an employee refuses to attend directed medical examinations. Other minor proposed changes are discussed below.

Medical Treatment and Related Issues

The Department proposes to move language in current § 30.400(a) to proposed new § 30.400(d) in order to bring attention to its longstanding policy regarding the payment of certain medical benefits to survivors. The Department also proposes to make a number of changes to § 30.400(c). First, the Department proposes to add new language in this paragraph to explain the current qualifications that must be met before hospitals and providers of medical services or supplies may furnish appropriate services, drugs, supplies and appliances to covered employees. In addition, the Department proposes to add authority for it to offset the cost of prior rental payments against the future purchase of an appliance or supply, and to provide refurbished equipment where appropriate. Further, the Department is adding language recognizing its existing authority to pay for durable medical equipment and modifications to a home or vehicle that it deems necessary and reasonable. Lastly, the Department seeks to codify its authority to contract with specific providers to provide non-physician services and appliances. The Department believes that providing such services in this manner may aid in delivering some types of benefits.

The Department proposes to reorganize § 30.403 into three separate paragraphs, and to better focus the section on its payment of claims under section 7384t of EEOICPA for home health care, nursing home, and assisted living services, which comprise the bulk of services of this type being provided. Proposed § 30.403(a) incorporates the descriptive text in current § 30.403 with minor modifications, and proposed § 30.403(b) describes OWCP's general requirements for payment of a claim for nursing home and assisted living services. Furthermore, proposed paragraph (c) in § 30.403 sets out the particular pre-authorization process used to file an initial claim under section 7384t of EEOICPA for home health care, nursing home, and assisted living services. The proposed changes to paragraph (c) in § 30.405 clarify the Department's policy for approving or denying an employee's request to change treating physicians.

Directed Medical Examinations

The Department proposes to amend §§ 30.410(c) and 30.411(d) to memorialize the Department's existing authority to administratively close an employee's claim when he or she refuses to attend a second opinion examination or a referee medical examination, respectively.

Medical Reports

Proposed § 30.416(a) removes language that a physician's stamp will be accepted in lieu of his or her signature on such a report, and specifies that the physician's handwritten or electronic signature should be on his or her medical report.

Subpart F—Survivors; Payments and Offsets; Overpayments

The proposed changes to the regulations in this subpart involve memorializing the Department's policy determinations relating to the definition of a ''child'' under Parts B and E, and the eligibility requirements for a ''covered child'' under Part E.

Survivors

The Department proposes to amend the first sentence in § 30.500(a)(2) to

provide the Department's policy determination that a ''child'' under Parts B and E of EEOICPA means only a biological child, a stepchild or an adopted child of a deceased covered Part B or Part E employee. Also, the Department proposes to move the statutory definition of a ''covered child'' currently stated in the second sentence of § 30.500(a)(2) to its own new paragraph in proposed § 30.500(c). Proposed § 30.500(c) further provides that a child's marital status or dependency on the covered employee for support is irrelevant to his or her eligibility for benefits as a covered child under Part E, and that *incapable of self-support* means that the child must have been physically and/or mentally incapable of self-support at the time of the covered employee's death. The above new language codifies the Department's current policy and case law. *See Watson* v. *Solis,* 693 F.3d 620 (6th Cir. 2012). Finally, proposed §§ 30.501 and 30.502 update the cross-references in those sections.

Subpart G—Special Provisions

The Department proposes to modify § 30.600 to clearly state that a representative does not have the authority to sign either Form EE–1 or Form EE–2, to be consistent with proposed §§ 30.100 and 30.101. Proposed § 30.601 adds language to provide that a representative must comply with the Department's conflict of interest policy. Proposed § 30.603 clarifies that a representative may charge a claimant for costs and expenses related to a claim in addition to the fee limitations specified in § 30.603(b).

Subpart H—Information for Medical Providers

The majority of changes in this subpart update the regulations to take into account the Department's electronic bill processing and authorization system. In addition, the Department seeks to modify the method by which it excludes medical providers so that the Department of Labor's Office of Inspector General (DOL OIG) is involved in that process.

Medical Records and Bills

The Department proposes to amend § 30.700 to describe, for the first time, its provider enrollment process and automated bill processing and authorization system. Proposed § 30.701(a) recognizes that the Department may withhold payment for services until the required medical evidence described in § 30.700 is provided, and clarifies that charges for medicinal drugs dispensed in a physician's office must be reported on Form OWCP–1500 or CMS–1500.

Proposed § 30.701(b) describes the Department's existing discretion to determine which codes to use in the billing process, and to create and supply specific codes to be used by providers. Proposed § 30.701(c)(1) clarifies the Department's current billing procedures for providers to follow when submitting charges, and alerts providers that the Department may adopt the Home Health Prospective Payment System, which was devised by the Centers for Medicare and Medicaid Services (CMS) within HHS. Proposed § 30.701(d) makes clear that providers must adhere to accepted industry standards when billing, and that billing practices such as upcoding and unbundling are not in accord with those industry standards. Proposed § 30.701(e) describes the Department's current practice of rejecting a bill that does not conform to the requirements in § 30.701, after which the rejected bill is returned to the provider to be corrected and resubmitted. Proposed § 30.701(e) also makes clear the Department's policy that a bill must contain the provider's handwritten or electronic signature when required by the pertinent billing form, and removes language that a provider's stamp will be accepted in lieu of his or her signature on the bill.

The changes to § 30.702 clarify how an employee currently seeks reimbursement for out-of-pocket expenses. Proposed § 30.702(a) adds a reference to Forms OWCP–04 and UB–04 to clarify that those forms are required for reimbursement of hospital charges. In addition, proposed paragraph (a)(1) in § 30.702 provides that the Department will reject a reimbursement request if a provider does not indicate the code or a description of the service, so that the employee can correct and resubmit the required information. The Department proposes to amend § 30.702(d), which currently provides that the Department's decision regarding reimbursement to an employee for out-of-pocket expenses is final, and to instead provide that the Department will issue a letter decision in such circumstances. A claimant who disagrees with the letter decision may request a formal recommended decision and utilize the adjudicatory process described in subpart D. Lastly, the Department seeks to add paragraph (h) to § 30.702 to require that an employee submit Form OWCP–957, along with proof of payment, with a request for reimbursement for the costs and expenses specified.

Medical Fee Schedule

The Department proposes to modify § 30.705 to provide that it may require nursing homes to abide by a fee schedule, and also proposes to update the indices used to determine maximum fees in §§ 30.706 and 30.707. The Department proposes to modify the introductory text in § 30.709 to provide the Department with the authority to contract for, or require the use of, specific providers for medicinal drugs, and proposed § 30.709(a) clarifies that the fee schedule for medicinal drugs applies whether the drugs are dispensed by a pharmacy or by a doctor in his office. Finally, proposed § 30.709(c) codifies the Department's authority to require the use of generic drugs, where appropriate.

Proposed § 30.710 changes the terminology used in that section to refer to the ''Inpatient Prospective Payment System'' devised by CMS, instead of the obsolete ''Prospective Payment System.'' The Department also proposes to add new § 30.711 to explain its current practice of paying hospitals for outpatient medical services according to Ambulatory Payment Classifications based on the Outpatient Prospective Payment System devised by CMS.

To accommodate the proposed addition of new § 30.711, existing §§ 30.711, 30.712 and 30.713 appear below as §§ 30.712, 30.713 and 30.714. In addition, the Department proposes to change existing § 30.711(a), which appears below as new § 30.712(a), to clearly state that the Department will not correct procedure or diagnosis codes on submitted bills. Rather, those bills will be returned to the provider for correction because the responsibility for proper submission lies with the provider. The Department also proposes to amend existing § 30.712(b), which appears below as § 30.713(b), to reflect the current process used by providers to challenge a reduction of a fee based on a fee schedule.

Exclusion of Providers

The Department proposes to amend § 30.715 by adding paragraphs (i) and (j), which set out additional, reasonable bases for excluding providers. In proposed § 30.715(i), a provider may be excluded for failing to inform the Department of any change in their provider status, and in proposed § 30.715(j), a provider may be excluded for engaging in conduct related to care found by the Department to be misleading, deceptive or unfair. Proposed § 30.716(c) also adds language to clarify that a provider may voluntarily choose to be excluded

without undergoing the exclusion process. This clarification is meant to address situations where providers agree to be excluded when a provider may be faced with criminal charges. Most importantly, the Department proposes to amend § 30.717 to provide that the DOL OIG will be primarily responsible for investigating all possible exclusions of providers. This function was previously handled by OWCP; however, OWCP has no investigatory arm and lacks resources to carry out this responsibility. The Department also proposes amending §§ 30.718 through 30.721 in order to permit the Director for Energy Employees Occupational Illness Compensation to specify the deciding official, as appropriate. Proposed §§ 30.718 through 30.721 will recognize the new role of DOL OIG in this process.

The Department proposes revising §§ 30.723 through 30.724 to modify the manner in which the administrative law judge's recommended decision on exclusion becomes final. Currently, the decision becomes final if no objection is filed, and the proposed change states that no recommended decision regarding exclusion will become final until the Director for Energy Employees Occupational Illness Compensation issues the decision in final form. Finally, the Department proposes to amend § 30.725 to add language stating that it will notify the state or local authority responsible for licensing or certifying the excluded party of the exclusion, and also proposes revising § 30.726 to correct outdated terminology.

Subpart I—Wage-Loss Determinations Under Part E of EEOICPA

The proposed changes in this subpart involve both expanding upon existing definitional regulations and adding new definitions that memorialize programmatic determinations. Also, the Department proposes to reorganize existing §§ 30.805 through 30.806, and to add proposed § 30.807 in order to better describe the process it currently uses to evaluate evidence in a wage-loss claim.

General Provisions

In addition to updating the cross-references in proposed § 30.800, the Department proposes to use months instead of quarters in the definition of *average annual wage* in § 30.801(a), to conform with 42 U.S.C. 7385s–2(a)(2)(A)(ii) and its current practices. In proposed § 30.801(c), the Department seeks to add a definition of the term *month during which the employee was unemployed,* and adjusts the constant dollars in the definition of a *quarter during which the employee was unemployed* to 2013 constant dollars in proposed § 30.801(e). Also, the Department proposes to define a *trigger month* in new § 30.801(f), consistent with the statute, as the calendar month during which a covered Part E employee first experienced a loss of wages due to exposure to a toxic substance at a DOE facility or RECA section 5 facility. The Department proposes to move the definition of *wages,* which is currently referenced in the last sentence of § 30.805(a), to its own new paragraph in proposed § 30.801(g), and to amend that definition to focus on earned income from regular employment, rather than just taxable income, and to provide examples of what the Department considers as *wages* for the purposes of this subpart.

Evidence of Wage-Loss

Proposed § 30.805(a) sets out in detail the criteria for establishing eligibility for wage-loss benefits under Part E. Proposed § 30.805(b) explains that the Department may discontinue development of a covered Part E employee's request for wage-loss benefits at any point when the claimant is unable to meet his or her burden of proof to submit factual and/or medical evidence to establish the criteria specified in proposed § 30.805(a). Proposed § 30.806 is substantially similar to current § 30.805(b), except that it provides an explanation of what the Department considers to be ''rationalized'' medical evidence, *i.e.,* medical evidence based on a physician's fully explained and reasoned decision, which a covered Part E employee must submit in order to establish that the wage-loss at issue was causally related to the employee's covered illness.

Additionally, proposed § 30.806 memorializes the Department's policy and federal district court jurisprudence that wage-loss sustained due to something other than a covered illness is not compensable wage-loss under Part E of EEOICPA. *See Trego* v. *U.S. Dep't of Labor,* 681 F.Supp.2d 894 (E.D. Tenn. 2009). Proposed § 30.807(a) is substantially similar to current § 30.805(a), except to state that the Department may rely upon annual, as well as quarterly wage information, that has been reported to the Social Security Administration (SSA). The current provision refers to only quarterly wage information reported to SSA; however, employers also report wages on an annual basis to SSA. Also, as discussed above, the Department seeks to remove language defining ''wages'' in current § 30.805(a) and place it in new § 30.801(g). Proposed § 30.807(b) is largely the same as current § 30.806.

Determinations of Average Annual Wage and Percentages of Loss

The Department proposes to revise § 30.810 to state that it will calculate the average annual wage of a covered Part E employee using months instead of quarters, to be consistent with proposed § 30.801(a). Proposed § 30.811(a) combines the text from paragraphs (a) and (b) in current § 30.811, since the Department believes that the current language in those paragraphs is repetitive.

Subpart J—Impairment Benefits Under Part E of EEOICPA

The Department proposes to revise subpart J to update obsolete terminology and clarify its requirements for impairment rating determinations. Also in subpart J, the Department proposes to include in the regulations its existing policy for reducing the amount of an impairment award that is subject to any required offset and/or coordination of benefits.

General Provisions

Proposed §§ 30.901 and 30.902 replace the term ''minimum impairment rating'' with ''impairment rating,'' since the earlier term has no meaning in the Act. The Department also proposes to add text in new § 30.902(b) regarding its current policy of proportionately reducing an impairment award in circumstances when such award is payable based on a whole person impairment rating and at least one of the impairments is subject to a reduction under §§ 30.505(b) and/or 30.626.

Medical Evidence of Impairment

Proposed § 30.908 also replaces the term ''minimum impairment rating'' with ''impairment rating,'' to be consistent with the changes in §§ 30.102(a), 30.901 and 30.902.

III. Statutory Authority

Section 7384d of EEOICPA provides general statutory authority, which E.O. 13179 allocates to the Secretary, to prescribe rules and regulations necessary for administration of Part B of the Act. Section 7385s–10 provides the Secretary with the general statutory authority to administer Part E of the Act. Sections 7384t, 7384u and 7385s–8 provide the specific authority regarding medical treatment and care, including authority to determine the appropriateness of charges. The Federal Claims Collection Act of 1966, as amended (31 U.S.C. 3701 *et seq.*), authorizes imposition of interest charges

and collection of debts by withholding funds due the debtor.

IV. Executive Orders 12866 and 13563

E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including distributive impacts, equity, and potential economic, environmental, public health and safety effects). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866.

Section 3(f) of E.O. 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule that: (1) Has an annual effect of $100 million or more, or adversely affects in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as economically significant); (2) creates serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impacts of entitlement grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raises novel legal or policy issues arising out of legal mandates, the Presidents priorities, or the principles set forth in E.O. 12866.

The Department believes that the proposed rule is needed to update the existing regulations to reflect the program's current processes, and to incorporate the policy and procedural changes that have been implemented since the existing regulations were issued in 2006.

The Department has considered the benefits and costs that would result from the proposed rule. As discussed in the Overview of the Proposed Rule below, proposed § 30.318 will benefit claimants by providing better and more transparent responses to objections to final dose reconstruction reports provided by NIOSH in claims for radiogenic cancer, because NIOSH is the agency with scientific expertise in the relevant field. Proposed §§ 30.700 through 30.726 will benefit private sector providers of medical services and supplies by clarifying and bringing the program's billing and exclusion regulations into conformance with the current practices of other benefit programs administered by OWCP. And finally, proposed § 30.403 will benefit claimants by standardizing the current process for requesting pre-authorization for in-home health care services and realigning that process to better serve the needs of the program's beneficiaries. The Department does not believe that any of the above significant policies in the proposed rule will result in increased or decreased administrative costs to either the program or the public, or any increase in benefits paid.

This rule has been designated a ''significant regulatory action'' although not economically significant under section 3(f) of E.O. 12866. The rule is not economically significant because it will not have an annual effect on the economy of $100 million or more. Accordingly, the rule has been reviewed by the Office of Management and Budget.

V. Regulatory Flexibility Act

This proposed rule has been reviewed in accordance with the Regulatory Flexibility Act of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 601–612. The Department has concluded that the rule does not involve regulatory and informational requirements regarding businesses, organizations, and governmental jurisdictions subject to the regulation.

VI. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations, 5 CFR part 1320, require that the Department consider the impact of paperwork and other information collection burdens imposed on the public. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

This notice of proposed rulemaking contains information collection requirements subject to the PRA. The information collection requirements set out in §§ 30.700, 30.701 and 30.702 of this proposed rule, which relate to information required to be submitted by claimants and medical providers in connection with the processing of bills, were both submitted to and approved by OMB under the PRA, and the currently approved collections in OMB Control Nos. 1240–0007 (expires January 31, 2016), 1240–0019 (expires January 31, 2016), 1240–0021 (expires January 31, 2016), 1240–0044 (expires December 31, 2015) and 1240–0050 (expires January 31, 2016) were not affected by any of the substantive changes that have been made in this proposed rule.

The information collection requirements in §§ 30.100, 30.101, 30.102, 30.103, 30.112, 30.113, 30.206, 30.207, 30.213, 30.222, 30.231, 30.232 and 30.416 of this proposed rule were also previously submitted to and approved by OMB under the PRA, and were assigned OMB Control No. 1240–0002 (expires December 31, 2016). This second group of information collection requirements was also not affected by any of the substantive changes that have been made in this rule. However, this rule revises the currently approved collection in OMB Control No. 1240–0002 by adding two new information collection requirements and by moving one existing information collection requirement; this revision of a currently approved collection will be submitted to OMB for review under the PRA on the date of publication of this rule. The new information collection requirements in this rule are in §§ 30.114 and 30.403 and relate to information required to be submitted by or on behalf of claimants as part of the EEOICPA claims adjudication process. While the information collection requirements in § 30.807(b) relating to information to be submitted by claimants in support of claims for wage-loss benefits are not new and have been approved under the PRA in OMB Control No. 1240–0002 (as 20 CFR 30.806), they have been moved in this proposed rule, without substantive change, to new § 30.807(b); this new location will be incorporated into OMB Control No. 1240–0002 in this revision. The Department is proposing to create two new forms to implement one of the new collections (see sections C and D below). The remaining new collections will be implemented by adding them to existing Forms EE/EN–11A and EE/EN–11B (see sections A and B below).

A. Letter to Claimant About Claiming for Impairment Benefits Under Part E, Sent With Enclosure EN–11A: Form EE–11A (§§ 30.114(b)(3), 30.905 and 30.907)

Summary: Employees and/or survivors claiming for the first time that a covered illness has resulted in permanent impairment must submit a narrative medical report from a physician that conforms to the methodology of the 5th Edition of the American Medical Association's *Guides to the Evaluation of Permanent Impairment* (AMA's *Guides*) and provides a rating of whole-person impairment. In order to obtain the necessary type of medical report, Form EE–11A explains the requirements for

that report to covered Part E employees (or their survivors), and enclosure EE–11A provides them with the opportunity to choose their own physician to submit the report, or to ask OWCP to arrange for the report.

Need: Proper medical evidence of permanent impairment is necessary to establish entitlement to benefits for permanent impairment under Part E of EEOICPA.

Respondents and proposed frequency of response: It is estimated that 3,767 Part E respondents annually will submit this collection of information once.

Estimated total annual burden: The time required to review instructions, search existing data sources, gather the data needed, and complete and review each collection of this information is estimated to take an average of 15 minutes per response for a total annual burden of 942 hours.

B. Letter to Claimant About Claiming for Wage-Loss Benefits Under Part E, Sent With Enclosure EE–11B: Form EE–11B (§§ 30.114(b)(3) and 30.807(b))

Summary: Employees and/or survivors claiming for the first time that a covered illness has resulted in wage-loss must submit both earnings information and a narrative medical report from a physician that shows a causal relationship between the claimed wage-loss and the accepted ''covered illness.'' In order to obtain the necessary earnings information and medical report, Form EE–11B explains the type of factual and medical evidence that is required to support an initial claim for wage-loss benefits, and enclosure EN–11B collects information on the period of time for which the claim for wage-loss benefits is being made.

Need: Factual and medical evidence of wage-loss is necessary to establish entitlement to benefits for wage-loss under Part E of EEOICPA.

Respondents and proposed frequency of response: It is estimated that 520 Part E respondents annually will submit this collection of information once.

Estimated total annual burden: The time required to review instructions, search existing data sources, gather the data needed, and complete and review each collection of this information is estimated to take an average of 30 minutes per response for a total annual burden of 260 hours.

C. Claim for Home Health Care, Nursing Home or Assisted Living Benefits Under the Energy Employees Occupational Illness Compensation Program Act: Form EE–17A (§ 30.403)

Summary: Covered Part B and covered Part E employees who have been awarded medical benefits for treatment of accepted illnesses by OWCP may file claims for Home Health Care, Nursing Home, or Assisted Living Benefits; all of these specific medical benefits require pre-authorization by OWCP and a Letter of Medical Necessity. In order to obtain the name and contact information for the beneficiary's treating physician, Form EE–17A requires covered Part B and Part E employees to provide the name, address and telephone number of the physician that OWCP should contact to obtain the Letter of Medical Necessity when they make their first claim for these benefits.

Need: A Form EE–17A claiming for Home Health Care, Nursing Home, or Assisted Living Benefits is necessary to initiate OWCP's first adjudication process for these specific pre-authorized medical benefits filed by covered Part B and covered Part E employees.

Respondents and proposed frequency of response: It is estimated that 3,286 respondents annually will file one Form EE–17A.

Estimated total annual burden: The time required to review instructions, search existing data sources, gather the data needed, and complete and review each Form EE–17A is estimated to take an average of five minutes per respondent for a total added annual burden of 274 hours.

D. Physician's Certification of Medical Necessity for Home Health Care, Nursing Home or Assisted Living Benefits Under the Energy Employees Occupational Illness Compensation Program Act: Form EE–17B (§ 30.403)

Summary: Covered Part B and covered Part E employees who have been awarded medical benefits for treatment of accepted illnesses by OWCP may file claims for Home Health Care, Nursing Home, or Assisted Living Benefits; these specific medical benefits require both pre-authorization by OWCP and a Letter of Medical Necessity from the treating physician that supports the need for the claimed benefits. In order to obtain the required Letter of Medical Necessity the first time a claim is filed, OWCP will send the beneficiary's treating physician a Form EE–17B requesting this required medical evidence. The Form EE–17B also asks the physician to verify that a face-to-face physical examination was conducted, which is required by OWCP procedures.

Need: A Form EE–17B requesting a Letter of Medical Necessity to support an initial claim for Home Health Care, Nursing Home, or Assisted Living Benefits filed by a covered Part B or covered Part E employee is needed so OWCP can adjudicate the initial claim for these pre-authorized medical benefits.

Respondents and proposed frequency of response: It is estimated that 3,286 respondents annually will file one Form EE–17B.

Estimated total annual burden: The time required to review instructions, search existing data sources, gather the data needed, and complete and review each Form EE–17B is estimated to take an average of 30 minutes per respondent for a total annual burden of 1,643 hours.

E. Information Collection Request (ICR) Submissions to OMB and Request for Comments

Consistent with requirements codified at 40 U.S.C. 3506(a)(1)(B), (c)(2)(b) and 3507(a)(1)(D), and 5 CFR 1320.11, the Department has submitted a series of ICRs to OMB for approval under the PRA, in order to update the information collection approvals to reflect this rulemaking and provide interested parties a specific opportunity to comment under the PRA. Allowing an opportunity for comment 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. OMB and the Department are particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

F. Burden Summaries

The information collections in this rule may be summarized as follows. The number of responses and burden estimates listed are not specific to the Energy program; instead, the estimates

are cumulative for all OWCP-administered compensation programs that collect this information.

1. *Title of Collection:* Energy Employees Occupational Illness Compensation Program Act Forms.
OMB Control Number: 1240–0002.
Total Estimated Number of Responses: 67,325 (1305 due to this rulemaking).
Total Estimated Annual Time Burden: 23,746 hours (556 due to this rulemaking).
Total Estimated Annual Other Costs Burden: $31,503 ($3,414 due to this rulemaking).

2. *Title of Collection:* Claim for Medical Reimbursement Form.
OMB Control Number: 1240–0007.
Total Estimated Number of Responses: 38,480.
Total Estimated Annual Time Burden: 6,388 hours.
Total Estimated Annual Other Costs Burden: $68,879.

3. *Title of Collection:* Uniform Billing Form (OWCP–04).
OMB Control Number: 1240–0019.
Total Estimated Number of Responses: 221,992.
Total Estimated Annual Time Burden: 25,503 hours.
Total Estimated Annual Other Costs Burden: $0.

4. *Title of Collection:* Provider Enrollment Form.
OMB Control Number: 1240–0021.
Total Estimated Number of Responses: 31,979.
Total Estimated Annual Time Burden: 4,252 hours.
Total Estimated Annual Other Costs Burden: $16,629.

5. *Title of Collection:* Health Insurance Claim Form.
OMB Control Number: 1240–0044.
Total Estimated Number of Responses: 2,777,034.
Total Estimated Annual Time Burden: 260,873 hours.
Total Estimated Annual Other Costs Burden: $0.

6. *Title of Collection:* Pharmacy Billing Requirements.
OMB Control Number: 1240–0050.
Total Estimated Number of Responses: 1,453,300.
Total Estimated Annual Time Burden: 24,421 hours.
Total Estimated Annual Other Costs Burden: $0.

VII. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531 *et seq.*) directs agencies to 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.'' For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any federal mandate that may result in increased annual expenditures in excess of $100 million by state, local or tribal governments in the aggregate, or by the private sector.

VIII. Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with E.O. 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' The proposed 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.''

IX. Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments)

The Department has reviewed this proposed rule in accordance with E.O. 13175 and has determined that it does not have ''tribal implications.'' The proposed rule does not ''have substantial direct effects 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.''

X. Executive Order 12988 (Civil Justice Reform)

This regulation has been drafted and reviewed in accordance with E.O. 12988, Civil Justice Reform, and will not unduly burden the Federal court system. The regulation has been written so as to minimize litigation and provide a clear legal standard for affected conduct, and has been reviewed carefully to eliminate drafting errors and ambiguities.

XI. Executive Order 13045 (Protection of Children From Environmental, Health Risks and Safety Risks)

In accordance with E.O. 13045, the Department has evaluated the environmental health and safety effects of this rule on children, and has determined that it will have no effect on children.

XII. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with E.O. 13211, the Department has evaluated the effects of this rule on energy supply, distribution or use, and has determined that it is not likely to have a significant adverse effect on them.

List of Subjects in 20 CFR Part 30

Administrative practice and procedure, Cancer, Claims, Kidney diseases, Leukemia, Lung diseases, Miners, Radioactive materials, Tort claims, Underground mining, Uranium, Workers' compensation.

Text of the Rule

For the reasons stated in the preamble, the Department of Labor proposes to amend subchapter C consisting of part 30 as follows:

SUBCHAPTER C—ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000

PART 30—CLAIMS FOR COMPENSATION UNDER THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS COMPENSATION PROGRAM ACT OF 2000, AS AMENDED

■ 1. The authority citation for part 30 is revised to read as follows:

Authority: 5 U.S.C. 301; 31 U.S.C. 3716 and 3717; 42 U.S.C. 7384d, 7384t, 7384u and 7385s–10; Executive Order 13179, 65 FR 77487, 3 CFR, 2000 Comp., p. 321; Secretary of Labor's Order No. 10–2009, 74 FR 58834.

■ 2. Revise § 30.1 to read as follows:

§ 30.1 What rules govern the administration of EEOICPA and this chapter?

In accordance with EEOICPA, Executive Order 13179 and Secretary's Order No. 10–2009, the primary responsibility for administering the Act, except for those activities assigned to the Secretary of Health and Human Services (HHS), the Secretary of Energy and the Attorney General, has been delegated to the Director of the Office of Workers' Compensation Programs (OWCP). Except as otherwise provided by law, the Director of OWCP and his or her designees have the exclusive authority to administer, interpret and enforce the provisions of the Act.

■ 3. Amend § 30.2 by revising paragraph (b) to read as follows:

§ 30.2 In general, how have the tasks associated with the administration of EEOICPA claims process been assigned?

* * * * *

(b) However, HHS has exclusive control of the portion of the claims process under which it provides reconstructed doses for certain radiogenic cancer claims (see § 30.115), which it delegated to the National Institute for Occupational Safety and Health (NIOSH) in 42 CFR 82.1. HHS also has exclusive control of the process for designating classes of employees to be added to the Special Exposure Cohort under Part B of the Act, and has promulgated regulations governing that process at 42 CFR part 83. Finally, HHS has promulgated regulations at 42 CFR part 81 that set out guidelines that OWCP follows when it assesses the compensability of an employee's radiogenic cancer (see § 30.213). DOE and DOJ must, among other things, notify potential claimants and submit evidence that OWCP deems necessary for its adjudication of claims under EEOICPA (see §§ 30.105, 30.112, 30.206, 30.212 and 30.221).

■ 4. Amend § 30.5 as follows:

■ a. Revise paragraphs (c)(2)(i) and (i);

■ b. Redesignate paragraphs (j) through (hh) and paragraphs (ii) and (jj) as paragraphs (k) through (ii) and (kk) and (ll), respectively;

■ c. Add paragraphs (j) and (jj);

■ d. Revise newly designated paragraphs (k)(2) introductory text and (w);

■ e. In newly designated paragraph (x)(2)(ii), remove the period at the end of the paragraph and add ''; or'' in its place;

■ f. Add paragraph (x)(2)(iii) to newly designated paragraph (x);

■ g. Revise newly designated paragraphs (ee) and the introductory text to (gg); and

■ h. Revise newly designated paragraph (ii) introductory text, further redesignate paragraphs (ii)(1), (2) and (3) as paragraphs (ii)(1)(i), (ii) and (iii), respectively, and add paragraphs (ii)(1) and (2).

The revisions and additions read as follows:

§ 30.5 What are the definitions used in this part?

* * * * *

(c) * * *

(2)(i) An individual employed at a facility that NIOSH reported had a potential for significant residual contamination outside of the period described in paragraph (c)(1) of this section;

* * * * *

(i) *Beryllium vendor* means the specific corporations and named predecessor corporations listed in section 7384l(6) of the Act and any of the facilities designated as such by DOE on December 27, 2002.

(j) *Beryllium vendor facility* means a facility owned and operated by a beryllium vendor.

(k) * * *

(2) A written diagnosis of silicosis is made by a licensed physician and is accompanied by:

* * * * *

(w) *Department of Energy* or *DOE* includes the predecessor agencies of DOE back to the establishment of the Manhattan Engineer District on August 13, 1942.

(x) * * *

(2) * * *

(iii) A civilian employee of a state or federal government agency if the agency employing that individual is found to have entered into a contract with DOE for the provision of one or more services it was not statutorily obligated to perform, and DOE compensated the agency for those services. The delivery or removal of goods from the premises of a DOE facility does not constitute a service for the purposes of determining a worker's coverage under this paragraph (x).

* * * * *

(ee) *Physician* means surgeons, podiatrists, dentists, clinical psychologists, optometrists, chiropractors and osteopathic practitioners, within the scope of their practice as defined by state law. The services of chiropractors that may be reimbursed are limited to treatment consisting of manual manipulation of the spine to correct a subluxation as demonstrated by x-ray to exist.

* * * * *

(gg) *Specified cancer* means:

* * * * *

(ii) *Time of injury* is defined as follows:

(1) For an employee's claim, this term means:

* * * * *

(2) For a survivor's claim, the date of the employee's death is the time of injury.

(jj) *Time of payment* or *payment* means the date that a paper check issued by the Department of the Treasury was received by the payee or by someone who was legally able to act for the payee, or the date the Department of the Treasury made an Electronic Funds Transfer to the payee's financial institution.

* * * * *

■ 5. Amend § 30.100 by revising paragraphs (a), (c) introductory text, (c)(1) and (d) to read as follows:

§ 30.100 In general, how does an employee file an initial claim for benefits?

(a) To claim benefits under EEOICPA, an employee must file a claim in writing with OWCP. Form EE–1 should be used for this purpose, but any written communication that requests benefits under EEOICPA will be considered a claim. It will, however, be necessary for an employee to submit a Form EE–1 for OWCP to fully develop the claim. Copies of Form EE–1 may be obtained from OWCP or on the Internet at *http://www.dol.gov/owcp/energy/index.htm*. The employee must sign the written claim that is filed with OWCP, but another person may present the claim to OWCP on the employee's behalf.

* * * * *

(c) Except as provided in paragraph (d) of this section, a claim is considered to be ''filed'' on the date that the employee mails his or her claim to OWCP, as determined by postmark or other carrier's date marking, or on the date that the claim is received by OWCP, whichever is the earliest determinable date. However, in no event will a claim under Part B of EEOICPA be considered to be ''filed'' earlier than July 31, 2001, nor will a claim under Part E of EEOICPA be considered to be ''filed'' earlier than October 30, 2000.

(1) The employee shall affirm that the information provided on the Form EE–1 is true, and must inform OWCP of any subsequent changes to that information.

* * * * *

(d) For those claims under Part E of EEOICPA that were originally filed with DOE as claims for assistance under former section 7385o of EEOICPA (which was repealed on October 28, 2004), a claim is considered to be ''filed'' on the date that the employee mailed his or her claim to DOE, as determined by postmark or other carrier's date marking, or on the date that the claim was received by DOE, whichever is the earliest determinable date. However, in no event will a claim referred to in this paragraph be considered to be ''filed'' earlier than October 30, 2000.

■ 6. Amend § 30.101 by revising paragraphs (a), (d) introductory text, (d)(1) and (e) to read as follows:

§ 30.101 In general, how is a survivor's claim filed?

(a) A survivor of an employee must file a claim for compensation in writing with OWCP. Form EE–2 should be used for this purpose, but any written communication that requests survivor benefits under the Act will be considered a claim. It will, however, be necessary for a survivor to submit a

Form EE–2 for OWCP to fully develop the claim. Copies of Form EE–2 may be obtained from OWCP or on the Internet at *http://www.dol.gov/owcp/energy/index.htm*. The survivor must sign the written claim that is filed with OWCP, but another person may present the claim to OWCP on the survivor's behalf. Although only one survivor needs to file a claim under this section to initiate the development process, OWCP will distribute any monetary benefits payable on the claim among all eligible surviving beneficiaries who have filed claims with OWCP.

* * * * *

(d) Except as provided in paragraph (e) of this section, a survivor's claim is considered to be ''filed'' on the date that the survivor mails his or her claim to OWCP, as determined by postmark or other carrier's date making, or the date that the claim is received by OWCP, whichever is the earliest determinable date. However, in no event will a survivor's claim under Part B of the Act be considered to be ''filed'' earlier than July 31, 2001, nor will a survivor's claim under Part E of the Act be considered to be ''filed'' earlier than October 30, 2000.

(1) The survivor shall affirm that the information provided on the Form EE–2 is true, and must inform OWCP of any subsequent changes to that information.

* * * * *

(e) For those claims under Part E of EEOICPA that were originally filed with DOE as claims for assistance under former section 7385o of EEOICPA (which was repealed on October 28, 2004), a claim is considered to be ''filed'' on the date that the survivor mailed his or her claim to DOE, as determined by postmark or other carrier's date marking, or on the date that the claim was received by DOE, whichever is the earliest determinable date. However, in no event will a claim referred to in this paragraph be considered to be ''filed'' earlier than October 30, 2000.

* * * * *

■ 7. Amend § 30.102 by revising paragraph (a) to read as follows:

§ 30.102 In general, how does an employee file a claim for additional impairment or wage-loss under Part E of EEOICPA?

(a) An employee previously awarded impairment benefits by OWCP may file a claim for additional impairment benefits. Such claim must be based on an increase in the employee's impairment rating attributable to the covered illness or illnesses from the impairment rating that formed the basis for the last award of such benefits by OWCP. OWCP will only adjudicate claims for such an increased rating that are filed at least two years from the date of the last award of impairment benefits. However, OWCP will not wait two years before it will adjudicate a claim for additional impairment that is based on an allegation that the employee sustained a new covered illness.

* * * * *

■ 8. Amend § 30.103 by revising paragraph (b) to read as follows:

§ 30.103 How does a claimant make sure that OWCP has the evidence necessary to process the claim?

* * * * *

(b) Copies of the forms listed in this section are available for public inspection at the U.S. Department of Labor, Office of Workers' Compensation Programs, Washington, DC 20210. They may also be obtained from OWCP district offices and on the Internet at *http://www.dol.gov/owcp/energy/index.htm.*

■ 9. Amend § 30.110 by revising paragraphs (a)(1) and (4) and (b) to read as follows:

§ 30.110 Who is entitled to compensation under the Act?

(a) * * *

(1) A ''covered beryllium employee'' (as described in § 30.205(a)) with a covered beryllium illness (as defined in § 30.5(p)) who was exposed to beryllium in the performance of duty (in accordance with § 30.206).

* * * * *

(4) A ''covered uranium employee'' (as defined in § 30.5(t)).

(b) Under Part E of EEOICPA, compensation is payable to a ''covered Part E employee'' (as defined in § 30.5(q)), or his or her survivors.

* * * * *

■ 10. Amend § 30.112 by revising paragraph (b)(3) to read as follows:

§ 30.112 What kind of evidence is needed to establish covered employment and how will that evidence be evaluated?

* * * * *

(b) * * *

(3) If the only evidence of covered employment is a written affidavit or declaration subject to penalty of perjury by the employee, survivor or any other person, and DOE or another entity either disagrees with the assertion of covered employment or cannot concur or disagree with the assertion of covered employment, then OWCP will evaluate the probative value of the affidavit in conjunction with the other evidence of employment, and may determine that the claimant has not met his or her burden of proof under § 30.111.

■ 11. Amend § 30.113 by revising paragraph (c) to read as follows:

§ 30.113 What are the requirements for written medical documentation, contemporaneous records, and other records or documents?

* * * * *

(c) If a claimant submits a certified statement, by a person with knowledge of the facts, that the medical records containing a diagnosis and date of diagnosis of a covered medical condition no longer exist, then OWCP may consider other evidence to establish a diagnosis and date of diagnosis of a covered medical condition. However, OWCP will evaluate the probative value of such other evidence to determine whether it is sufficient proof of a covered medical condition.

■ 12. Amend § 30.114 as follows:

■ a. Revise paragraphs (b)(1) and (2);

■ b. Redesignate paragraph (b)(3) as paragraph (b)(4); and

■ c. Add paragraph (b)(3).

The revisions and addition read as follows:

§ 30.114 What kind of evidence is needed to establish a compensable medical condition and how will that evidence be evaluated?

* * * * *

(b) * * *

(1) For covered beryllium illnesses under Part B of EEOICPA, additional medical evidence, as set forth in § 30.207, is required to establish a beryllium illness.

(2) For chronic silicosis under Part B of EEOICPA, additional medical evidence, as set forth in § 30.222, is required to establish chronic silicosis.

(3) For covered illnesses under Part E of EEOICPA, additional medical evidence, as set forth in § 30.232, is required to establish a covered illness.

(i) For impairment benefits under Part E of EEOICPA, additional medical evidence, as set forth in § 30.901, is required to establish an impairment that is the result of a covered illness referred to in § 30.900.

(ii) For wage-loss benefits under Part E of EEOICPA, additional medical evidence, as set forth in § 30.806, is required to establish wage-loss that is the result of a covered illness referred to in § 30.800.

* * * * *

■ 13. Amend § 30.115 by revising paragraphs (a) introductory text, (a)(2) and (b) to read as follows:

§ 30.115 For those radiogenic cancer claims that do not seek benefits under Part B of the Act pursuant to the Special Exposure Cohort provisions, what will OWCP do once it determines that an employee contracted cancer?

(a) Other than claims seeking benefits under Part E of the Act that have

previously been accepted under section 7384u of the Act or claims previously accepted under Part B pursuant to the Special Exposure Cohort provisions, OWCP will forward the claim package (including, but not limited to, Forms EE–1, EE–2, EE–3, EE–4 and EE–5, as appropriate) to NIOSH for dose reconstruction. At that point in time, development of the claim by OWCP may be suspended.

* * * * *

(2) NIOSH will then reconstruct the radiation dose of the employee and provide the claimant and OWCP with the final dose reconstruction report. The final dose reconstruction record will be delivered to OWCP with the final dose reconstruction report and to the claimant upon request.

(b) Following its receipt of the final dose reconstruction report from NIOSH, OWCP will resume its adjudication of the cancer claim and consider whether the claimant has met the eligibility criteria set forth in subpart C of this part. However, during the period before it receives a reconstructed dose from NIOSH, OWCP may continue to develop other aspects of a claim, to the extent that it deems such development to be appropriate.

■ 14. Amend § 30.205 by revising paragraphs (a)(1) and (a)(3)(i) to read as follows:

§ 30.205 What are the criteria for eligibility for benefits relating to beryllium illnesses covered under Part B of EEOICPA?

* * * * *

(a) * * *

(1) The employee is a ''current or former employee as defined in 5 U.S.C. 8101(1)'' (see § 30.5(u)) who may have been exposed to beryllium at a DOE facility or at a facility owned, operated or occupied by a beryllium vendor; or

* * * * *

(3) * * *

(i) Employed at a DOE facility (as defined in § 30.5(y)); or

* * * * *

■ 15. Amend § 30.206 by revising paragraph (a) to read as follows:

§ 30.206 How does a claimant prove that the employee was a ''covered beryllium employee'' exposed to beryllium dust, particles or vapor in the performance of duty?

(a) Proof of employment or physical presence at a DOE facility, or a beryllium vendor facility as defined in § 30.5(j), because of employment by the United States, a beryllium vendor, or a contractor or subcontractor of a beryllium vendor during a period when beryllium dust, particles or vapor may have been present at such facility, may be made by the submission of any trustworthy records that, on their face or in conjunction with other such records, establish that the employee was employed or present at a covered facility and the time period of such employment or presence.

* * * * *

■ 16. Amend § 30.207 as follows:

■ a. Revise paragraph (a);

■ b. Redesignate paragraph (d) as paragraph (e); and

■ c. Add paragraph (d).

The revision and addition read as follows:

§ 30.207 How does a claimant prove a diagnosis of a beryllium disease covered under Part B?

(a) Written medical documentation is required in all cases to prove that the employee developed a covered beryllium illness. Proof that the employee developed a covered beryllium illness must be made by using the procedures outlined in paragraph (b), (c), (d) or (e) of this section.

* * * * *

(d) OWCP will use the criteria in either paragraph (c)(1) or (2) of this section to establish that the employee developed chronic beryllium disease as follows:

(1) If the earliest dated medical evidence shows that the employee was either treated for or diagnosed with a chronic respiratory disorder before January 1, 1993, the criteria set forth in paragraph (c)(2) of this section may be used;

(2) If the earliest dated medical evidence shows that the employee was either treated for or diagnosed with a chronic respiratory disorder on or after January 1, 1993, the criteria set forth in paragraph (c)(1) of this section must be used; and

(3) If the employee was treated for a chronic respiratory disorder before January 1, 1993 and medical evidence verifies that such treatment was performed before January 1, 1993, but the medical evidence is dated on or after January 1, 1993, the criteria set forth in paragraph (c)(2) of this section may be used.

* * * * *

■ 17. Amend § 30.210 by revising paragraph (a)(1) to read as follows:

§ 30.210 What are the criteria for eligibility for benefits relating to radiogenic cancer?

(a) * * *

(1) The employee has been diagnosed with one of the forms of cancer specified in § 30.5(gg); and

* * * * *

■ 18. Revise § 30.211 to read as follows:

§ 30.211 How does a claimant establish that the employee has or had contracted cancer?

A claimant establishes that the employee has or had contracted a specified cancer (as defined in § 30.5(gg)) or other cancer with medical evidence that sets forth an explicit diagnosis of cancer and the date on which that diagnosis was first made.

■ 19. Amend § 30.213 by revising paragraph (a) to read as follows:

§ 30.213 How does a claimant establish that the radiogenic cancer was at least as likely as not related to employment at the DOE facility, the atomic weapons employer facility, or the RECA section 5 facility?

(a) HHS, with the advice of the Advisory Board on Radiation and Worker Health, has issued regulatory guidelines at 42 CFR part 81 that OWCP uses to determine whether radiogenic cancers claimed under Parts B and E were at least as likely as not related to employment at a DOE facility, an atomic weapons employer facility, or a RECA section 5 facility. Persons should consult HHS's regulations for information regarding the factual evidence that will be considered by OWCP, in addition to the employee's final dose reconstruction report that will be provided to OWCP by NIOSH, in making this particular factual determination.

* * * * *

■ 20. Amend § 30.220 by revising paragraph (a) to read as follows:

§ 30.220 What are the criteria for eligibility for benefits relating to chronic silicosis?

* * * * *

(a) The employee is a civilian DOE employee, or a civilian DOE contractor employee, who was present for a number of workdays aggregating at least 250 workdays during the mining of tunnels at a DOE facility (as defined in § 30.5(y)) located in Nevada or Alaska for tests or experiments related to an atomic weapon, and has been diagnosed with chronic silicosis (as defined in § 30.5(k)); or

* * * * *

■ 21. Amend § 30.222 by revising paragraph (a) introductory text to read as follows:

§ 30.222 How does a claimant establish that the employee has been diagnosed with chronic silicosis or has sustained a consequential injury, illness, impairment or disease?

(a) A written diagnosis of the employee's chronic silicosis (as defined in § 30.5(k)) shall be made by a licensed physician and accompanied by one of the following:

* * * * *

■ 22. Amend § 30.230 by revising paragraphs (a) and (d)(1) introductory text to read as follows:

§ 30.230 What are the criteria necessary to establish that an employee contracted a covered illness under Part E of EEOICPA?

* * * * *

(a) That OWCP has determined under Part B of EEOICPA that the employee is a DOE contractor employee as defined in § 30.5(x), and that he or she has been awarded compensation under that Part of the Act for an occupational illness;

* * * * *

(d)(1) That the employee is a civilian DOE contractor employee as defined in § 30.5(x), or a civilian who was employed in a uranium mine or mill located in Colorado, New Mexico, Arizona, Wyoming, South Dakota, Washington, Utah, Idaho, North Dakota, Oregon or Texas at any time during the period from January 1, 1942 through December 31, 1971, or was employed in the transport of uranium ore or vanadium-uranium ore from such a mine or mill during that same period, and that he or she:

* * * * *

■ 23. Amend § 30.231 by revising paragraphs (a) and (b) to read as follows:

§ 30.231 How does a claimant prove employment-related exposure to a toxic substance at a DOE facility or a RECA section 5 facility?

* * * * *

(a) Proof of employment may be established by any trustworthy records that, on their face or in conjunction with other such records, establish that the employee was so employed and the time period(s) of such employment. If the only evidence of covered employment is a written affidavit or declaration subject to penalty of perjury by the employee, survivor or any other person, and DOE or another entity either disagrees with the assertion of covered employment or cannot concur or disagree with the assertion of covered employment, then OWCP will evaluate the probative value of the affidavit in conjunction with the other evidence of employment, and may determine that the claimant has not met his or her burden of proof under § 30.111.

(b) Proof of exposure to a toxic substance may be established by the submission of any appropriate document or information that is evidence that such substance was present at the facility where the employee was employed and that the employee came into contact with such substance. Information from the following sources may be considered as probative factual evidence for purposes of establishing an employee's exposure to a toxic substance at a DOE facility or a RECA section 5 facility:

(1) To the extent practicable and appropriate, from DOE, a DOE-sponsored Former Worker Program, or an entity that acted as a contractor or subcontractor to DOE;

(2) OWCP's Site Exposure Matrices; or

(3) Any other entity deemed by OWCP to be a reliable source of information necessary to establish that the employee was exposed to a toxic substance at a DOE facility or RECA section 5 facility.

■ 24. Amend § 30.232 as follows:

■ a. Revise paragraphs (a)(1) and (2);

■ b. Remove paragraphs (a)(3) and (4) and (b); and

■ c. Redesignate paragraph (c) as paragraph (b) and revise newly designated paragraph (b).

The revisions read as follows:

§ 30.232 How does a claimant establish that the employee has been diagnosed with a covered illness, or sustained an injury, illness, impairment or disease as a consequence of a covered illness?

(a) * * *

(1) Written medical evidence containing a physician's diagnosis of the employee's covered illness (as that term is defined in § 30.5(s)), and the physician's reasoning for his or her opinion regarding causation; and

(2) Any other evidence OWCP may deem necessary to show that the employee has or had an illness that resulted from an exposure to a toxic substance while working at either a DOE facility or a RECA section 5 facility.

(b) An injury, illness, impairment or disease sustained as a consequence of a covered illness (as defined in § 30.5(s)) must be established with a fully rationalized medical report by a physician that shows the relationship between the injury, illness, impairment or disease and the covered illness. Neither the fact that the injury, illness, impairment or disease manifests itself after a diagnosis of a covered illness, nor the belief of the claimant that the injury, illness, impairment or disease was caused by the covered illness, is sufficient in itself to prove a causal relationship.

■ 25. Add an undesignated center heading preceding § 30.300 and revise § 30.300 to read as follows:

General Provisions

§ 30.300 What administrative process will OWCP use to decide claims for entitlement, and how can claimants obtain judicial review of final decisions on their claims?

OWCP district offices will issue recommended decisions with respect to claims for entitlement under Part B and/or Part E of EEOICPA that are filed pursuant to the regulations set forth in subpart B of this part. In circumstances where a claim is made for more than one benefit available under Part B and/or Part E of the Act, OWCP may issue a recommended decision on only part of that particular claim in order to adjudicate that portion of the claim as quickly as possible. Should this occur, OWCP will issue one or more recommended decisions on the deferred portions of the claim when the adjudication of those portions is completed. All recommended decisions granting and/or denying claims for entitlement under Part B and/or Part E of the Act will be forwarded to the Final Adjudication Branch (FAB). Claimants will be given an opportunity to object to all or part of the recommended decision before the FAB. The FAB will consider objections filed by a claimant and conduct a hearing, if requested to do so by the claimant, before issuing a final decision on the claim for entitlement. Claimants may request judicial review of a final decision of FAB by filing an action in federal district court.

■ 26. Amend § 30.301 by revising paragraph (b)(1) to read as follows:

§ 30.301 May subpoenas be issued for witnesses and documents in connection with a claim under Part B of EEOICPA?

* * * * *

(b) * * *

(1) Submit the request in writing and send it to the FAB reviewer as early as possible, but no later than 30 days (as evidenced by postmark or other carrier's date marking) after the date of the original hearing request;

* * * * *

■ 27. Amend § 30.305 by revising paragraph (a) to read as follows:

§ 30.305 How does OWCP determine entitlement to EEOICPA compensation?

(a) In reaching a recommended decision with respect to EEOICPA compensation, OWCP considers the claim presented by the claimant, the factual and medical evidence of record, the dose reconstruction report prepared by NIOSH (if any), any report submitted by DOE and the results of such investigation as OWCP may deem necessary.

* * * * *

■ 28. Revise § 30.306 to read as follows:

§ 30.306 What does the recommended decision include?

The recommended decision shall include a discussion of the district office's findings of fact and conclusions of law in support of the recommendation. The recommended

decision may recommend acceptance or rejection of the claim in its entirety, or of a portion of the claim presented. It is accompanied by a notice of the claimant's right to file objections with, and request a hearing before, the FAB.

§ 30.307 [Redesignated as § 30.308]

■ 29a. Redesignate § 30.307 as § 30.308.

■ 29b. Add § 30.307 to read as follows:

§ 30.307 Can one recommended decision address the entitlement of multiple claimants?

(a) When multiple individuals have filed survivor claims under Part B and/or Part E of EEOICPA relating to the same deceased employee, the entitlement of all of those individuals shall be determined in the same recommended decision, except as described in paragraph (b) of this section.

(b) If another individual subsequently files a survivor claim for the same award, the recommended decision on that claim will not address the entitlement of the earlier claimants if the district office recommended that the later survivor claim be denied.

■ 30. Revise § 30.310 to read as follows:

§ 30.310 What must the claimant do if he or she objects to the recommended decision or wants to request a hearing?

(a) Within 60 days from the date the recommended decision is issued, the claimant must state, in writing, whether he or she objects to any of the findings of fact and/or conclusions of law discussed in such decision, including NIOSH's reconstruction of the radiation dose to which the employee was exposed (if any), and whether a hearing is desired. This written statement should be filed with the FAB at the address indicated in the notice accompanying the recommended decision.

(b) For purposes of determining whether the written statement referred to in paragraph (a) of this section has been timely filed with the FAB, the statement will be considered to be ''filed'' on the date that the claimant mails it to the FAB, as determined by postmark or other carrier's date marking, or on the date that such written statement is actually received, whichever is the earliest determinable date.

■ 31. Amend § 30.313 by revising paragraph (c) to read as follows:

§ 30.313 How is a review of the written record conducted?

* * * * *

(c) Any objection that is not presented to the FAB reviewer, including any objection to NIOSH's reconstruction of the radiation dose to which the employee was exposed (if any), whether or not the pertinent issue was previously presented to the district office, is deemed waived for all purposes.

■ 32. Amend § 30.314 by revising paragraphs (a) introductory text and (b) to read as follows:

§ 30.314 How is a hearing conducted?

(a) The FAB reviewer retains complete discretion to set the time and place of the hearing, including the amount of time allotted for the hearing, considering the issues to be resolved. At the discretion of the reviewer, the hearing may be conducted by telephone, teleconference, videoconference or other electronic means. As part of the hearing process, the FAB reviewer will consider the written record forwarded by the district office and any additional evidence and/or argument submitted by the claimant. The reviewer may also conduct whatever investigation is deemed necessary.

* * * * *

(b) The FAB reviewer will mail a notice of the time and place of the hearing to the claimant and any representative at least 30 days before the scheduled hearing date. The FAB reviewer may mail a hearing notice less than 30 days prior to the hearing if the claimant and/or representative waives the above 30-day notice period in writing. If the claimant only objects to part of the recommended decision, the FAB reviewer may issue a final decision accepting the remaining part of the recommendation of the district office without first holding a hearing (see § 30.316). Any objection that is not presented to the FAB reviewer, including any objection to NIOSH's reconstruction of the radiation dose to which the employee was exposed (if any), whether or not the pertinent issue was previously presented to the district office, is deemed waived for all purposes.

* * * * *

■ 33. Amend § 30.315 by revising paragraph (a) to read as follows:

§ 30.315 May a claimant postpone a hearing?

(a) The FAB will entertain any reasonable request for scheduling the time and place of the hearing, but such requests should be made at the time that the hearing is requested. Scheduling is at the discretion of the FAB, and is not reviewable. In most instances, once the hearing has been scheduled and appropriate written notice has been mailed, it cannot be postponed at the claimant's request for any reason except those stated in paragraph (b) of this section, unless the FAB reviewer can reschedule the hearing on the same docket (that is, during the same hearing trip). If a request to postpone a scheduled hearing does not meet one of the tests of paragraph (b) and cannot be accommodated on the same docket, or if the claimant and/or representative cancels or fails to attend a scheduled hearing, no further opportunity for a hearing will be provided. Instead, the FAB will consider the claimant's objections by means of a review of the written record. In the alternative, a teleconference may be substituted for the hearing at the discretion of the reviewer.

* * * * *

■ 34. Revise § 30.318 to read as follows:

§ 30.318 How will FAB consider objections to NIOSH's reconstruction of a radiation dose, or to OWCP's calculation of the recommended probability of causation, in a Part B claim for radiogenic cancer?

(a) If the claimant objects to NIOSH's reconstruction of the radiation dose to which the employee was exposed, either in writing or at the oral hearing, the FAB reviewer has the discretion to consult with NIOSH as part of his or her consideration of any objection. However, the HHS dose reconstruction regulation, which provides guidance for the technical methods developed and used by NIOSH to provide a reasonable estimate of the radiation dose received by an employee, is binding on FAB. Should this consultation take place, the FAB reviewer will properly document it in the case. Whether or not NIOSH is consulted, and as provided for in § 30.317, the FAB reviewer may decide to return the case to the district office for referral to NIOSH for such further action as may be appropriate.

(b) If the claimant objects to OWCP's calculation of the recommended probability of causation in a Part B radiogenic cancer claim, the FAB reviewer has the discretion to consider if OWCP used incorrect factual information when it performed this calculation. However, the statute requires that OWCP use a particular methodology, established by regulations issued by HHS at 42 CFR part 81, when it calculates the recommended probability of causation.

■ 35. Amend § 30.319 by revising paragraph (b) to read as follows:

§ 30.319 May a claimant request reconsideration of a final decision of the FAB?

* * * * *

(b) For purposes of determining whether the written request referred to

in paragraph (a) of this section has been timely filed with the FAB, the request will be considered to be ''filed'' on the date that the claimant mails it to the FAB, as determined by postmark or other carrier's date marking, or on the date that such written request is actually received, whichever is the earliest determinable date.

* * * * *

■ 36. Amend § 30.320 by revising paragraph (b) to read as follows:

§ 30.320 Can a claim be reopened after the FAB has issued a final decision?

* * * * *

(b) At any time after the FAB has issued a final decision pursuant to § 30.316, a claimant may file a written request that the Director for Energy Employees Occupational Illness Compensation reopen his or her claim, provided that the claimant also submits new evidence of a diagnosed medical condition, covered employment, or exposure to a toxic substance. A written request to reopen a claim may also be supported by identifying either a change in the PoC guidelines, a change in the dose reconstruction methods or an addition of a class of employees to the Special Exposure Cohort. If the Director concludes that the evidence submitted or matter identified in support of the claimant's request is material to the claim, the Director will reopen the claim and return it to the district office for such further development as may be necessary, to be followed by a new recommended decision.

* * * * *

■ 37. Amend § 30.400 by revising paragraphs (a) and (c) and adding paragraph (d) to read as follows:

§ 30.400 What are the basic rules for obtaining medical treatment?

(a) A covered Part B employee or a covered Part E employee who fits into at least one of the compensable claim categories described in subpart C of this part is entitled to receive all medical services, appliances or supplies that a qualified physician prescribes or recommends and that OWCP considers necessary to treat his or her occupational illness or covered illness, retroactive to the date the claim for benefits for that occupational illness or covered illness under Part B or Part E of EEOICPA was filed. The employee need not be disabled to receive such treatment. If there is any doubt as to whether a specific service, appliance or supply is necessary to treat the occupational illness or covered illness, the employee should consult OWCP prior to obtaining it through the automated authorization process described in § 30.700. In situations where the occupational illness or covered illness is a secondary cancer, such treatment may include treatment of the underlying primary cancer when it is medically necessary or related to treatment of the secondary cancer; however, payment for medical treatment of the underlying primary cancer under these circumstances does not constitute a determination by OWCP that the primary cancer is a covered illness under Part E of EEOICPA.

* * * * *

(c) Any qualified physician may provide medical services, appliances and supplies to the covered Part B employee or the covered Part E employee. A hospital or a provider of medical services or supplies may furnish appropriate services, drugs, supplies and appliances, so long as such provider possesses all applicable licenses required under State law and has not been excluded from participation in the program under subpart H of this part. OWCP may apply a test of cost-effectiveness when it decides if appliances and supplies are necessary to treat an occupational illness or covered illness, may offset the cost of prior rental payments against a future purchase price, and may provide refurbished appliances where appropriate. Also, OWCP may authorize payment for durable medical equipment and modifications to a home or vehicle, to the extent that OWCP deems it necessary and reasonable. With respect to prescribed medications, OWCP may require the use of generic equivalents where they are available. OWCP may contract with a specific provider or providers to supply non-physician medical services or supplies.

(d) In circumstances when a covered employee dies after filing a claim but before such claim is accepted, OWCP will pay for medical treatment for all accepted illnesses, retroactive to the date that the employee filed the claim, if the deceased employee's survivor(s) files a claim that is accepted under Part B and/or Part E of EEOICPA. If this occurs, OWCP shall only pay either the provider(s) or the employee's estate for medical treatment that the employee obtained after filing his or her claim.

■ 38. Revise § 30.403 to read as follows:

§ 30.403 Will OWCP pay for home health care, nursing home, and assisted living services?

(a) OWCP will authorize and pay for home health care claimed under section 7384t of the Act, whether or not such care constitutes skilled nursing care, so long as the care has been determined to be medically necessary. OWCP will pay for approved periods of care by a registered nurse, licensed practical nurse, home health aide or similarly trained individual, subject to the pre-authorization requirements described in paragraph (c) of this section.

(b) OWCP will also authorize and pay for periods of nursing home and assisted living services claimed under section 7384t of the Act, so long as such services have been determined to be medically necessary, subject to the pre-authorization requirements described in paragraph (c) of this section.

(c) To file an initial claim for home health care, nursing home, or assisted living services, the beneficiary must submit Form EE–17A to OWCP and identify his or her treating physician. OWCP then provides the treating physician with Form EE–17B, which asks the physician to submit a letter of medical necessity and verify that a timely face-to-face physical examination of the beneficiary took place. This particular pre-authorization process must be followed only for the initial claim for home health care, nursing home, and assisted living services; any subsequent request for pre-authorization must satisfy OWCP's usual medical necessity requirements. If a claimant disagrees with the decision of OWCP that the claimed services are not medically necessary, he or she may utilize the adjudicatory process described in subpart D of this part.

■ 39. Amend § 30.405 by revising paragraphs (b) and (c) to read as follows:

§ 30.405 After selecting a treating physician, may an employee choose to be treated by another physician instead?

* * * * *

(b) OWCP will approve the request if it determines that the reasons submitted are credible and supported by probative factual and/or medical evidence, as appropriate. Requests that are often approved include those for transfer of care from a general practitioner to a physician who specializes in treating the occupational illnesses or covered illnesses covered by EEOICPA, or the need for a new physician when an employee has moved.

(c) OWCP may deny a requested change of physician if it determines that the reasons submitted are not both credible and supported by probative evidence. If a claimant disagrees with such an informal denial, he or she may utilize the adjudicatory process described in subpart D of this part.

■ 40. Amend § 30.410 by adding paragraph (c) to read as follows:

§ 30.410 Can OWCP require an employee to be examined by another physician?

* * * * *

(c) OWCP may administratively close the claim and suspend adjudication of any pending matters if the employee refuses to attend a second opinion examination.

■ 41. Amend § 30.411 by adding paragraph (d) to read as follows:

§ 30.411 What happens if the opinion of the physician selected by OWCP differs from the opinion of the physician selected by the employee?

* * * * *

(d) OWCP may administratively close the claim and suspend adjudication of any pending matters if the employee refuses to attend a referee medical examination.

■ 42. Amend § 30.416 by revising paragraph (a) to read as follows:

§ 30.416 How and when should medical reports be submitted?

(a) The initial medical report (and any subsequent reports) should be made in narrative form on the physician's letterhead stationery. The physician should use the Form EE–7 as a guide for the preparation of his or her initial medical report in support of a claim under Part B and/or Part E of EEOICPA. The report should bear the physician's handwritten or electronic signature. OWCP may require an original signature on the report.

* * * * *

■ 43. Amend § 30.500 by revising paragraph (a)(2) and adding paragraph (c) to read as follows:

§ 30.500 What special statutory definitions apply to survivors under EEOICPA?

(a) * * *

(2) *Child* of a deceased covered Part B employee or deceased covered Part E employee means only a biological child, a stepchild or an adopted child of that individual.

* * * * *

(c) For the purposes of paying compensation to survivors under Part E of EEOICPA, OWCP will use the following additional definitions:

(1) *Covered child* means a child that is, as of the date of the deceased covered Part E employee's death, either under the age of 18 years, or under the age of 23 years and a full-time student who was continuously enrolled in one or more educational institutions since attaining the age of 18 years, or any age and incapable of self-support. A child's marital status or dependency on the covered employee for support is irrelevant to his or her eligibility for benefits as a covered child under Part E.

(2) *Incapable of self-support* means that the child must have been physically and/or mentally incapable of self-support at the time of the covered employee's death.

■ 44. Amend § 30.501 by revising paragraphs (a) introductory text and (b) introductory text to read as follows:

§ 30.501 What order of precedence will OWCP use to determine which survivors are entitled to receive compensation under EEOICPA?

(a) Under Part B of the Act, if OWCP determines that a survivor or survivors are entitled to receive compensation under EEOICPA because a covered Part B employee who would otherwise have been entitled to benefits is deceased, that compensation will be disbursed as follows, subject to the qualifications set forth in § 30.5(hh)(3):

* * * * *

(b) Under Part E of the Act, if OWCP determines that a survivor or survivors are entitled to receive compensation under EEOICPA because a covered Part E employee who would otherwise have been entitled to benefits is deceased, that compensation will be disbursed as follows, subject to the qualifications set forth in § 30.5(hh)(3):

* * * * *

■ 45. Revise § 30.502 to read as follows:

§ 30.502 When is entitlement for survivors determined for purposes of EEOICPA?

Entitlement to any lump-sum payment for survivors under the EEOICPA, other than for ''covered'' children under Part E, will be determined as of the time OWCP makes such a payment. As noted in § 30.500(c)(1), a child of a deceased Part E employee will only qualify as a ''covered'' child of that individual if he or she satisfied one of the additional statutory criteria for a ''covered'' child as of the date of the deceased Part E employee's death.

■ 46. Amend § 30.509 by revising paragraph (c) to read as follows:

§ 30.509 Under what circumstances may a survivor claiming under Part E of the Act choose to receive the benefits that would otherwise be payable to a covered Part E employee who is deceased?

* * * * *

(c) OWCP only makes impairment determinations based on rationalized medical evidence in the case file that is sufficiently detailed and meets the various requirements for the many different types of impairment determinations possible under the 5th Edition of the American Medical Association's *Guides to the Evaluation of Permanent Impairment* (AMA's *Guides*). Therefore, OWCP will only make an impairment determination for a deceased covered Part E employee pursuant to this section if the medical evidence of record is sufficient to satisfy the pertinent requirements in the AMA's *Guides* and subpart J of this part.

■ 47. Amend § 30.600 by revising paragraph (c)(2) to read as follows:

§ 30.600 May a claimant designate a representative?

* * * * *

(c) * * *

(2) A representative does not have authority to sign the Form EE–1 (described in § 30.100(a)) or the Form EE–2 (described in § 30.101(a)) for his or her client. A representative also does not have authority to sign the Form EN–20 (described in § 30.505(c)) for his or her client.

■ 48. Amend § 30.601 by revising the introductory text to read as follows:

§ 30.601 Who may serve as a representative?

A claimant may authorize any individual to represent him or her in regard to a claim under EEOICPA, unless that individual's service as a representative would violate any applicable provision of law (such as 18 U.S.C. 205 and 208) or the standards regarding conflicts of interest adopted by OWCP. A federal employee may act as a representative only:

* * * * *

■ 49. Amend § 30.603 by revising paragraph (a) to read as follows:

§ 30.603 Are there any limitations on what the representative may charge the claimant for his or her services?

(a) Notwithstanding any contract, the representative may not receive, for services rendered in connection with a claim pending before OWCP, more than the percentages of the lump-sum payment made to the claimant set out in paragraph (b) of this section, exclusive of costs and expenses.

* * * * *

■ 50. Amend § 30.617 by revising paragraph (b)(2) to read as follows:

§ 30.617 What happens if this type of tort suit was filed during the period from October 30, 2000 through December 28, 2001?

* * * * *

(b) * * *

(2) The date that is 30 months after the date the claimant or claimants first became aware that an illness of the covered Part B employee may be connected to his or her exposure to beryllium or radiation covered by EEOICPA. For purposes of determining when this 30-month period begins, ''the date the claimant or claimants first became aware'' will be deemed to be the date they received either a reconstructed

dose from NIOSH, or a diagnosis of a covered beryllium illness, as applicable.

■ 51. Amend § 30.618 by revising paragraph (c)(2) to read as follows:

§ 30.618 What happens if this type of tort suit was filed after December 28, 2001?

* * * * *

(c) * * *

(2) The date that is 30 months after the date the claimant or claimants first became aware that an illness of the covered Part B employee may be connected to his or her exposure to beryllium or radiation covered by EEOICPA. For purposes of determining when this 30-month period begins, ''the date the claimant or claimants first became aware'' will be deemed to be the date they received either a reconstructed dose from NIOSH, or a diagnosis of a covered beryllium illness, as applicable.

■ 52. Revise §§ 30.700 through 30.702 to read as follows:

§ 30.700 In general, what responsibilities do providers have with respect to enrolling with OWCP, seeking authorization to provide services, billing, and retaining medical records?

(a) All providers must enroll with OWCP or its designated bill processing agent (hereinafter OWCP in this subpart) to have access to the automated authorization system and to submit medical bills to OWCP. To enroll, the provider must complete and submit a Form OWCP–1168 to the appropriate location noted on that form. By completing and submitting this form, providers certify that they satisfy all applicable federal and state licensure and regulatory requirements that apply to their specific provider or supplier type. The provider must maintain documentary evidence indicating that it satisfies those requirements. The provider is also required to notify OWCP immediately if any information provided to OWCP in the enrollment process changes. Federal government medical officers, private physicians and hospitals are also required to keep records of all cases treated by them under EEOICPA so they can supply OWCP with a history of the claimed occupational illness or covered illness, a description of the nature and extent of the claimed occupational illness or covered illness, the results of any diagnostic studies performed and the nature of the treatment rendered. This requirement terminates after a provider has supplied OWCP with the above-noted information, and otherwise terminates ten years after the record was created.

(b) Where a medical provider intends to bill for a procedure where prior authorization is required, authorization must be requested from OWCP.

(c) After enrollment, a provider must submit all medical bills to OWCP through its bill processing portal and include the Provider Number/ID obtained through enrollment or other identifying number required by OWCP.

§ 30.701 How are medical bills to be submitted?

(a) All charges for medical and surgical treatment, appliances or supplies furnished to employees, except for treatment and supplies provided by nursing homes, shall be supported by medical evidence as provided in § 30.700. OWCP may withhold payment for services until such report or evidence is provided. The physician or provider shall itemize the charges on Form OWCP–1500 or CMS–1500 (for professional charges or medicinal drugs dispensed in the office), Form OWCP–04 or UB–04 (for hospitals), an electronic or paper-based bill that includes required data elements (for pharmacies) or other form as warranted, and submit the form or bill promptly to OWCP.

(b) The provider shall identify each service performed using the Physician's Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the National Drug Code (NDC) number, or the Revenue Center Code (RCC), with a brief narrative description. OWCP has discretion to determine which of these codes may be utilized in the billing process. OWCP also has the authority to create and supply specific procedure codes that will be used by OWCP to better describe and allow specific payments for special services. These OWCP-created codes will be issued to providers by OWCP as appropriate and may only be used as authorized by OWCP. For example, a physician conducting a referee or second opinion examination as described in §§ 30.410 through 30.412 will be furnished an OWCP-created code. A provider may not use an OWCP-created code for other types of medical examinations or services. When no code is submitted to identify the services performed, the bill will be returned to the provider and/or denied.

(c) For professional charges billed on Form OWCP–1500 or CMS–1500, the provider shall also state each diagnosed condition and furnish the corresponding diagnostic code using the ''International Classification of Disease, 9th Edition, Clinical Modification'' (ICD–9–CM), or as revised. A separate bill shall be submitted when the employee is discharged from treatment or monthly, if treatment for the occupational illness or covered illness is necessary for more than 30 days.

(1)(i) Hospitals shall submit charges for both inpatient and outpatient medical and surgical treatment or supplies promptly to OWCP on Form OWCP–04 or UB–04.

(ii) OWCP may adopt a Home Health Prospective Payment System (HHPPS), as developed and implemented by the Centers for Medicare and Medicaid Services (CMS) within HHS for Medicare, while modifying the allowable costs under Medicare to account for deductibles and other additional costs that are covered by EEOICPA. If adopted, home health care providers will be required to submit bills on Form OWCP–04 or UB–04 and to use Health Insurance Prospective Payment System codes and other coding schemes.

(2) Pharmacies shall itemize charges for prescription medications, appliances or supplies on electronic or paper-based bills and submit them promptly to OWCP. Bills for prescription medications must include all required data elements, including the NDC number assigned to the product, the generic or trade name of the drug provided, the prescription number, the quantity provided, and the date the prescription was filled.

(3) Nursing homes shall itemize charges for appliances, supplies or services on the provider's billhead stationery and submit them promptly to OWCP. Such charges shall be subject to any applicable OWCP fee schedule.

(d) By submitting a bill and/or accepting payment, the provider signifies that the service for which payment is sought was performed as described and was necessary, appropriate and properly billed in accordance with accepted industry standards. For example, accepted industry standards preclude upcoding billed services for extended medical appointments when the employee actually had a brief routine appointment, or charging for the services of a professional when a paraprofessional or aide performed the service. Also, industry standards prohibit unbundling services to charge separately for services that should be billed as a single charge. In addition, the provider thereby agrees to comply with all regulations set forth in this subpart concerning the rendering of treatment and/or the process for seeking payment for medical services, including the limitation imposed on the amount to be paid for such services.

(e) In summary, bills submitted by providers must: Be itemized on Form

OWCP–1500 or CMS–1500 (for physicians), Form OWCP–04 or UB–04 (for hospitals), or an electronic or paper-based bill that includes required data elements (for pharmacies); contain the handwritten or electronic signature of the provider when required; and identify the procedures using HCPCS/CPT codes, RCCs or NDC numbers. Otherwise, OWCP may deny the bill, and the provider must correct and resubmit the bill. The decision of OWCP whether to pay a provider's bill is final when issued and is not subject to the adjudicatory process described in subpart D of this part.

§ 30.702 How should an employee prepare and submit requests for reimbursement for medical expenses, transportation costs, loss of wages, and incidental expenses?

(a) If an employee has paid bills for medical, surgical or other services, supplies or appliances provided by a professional due to an occupational illness or a covered illness, he or she must submit a request for reimbursement on Form OWCP–915, together with an itemized bill on Form OWCP–1500 or CMS–1500 prepared by the provider, or Form OWCP–04 or UB–04 prepared by the provider, and a medical report as provided in § 30.700, to OWCP for consideration.

(1) The provider of such service shall state each diagnosed condition and furnish the applicable ICD–9–CM code, or as revised, and identify each service performed using the applicable HCPCS/CPT code, with a brief narrative description of the service performed, or, where no code is applicable, a detailed description of that service. If no code or description is received, OWCP will deny the reimbursement request and correction and resubmission will be required.

(2) The reimbursement request must be accompanied by evidence that the provider received payment for the service from the employee and a statement of the amount paid. Acceptable evidence that payment was received includes, but is not limited to, a signed statement by the provider, a mechanical stamp or other device showing receipt of payment, a copy of the employee's canceled check (both front and back), a copy of the employee's credit card receipt or a provider billing form indicating a zero balance due.

(b) If a pharmacy or nursing home provided services for which the employee paid, the employee must also use Form OWCP–915 to request reimbursement and should submit the request in accordance with the provisions of § 30.701(a). Any such request for reimbursement must be accompanied by evidence, as described in paragraph (a)(2) of this section, that the provider received payment for the service from the employee and a statement of the amount paid.

(c) OWCP may waive the requirements of paragraphs (a) and (b) of this section if extensive delays in the filing or the adjudication of a claim make it unusually difficult for the employee to obtain the required information.

(d) Copies of bills submitted for reimbursement must bear the handwritten or electronic signature of the provider when required, with evidence of payment. Payment for medical and surgical treatment, appliances or supplies shall in general be no greater than the maximum allowable charge for such service determined by OWCP, as set forth in § 30.705. OWCP will issue a letter decision on whether to reimburse an employee for out-of-pocket medical expenses, and the amount of any reimbursement. A claimant who disagrees with OWCP's letter decision may request a formal recommended decision and utilize the adjudicatory process described in subpart D of this part.

(e) An employee will be only partially reimbursed for a medical expense if the amount he or she paid to a provider for the service exceeds the maximum allowable charge set by OWCP's schedule. If this happens, OWCP shall advise the employee of the maximum allowable charge for the service in question and of his or her responsibility to ask the provider to refund to the employee, or credit to the employee's account, the amount he or she paid which exceeds the maximum allowable charge. The provider that the employee paid, but not the employee, may request reconsideration of the fee determination as set forth in § 30.712.

(f) If the provider fails to make appropriate refund to the employee, or to credit the employee's account, within 60 days after the employee requests a refund of any excess amount, or the date of a subsequent reconsideration decision which continues to disallow all or a portion of the disputed amount, OWCP will initiate exclusion procedures as provided by § 30.715.

(g) If the provider does not refund to the employee or credit to his or her account the amount of money paid in excess of the charge which OWCP allows, the employee should submit documentation of the attempt to obtain such refund or credit to OWCP. OWCP may authorize reasonable reimbursement to the employee after reviewing the facts and circumstances of the case.

■ 53. Revise §§ 30.705 through 30.707 to read as follows:

§ 30.705 What services are covered by the OWCP fee schedule?

(a) Payment for medical and other health services, devices and supplies furnished by physicians, hospitals and other providers for occupational illnesses or covered illnesses shall not exceed a maximum allowable charge for such service as determined by OWCP, except as provided in this section.

(b) The schedule of maximum allowable charges does not apply to charges for services provided in nursing homes, but it does apply to charges for treatment furnished in a nursing home by a physician or other medical professional. In the future, OWCP may also decide to implement a fee schedule for services provided in nursing homes.

(c) The schedule of maximum allowable charges also does not apply to charges for appliances, supplies, services or treatment furnished by medical facilities of the U.S. Public Health Service or the Departments of the Army, Navy, Air Force and Veterans Affairs.

§ 30.706 How are the maximum fees for professional medical services defined?

For professional medical services, OWCP shall maintain a schedule of maximum allowable fees for procedures performed in a given locality. The schedule shall consist of: An assignment of a Relative Value Unit (RVU) to procedures identified by HCPCS/CPT code which represents the relative skill, effort, risk and time required to perform the procedure, as compared to other procedures of the same general class; an assignment of Geographic Practice Cost Index (GPCI) values which represent the relative work, practice expenses and malpractice expenses relative to other localities throughout the country; and a monetary value assignment (conversion factor) for one unit of value for each coded service.

§ 30.707 How are payments to providers calculated?

Payment for a procedure, service or device identified by a HCPCS/CPT code shall not exceed the amount derived by multiplying the RVU values for that procedure by the GPCI values for services in that area and by the conversion factor to arrive at a dollar amount assigned to one unit in that category of service.

(a) The ''locality'' which serves as a basis for the determination of cost is defined by the Bureau of Census Metropolitan Statistical Areas. OWCP

shall base the determination of the relative per capita cost of medical care in a locality using information about enrollment and medical cost per county, provided by CMS.

(b) OWCP shall assign the RVUs published by CMS to all services for which CMS has made assignments, using the most recent revision. Where there are no RVUs assigned to a procedure, OWCP may develop and assign any RVUs it considers appropriate. The geographic adjustment factor shall be that designated by GPCI values for Metropolitan Statistical Areas as devised for CMS and as updated or revised by CMS from time to time. OWCP will devise conversion factors for each category of service as appropriate using OWCP's processing experience and internal data.

(c) For example, if the RVUs for a particular surgical procedure are 2.48 for physician's work (W), 3.63 for practice expense (PE), and 0.48 for malpractice insurance (M), and the conversion factor assigned to one unit in that category of service (surgery) is $61.20, then the maximum allowable charge for one performance of that procedure is the product of the three RVUs times the corresponding GPCI values for the locality times the conversion factor. If the GPCI values for the locality are 0.988(W), 0.948 (PE), and 1.174 (M), then the maximum payment calculation is:

$[(2.48)(0.988) + (3.63)(0.948) + (0.48)(1.174)] \times \$61.20$

$[2.45 + 3.44 + .56] \times \$61.20$

$6.45 \times \$61.20 = \$394.74$

■ 54. Revise §§ 30.709 and 30.710 to read as follows:

§ 30.709 How are payments for medicinal drugs determined?

Unless otherwise specified by OWCP, payment for medicinal drugs prescribed by physicians shall not exceed the amount derived by multiplying the average wholesale price of the medication by the quantity or amount provided, plus a dispensing fee. OWCP may, in its discretion, contract for or require the use of specific providers for certain medications.

(a) All prescription medications identified by NDC number will be assigned an average wholesale price representing the product's nationally recognized wholesale price as determined by surveys of manufacturers and wholesalers. OWCP will establish the dispensing fee, which will not be affected by the location or type of provider dispensing the medication.

(b) The NDC numbers, the average wholesale prices, and the dispensing fee shall be reviewed from time to time and updated as necessary.

(c) With respect to prescribed medications, OWCP may require the use of generic equivalents where they are available.

§ 30.710 How are payments for inpatient medical services determined?

(a) OWCP will pay for inpatient medical services according to pre-determined, condition-specific rates based on the Inpatient Prospective Payment System (IPPS) devised by CMS. Using this system, payment is derived by multiplying the diagnosis-related group (DRG) weight assigned to the hospital discharge by the provider-specific factors.

(1) All inpatient hospital discharges will be classified according to the DRGs prescribed by CMS in the form of the DRG Grouper software program. On this list, each DRG represents the average resources necessary to provide care in a case in that DRG relative to the national average of resources consumed per case.

(2) The provider-specific factors will be provided by CMS in the form of their IPPS Pricer software program. The software takes into consideration the type of facility, census division, actual geographic location of the hospital, case mix cost per discharge, number of hospital beds, intern/beds ratio, operating cost to charge ratio, and other factors used by CMS to determine the specific rate for a hospital discharge under their IPPS. OWCP may devise price adjustment factors as appropriate using OWCP's processing experience and internal data.

(3) OWCP will base payments to facilities excluded from CMS's IPPS on consideration of detailed medical reports and other evidence.

(4) OWCP shall review the pre-determined hospital rates at least once a year, and may adjust any or all components when OWCP deems it necessary or appropriate.

(b) OWCP shall review the schedule of fees at least once a year, and may adjust the schedule or any of its components when OWCP deems it necessary or appropriate.

§§ 30.711 through 30.713 [Redesignated as §§ 30.712 through 30.714]

■ 55a. Redesignate §§ 30.711 through 30.713 as §§ 30.712 through 30.714.

■ 55b. Add § 30.711 to read as follows:

§ 30.711 How are payments for outpatient medical services determined?

(a) OWCP will pay for outpatient medical services according to Ambulatory Payment Classifications (APC) based on the Outpatient Prospective Payment System devised by CMS.

(b) All outpatient medical services will be classified according to the APC prescribed by CMS for that service in the form of the Outpatient Prospective Payment System Grouper software program. Each payment is derived by multiplying the prospectively established scaled relative weight for the service's clinical APC by a conversion factor to arrive at a national unadjusted payment rate for the APC. The labor portion of the national unadjusted payment rate is further adjusted by the hospital wage index for the area where payment is being made.

(c) If a payable service has no assigned APC, the payment will be derived from the OWCP Medical Fee Schedule.

(d) OWCP shall review the pre-determined outpatient hospital rates at least once a year, and may adjust any or all components when OWCP deems it necessary or appropriate.

■ 55c. Revise newly designated §§ 30.712 and 30.713 to read as follows:

§ 30.712 When and how are fees reduced?

(a) OWCP shall accept a provider's designation of the code to identify a billed procedure or service if the code is consistent with medical reports and other evidence, and will pay no more than the maximum allowable fee for that procedure. If the code is not consistent with the medical and other evidence or where no code is supplied, the bill will be returned to the provider for correction and resubmission.

(b) If the charge submitted for a service supplied to an employee exceeds the maximum amount determined to be reasonable according to the schedule, OWCP shall pay the amount allowed by the schedule for that service and shall notify the provider in writing that payment was reduced for that service in accordance with the schedule. OWCP shall also notify the provider of the method for requesting reconsideration of the balance of the charge. The decision of OWCP to pay less than the charged amount is final when issued and is not subject to the adjudicatory process described in subpart D of this part.

§ 30.713 If OWCP reduces a fee, may a provider request reconsideration of the reduction?

(a) A physician or other provider whose charge for service is only partially paid because it exceeds a maximum allowable amount set by OWCP may, within 30 days, request reconsideration of the fee determination.

(1) The provider should make such a request to the district office with jurisdiction over the employee's claim. The request must be accompanied by documentary evidence that the procedure performed was either incorrectly identified by the original code, that the presence of a severe or concomitant medical condition made treatment especially difficult, or that the provider possessed unusual qualifications. In itself, board certification in a specialty is not sufficient evidence of unusual qualifications to justify a charge in excess of the maximum allowable amount set by OWCP. These are the only three circumstances that will justify reevaluation of the paid amount.

(2) A list of district offices and their respective areas of jurisdiction is available upon request from the U.S. Department of Labor, Office of Workers' Compensation Programs, Washington, DC 20210, or at *http://www.dol.gov/owcp/energy/index.htm.* Within 30 days of receiving the request for reconsideration, the district office shall respond in writing stating whether or not an additional amount will be allowed as reasonable, considering the evidence submitted.

(b) If the district office issues a decision that continues to disallow a contested amount, the provider may apply to the Regional Director of the region with jurisdiction over the district office. The application must be filed within 30 days of the date of such decision, and it may be accompanied by additional evidence. Within 60 days of receipt of such application, the Regional Director shall issue a decision in writing stating whether or not an additional amount will be allowed as reasonable, considering the evidence submitted. This decision is final, and shall not be subject to further review.

■ 56. Amend § 30.715 by adding paragraphs (i) and (j) to read as follows:

§ 30.715 What are the grounds for excluding a provider from payment under this part?

* * * * *

(i) Failed to inform OWCP of any change in their provider status as required in § 30.700.

(j) Engaged in conduct related to care of an employee's occupational illness or covered illness that OWCP finds to be misleading, deceptive or unfair.

■ 57. Amend § 30.716 by adding paragraphs (c) to read as follows:

§ 30.716 What will cause OWCP to automatically exclude a physician or other provider of medical services and supplies?

* * * * *

(c) A provider may be excluded on a voluntary basis at any time.

■ 58. Revise §§ 30.717 through 30.721 to read as follows:

§ 30.717 When are OWCP's exclusion procedures initiated?

(a) Upon receipt of information indicating that a physician, hospital or provider of medical services or supplies (hereinafter the provider) has or may have engaged in activities enumerated in paragraphs (c) through (j) of § 30.715, OWCP will forward that information to the Department of Labor's Office of Inspector General (DOL OIG) for its consideration. If the information was provided directly to DOL OIG, DOL OIG will notify OWCP of its receipt and implement the appropriate action within its authority, unless such notification will or may compromise the identity of confidential sources, or compromise or prejudice an ongoing or potential criminal investigation.

(b) DOL OIG will conduct such action as it deems necessary, and, when appropriate, provide a written report as described in paragraph (c) of this section to OWCP. OWCP will then determine whether to initiate procedures to exclude the provider from participation in the EEOICPA program. If DOL OIG determines not to take any further action, it will promptly notify OWCP of such determination.

(c) If DOL OIG discovers reasonable cause to believe that violations of § 30.715 have occurred, it shall, when appropriate, prepare a written report, *i.e.,* investigative memorandum, and forward the report along with supporting evidence to OWCP. The report shall be in the form of a single memorandum in narrative form with attachments.

(1) The report should contain all of the following elements:

(i) A brief description and explanation of the subject provider or providers;

(ii) A concise statement of the DOL OIG's findings upon which exclusion may be based;

(iii) A summary of the events that make up the DOL OIG's findings;

(iv) A discussion of the documentation supporting DOL OIG's findings;

(v) A discussion of any other information that may have bearing upon the exclusion process; and

(vi) The supporting documentary evidence including any expert opinion rendered in the case.

(2) The attachments to the report should be provided in a manner that they may be easily referenced from the report.

§ 30.718 How is a provider notified of OWCP's intent to exclude him or her?

Following receipt of the investigative report, OWCP will determine if there exists a reasonable basis to exclude the provider or providers. If OWCP determines that such a basis exists, OWCP shall initiate the exclusion process by sending the provider a letter, by certified mail and with return receipt requested (or equivalent services from a commercial carrier), which shall contain the following:

(a) A concise statement of the grounds upon which exclusion shall be based;

(b) A summary of the information, with supporting documentation, upon which OWCP has relied in reaching an initial decision that exclusion proceedings should begin;

(c) An invitation to the provider to:

(1) Resign voluntarily from participation in the EEOICPA program without admitting or denying the allegations presented in the letter; or

(2) Request a decision on exclusion based upon the existing record and any additional documentary information the provider may wish to furnish;

(d) A notice of the provider's right, in the event of an adverse ruling by the deciding official, to request a formal hearing before an administrative law judge;

(e) A notice that should the provider fail to respond (as described in § 30.719) the letter of intent within 60 days of receipt, the deciding official may deem the allegations made therein to be true and may order exclusion of the provider without conducting any further proceedings; and

(f) The address to where the response from the provider should be sent.

§ 30.719 What requirements must the provider's response and OWCP's decision meet?

(a) The provider's response shall be in writing and shall include an answer to OWCP's invitation to resign voluntarily. If the provider does not offer to resign, he or she shall request that a determination be made upon the existing record and any additional information provided.

(b) Should the provider fail to respond to the letter of intent within 60 days of receipt, the deciding official may deem the allegations made therein to be true and may order exclusion of the provider.

(c) The provider may inspect or request copies of information in the record at any time prior to the deciding official's decision by making such request to OWCP within 20 days of receipt of the letter of intent.

(d) OWCP shall have 30 days to answer the provider's response. That

answer will be forwarded to the provider, who shall then have 15 days to reply. Any response from the provider may be forwarded to DOL OIG, should OWCP deem it appropriate, to obtain additional information which may be relevant to the provider's response.

(e) The deciding official shall be the Regional Director in the region in which the provider is located unless otherwise specified by the Director for Energy Employees Occupational Illness Compensation.

(f) The deciding official shall issue his or her decision in writing, and shall send a copy of the decision to the provider by certified mail, return receipt requested (or equivalent service from a commercial carrier). The decision shall advise the provider of his or her right to request, within 30 days of the date of the adverse decision, a formal hearing before an administrative law judge under the procedures set forth in § 30.720. The filing of a request for a hearing within the time specified shall stay the effectiveness of the decision to exclude.

§ 30.720 How can an excluded provider request a hearing?

A request for a hearing shall be sent to the deciding official and shall contain:

(a) A concise notice of the issues on which the provider desires to give evidence at the hearing;

(b) Any request for the presentation of oral argument or evidence; and

(c) Any request for a certification of questions concerning professional medical standards, medical ethics or medical regulation for an advisory opinion from a competent recognized professional organization or federal, state or local regulatory body.

§ 30.721 How are hearings assigned and scheduled?

(a) If the deciding official receives a timely request for hearing, he or she shall refer the matter to the Chief Administrative Law Judge of the Department of Labor, who shall assign it for an expedited hearing. The administrative law judge assigned to the matter shall consider the request for hearing, act on all requests therein, and issue a Notice of Hearing and schedule for the conduct of the hearing. A copy of the hearing notice shall be served on the provider by certified mail, return receipt requested. The Notice of Hearing and the schedule shall include:

(1) A ruling on each item raised in the request for hearing;

(2) A schedule for the prompt disposition of all preliminary matters, including requests for the certification of questions to advisory bodies; and

(3) A scheduled hearing date not less than 30 days after the date the schedule is issued, and not less than 15 days after the scheduled conclusion of preliminary matters, provided that the specific time and place of the hearing may be set on 10 days' notice.

(b) The provider is entitled to be heard on any matter placed in issue by his or her response to the notice of intent to exclude, and may designate ''all issues'' for purposes of hearing. However, a specific designation of issues is required if the provider wishes to interpose affirmative defenses, or request the certification of questions for an advisory opinion.

■ 59. Amend § 30.723 by revising paragraph (b) to read as follows:

§ 30.723 How will the administrative law judge conduct the hearing and issue the recommended decision?

* * * * *

(b) The administrative law judge shall receive such relevant evidence as may be adduced at the hearing. Parties to the hearing are the provider and OWCP. Evidence shall be presented under oath, orally or in the form of written statements. The administrative law judge shall consider the notice and response, including all pertinent documents accompanying them, and may also consider any evidence which refers to the provider or to any claim with respect to which the provider has provided medical services, hospital services, or medical services and supplies, and such other evidence as the administrative law judge may determine to be necessary or useful in evaluating the matter.

* * * * *

■ 60. Revise § 30.724 to read as follows:

§ 30.724 How does a recommended decision become final?

(a) Within 30 days from the date the recommended decision is issued, each party may state, in writing, whether the party objects to the recommended decision. This written statement should be filed with the Director for Energy Employees Occupational Illness Compensation.

(b) For the purposes of determining whether the written statement referred to in paragraph (a) of this section has been timely filed with the Director for Energy Employees Occupational Illness Compensation, the statement will be considered to be ''filed'' on the date that the provider mails it to the Director, as determined by postmark or other carrier's date marking, or the date that such written statement is actually received by the Director, whichever is earlier.

(c) Written statements objecting to the recommended decision may be filed upon one or more of the following grounds:

(1) A finding or conclusion of material fact is not supported by substantial evidence;

(2) A necessary legal conclusion is erroneous;

(3) The decision is contrary to law or to the duly promulgated rules or decisions of the Director;

(4) A substantial question of law, policy, or discretion is involved; or

(5) A prejudicial error of procedure was committed.

(d) Each issue shall be separately numbered and plainly and concisely stated, and shall be supported by detailed citations to the record when assignments of error are based on the record, and by statutes, regulations or principal authorities relied upon. Except for good cause shown, no assignment of error by any party shall rely on any question of fact or law upon which the administrative law judge had not been afforded an opportunity to pass.

(e) If a written statement of objection is filed within the allotted period of time, the Director for Energy Employees Occupational Illness Compensation will review the objection. The Director will forward the written objection to DOL OIG, which will have 14 calendar days from that date to respond. Any response from DOL OIG will be forwarded to the provider, which will have 14 calendar days from that date to reply.

(f) The Director for Energy Employees Occupational Illness Compensation will consider the recommended decision, the written record and any response or reply received and will then issue a written, final decision either upholding or reversing the exclusion.

(g) If no written statement of objection is filed within the allotted period of time, the Director for Energy Employees Occupational Illness Compensation will issue a written, final decision accepting the recommendation of the administrative law judge.

(h) The decision of the Director for Energy Employees Occupational Illness Compensation shall be final with respect to the provider's participation in the program, and shall not be subject to further review.

■ 61. Amend § 30.725 by revising paragraph (a) to read as follows:

§ 30.725 What are the effects of non-automatic exclusion?

(a) OWCP shall give notice of the exclusion of a physician, hospital or

provider of medical services or supplies to:

(1) All OWCP district offices;

(2) CMS;

(3) All employees who are known to have had treatment, services or supplies from the excluded provider within the six-month period immediately preceding the order of exclusion; and

(4) The state or local authority responsible for licensing or certifying the excluded party.

* * * * *

■ 62. Amend § 30.726 by revising paragraph (c) to read as follows:

§ 30.726 How can an excluded provider be reinstated?

* * * * *

(c) A request for reinstatement may be accompanied by a request for oral presentation. Oral presentations will be allowed only in unusual circumstances where it will materially aid the decision process.

* * * * *

■ 63. Amend § 30.800 by revising paragraph (c) to read as follows:

§ 30.800 What types of wage-loss are compensable under Part E of EEOICPA?

* * * * *

(c) Whether the employee's inability to earn at least as much as his or her average annual wage was due to a covered illness as defined in § 30.5(s).

■ 64. Amend § 30.801 as follows:

■ a. Revise paragraph (a);

■ b. Redesignate paragraphs (c), (d) and (e) as paragraphs (d), (e) and (h), respectively;

■ c. Add paragraph (c);

■ d. Revise newly designated paragraph (e); and

■ e. Add paragraphs (f) and (g).

The revisions and additions read as follows:

§ 30.801 What special definitions does OWCP use in connection with Part E wage-loss determinations?

* * * * *

(a) *Average annual wage* means 12 times the average monthly wage of a covered Part E employee for the 36 months preceding the month during which he or she first experienced wage-loss due to exposure to a toxic substance at a DOE facility or RECA section 5 facility (referred to as the ''trigger month''), excluding any months during which the employee was unemployed. Because being ''retired'' is not equivalent to being ''unemployed,'' months during which an employee had no wages because he or she was retired will not be excluded from this calculation.

* * * * *

(c) *Month during which the employee was unemployed* means any month during which the covered Part E employee had $250 (in constant 2013 dollars) or less in wages unless the month is one during which the employee was retired.

* * * * *

(e) *Quarter during which the employee was unemployed* means any quarter during which the covered Part E employee had $750 (in constant 2013 dollars) or less in wages unless the quarter is one during which the employee was retired.

(f) *Trigger month* means the calendar month during which the employee first experienced a loss in wages due to exposure to a toxic substance at a DOE facility or RECA section 5 facility.

(g) *Wages* mean all monetary payments that the covered Part E employee earns from his or her regular employment or services that are taxed as income by the Internal Revenue Service. Salaries, overtime compensation, sick leave, vacation leave, tips, and bonuses received for employment services are considered wages under this subpart. However, capital gains, IRA distributions, pensions, annuities, unemployment compensation, state workers' compensation benefits, medical retirement benefits, and Social Security benefits are not considered wages.

* * * * *

■ 65. Revise § 30.805 to read as follows:

§ 30.805 What are the criteria for eligibility for wage-loss benefits under Part E?

(a) In addition to satisfying the general eligibility requirements applicable to all Part E claims, a claimant seeking benefits for calendar years of qualifying wage-loss has the burden of proof to establish each of the following criteria:

(1) He or she held a job at which he or she earned wages;

(2) He or she experienced a loss in those wages in a particular month (referred to as the ''trigger month'' in this section);

(3) The wage-loss in the trigger month was caused by the covered Part E employee's covered illness, *i.e.,* that he or she would have continued to earn wages in the trigger month from that employment *but for the covered illness;*

(4) His or her average annual wage;

(5) His or her normal retirement age and the calendar year in which he or she would reach that age;

(6) Beginning with the calendar year of the trigger month, the percentage of the average annual wage that was earned in each calendar year up to and including the retirement year;

(7) The number of those calendar years in which the covered illness caused the covered Part E employee to earn 50% or less of his or her average annual wage; and

(8) The number of those calendar years in which the covered illness caused him or her to earn more than 50% but not more than 75% of his or her average annual wage.

(b) OWCP will discontinue development of a request for wage-loss benefits, during which the claimant must meet his or her burden of proof to establish each of the criteria listed in paragraph (a) of this section, at any point when the claimant is unable to meet such burden.

■ 66. Revise § 30.806 to read as follows:

§ 30.806 What kind of medical evidence must the claimant submit to prove that he or she lost wages due to a covered illness?

OWCP requires the submission of rationalized medical evidence of sufficient probative value to convince the fact-finder that the covered Part E employee experienced a loss in wages in his or her trigger month due to a covered illness, *i.e.,* medical evidence based on a physician's fully explained and reasoned decision (see § 30.805(a)(3)). A loss in wages in the trigger month due solely to non-covered illness matters, such as a reduction in force or voluntary retirement, is not proof of compensable wage-loss under Part E.

■ 67. Add § 30.807 to read as follows:

§ 30.807 What factual evidence does OWCP use to determine a covered Part E employee's average annual wage?

(a) OWCP may rely on annual or quarterly wage information reported to the Social Security Administration to establish a covered Part E employee's presumed average annual wage (see § 30.810) and the duration and extent of any years of wage-loss that are compensable under Part E of the Act (see § 30.811). OWCP may also rely on other probative evidence of a covered Part E employee's wages, and may ask the claimant for additional evidence needed to make this determination, if necessary. For the purposes of making these two types of determinations, OWCP will consider all monetary payments that the covered Part E employee received as wages (see § 30.801(g)).

(b) A claimant who disagrees with the evidence OWCP has obtained under paragraph (a) of this section and alleges a different average annual wage for the covered Part E employee, or that there was a greater duration or extent of wage-loss, may submit records that were

produced in the ordinary course of business due to the employee's employment to rebut that evidence, to the extent that such records are determined to be authentic by OWCP. The average annual wage and/or wage-loss of the covered Part E employee will then be determined by OWCP in the exercise of its discretion.

■ 68. Amend § 30.810 by revising paragraphs (a), (b), (c), and (d) to read as follows:

§ 30.810 How will OWCP calculate the average annual wage of a covered Part E employee?

* * * * *

(a) Aggregate the wages for the 36 months that preceded the trigger month, excluding any month during which the employee was unemployed;

(b) Add any additional wages earned by the employee during those same months as evidenced by records described in § 30.807;

(c) Divide the sum of paragraphs (a) and (b) of this section by 36, less the number of months during which the employee was unemployed; and

(d) Multiply this figure by 12 to calculate the covered Part E employee's average annual wage.

■ 69. Amend § 30.811 as follows:

■ a. Revise paragraph (a);

■ b. Remove paragraph (b); and

■ c. Redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

The revision reads as follows:

§ 30.811 How will OWCP calculate the duration and extent of a covered Part E employee's initial period of compensable wage-loss?

(a) To determine the initial calendar years of wage-loss, OWCP will use the evidence it receives under §§ 30.805 through 30.807 to compare the calendar-year wages for the covered Part E employee, as adjusted, with the average annual wage determined under § 30.810 for each calendar year beginning with the calendar year that includes the trigger month, and concluding with the last calendar year of wage-loss prior to the submission of the claim or the calendar year in which the employee reached normal retirement age (as defined in § 30.801(b)), whichever occurred first.

* * * * *

■ 70. Amend § 30.901 by revising paragraphs (a) and (b) to read as follows:

§ 30.901 How does OWCP determine the extent of an employee's impairment that is due to a covered illness contracted through exposure to a toxic substance at a DOE facility or a RECA section 5 facility, as appropriate?

(a) OWCP will determine the amount of impairment benefits to which an employee is entitled based on one or more impairment evaluations submitted by physicians. An impairment evaluation shall contain the physician's opinion on the extent of whole person impairment of all organs and body functions of the employee that are compromised or otherwise affected by the employee's covered illness or illnesses, which shall be referred to as an ''impairment rating.''

(b) In making impairment benefit determinations, OWCP will only consider medical reports from physicians who are certified by the relevant medical board and who satisfy any additional criteria determined by OWCP to be necessary to qualify to perform impairment evaluations under Part E, including any specific training and experience related to particular conditions and other objective factors.

* * * * *

■ 71. Revise § 30.902 to read as follows:

§ 30.902 How will OWCP calculate the amount of the award of impairment benefits that is payable under Part E?

(a) OWCP will multiply the percentage points of the impairment rating by $2,500 to calculate the amount of the award.

(b) An employee's impairment rating may be comprised of multiple impairments of organs and body functions due to multiple covered illnesses. If an impairment award is payable based on a whole person impairment rating in which at least one of the impairments is subject to a reduction under §§ 30.505(b) and/or 30.626, OWCP will reduce the impairment award proportionately.

■ 72. Amend § 30.908 by revising paragraphs (b) and (c) to read as follows:

§ 30.908 How will the FAB evaluate new medical evidence submitted to challenge the impairment determination in the recommended decision?

* * * * *

(b) The employee shall bear the burden of proving that the additional impairment evaluation submitted is more probative than the evaluation relied upon by the district office to determine the employee's recommended impairment rating.

(c) If an employee submits an additional impairment evaluation that differs from the impairment evaluation relied upon by the district office, the FAB will review all relevant evidence of impairment in the record, and will base its determinations regarding impairment upon the evidence it considers to be most probative. The FAB will determine the impairment rating after it has evaluated all relevant evidence and argument in the record.

Signed at Washington, DC, this 20th day of October, 2015.

Leonard J. Howie III,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2015–27121 Filed 11–17–15; 8:45 am]

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FEDERAL REGISTER

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Part V

The President

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Title 3—

The President

Proclamation 9366 of November 13, 2015

American Education Week, 2015

By the President of the United States of America

A Proclamation

Education has the power to put aspirations within reach and help make real the promise of opportunity that defines America. That promise begins with making sure all who work hard have an equal shot. By supporting our students, educators, and schools, we can ensure the wellbeing of our Nation, earn back our status as having the highest proportion of college graduates in the world, and safeguard our legacy as a participatory and informed democracy. During American Education Week, we reaffirm our dedication to providing the finest tools, resources, and opportunities to our Nation's students and we recommit to making America a place where individuals are limited by nothing but the scope of their dreams.

In an increasingly competitive and interconnected global economy, nothing is more important than preparing rising generations for success from their earliest days of school. My Administration has made early childhood education a priority and we are working to expand access to high-quality preschool—one of the smartest investments we can make—and to improve the quality of child care in America. We have also offered critical incentives to States for boosting teaching and learning standards, expanded broadband and wireless connectivity in classrooms, and partnered with States and local communities to help close the school readiness gap in efforts to ensure all children's prospects are equal on their very first day in the classroom. I have also pushed to redesign American high schools to make them more innovative and responsive to student needs and more focused on extending science, technology, engineering, and math opportunities to our Nation's youth. And this year, my Administration announced new principles for assessing student learning, taking up less classroom time while still giving educators and parents the timely, actionable information they need to know children are learning.

Every American willing to work hard deserves a chance to pursue a higher education—no matter where they come from, what they look like, or what their circumstances are. That is why I have put forward a plan to make 2 years of community college as free and universal as high school is today. In addition, we have increased Pell Grant funding, expanded income-driven repayment options, and capped student loan repayments at 10 percent of a borrower's income while keeping interest rates low. To help more students obtain Federal financial aid and enroll in schools that are right for them, we have streamlined the FAFSA application process and released a new College Scorecard, which provides the most reliable national data on school costs, graduation rates, student loan debt, and post-college earnings. And just as our students require proper material support, they also need the support of those who guide their educational journeys—from preschool through high school and beyond. America's teachers and school communities make extraordinary sacrifices to cultivate a new generation of dreamers and change-makers, and as they do the important work of nurturing our Nation's students day in and day out, we must do our part to support them and ensure they have the tools and resources needed to perform their jobs effectively.

We have a responsibility to ensure every child has a pathway to success, and when we invest in the education and the future of our children and grandchildren, we place our bets on an America where dreams know no bounds. This week, let us pledge our support for our Nation's students by reaffirming the ideals that nobody should be priced out of an education, and everyone should have the chance to use their talents and abilities to contribute to our country's success.

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 November 15 through November 21, 2015, as American Education Week. I call upon all Americans to observe this week by supporting their local schools and educators through appropriate activities, events, and programs designed to help create opportunities for every school and student in America.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of November, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2015–29627
Filed 11–17–15; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Proclamation 9367 of November 13, 2015

Get Smart About Antibiotics Week, 2015

By the President of the United States of America

A Proclamation

The discovery of antibiotics marked an important medical moment in history, and for decades, antibiotics have served as crucial components of our fight against bacterial infectious diseases. Saving millions of lives around the world each year, antibiotics provide an effective method for treating patients and help us combat many diseases that were at one time considered fatal. However, their overuse and misuse has created bacteria with increased levels of antibiotic resistance, posing significant challenges to countering infectious disease. We must preserve the life-saving power of antibiotics so they will work when most needed for serious infections and for generations to come. This week, we recommit to raising awareness of antibiotic-resistant bacteria—a serious public health, economic, and national security threat—and we pledge to use antibiotics safely and responsibly.

Every year, more than 2 million people in the United States are infected with antibiotic-resistant bacteria, and over 23,000 people die as a direct result of these infections. The use of antibiotics is the biggest contributing factor to antibiotic resistance, and up to half of all antibiotics prescribed for humans are not needed or are not administered as effectively as possible. The misuse and overuse of antibiotics continue to obstruct our fight against bacterial drug resistance, leading to a loss of the efficacy of existing antibiotics. And to fully address antibiotic resistance, we must recognize that the health of humans, animals, and the environment are more connected than ever before.

My Administration is committed to preventing infections and improving the ways in which antibiotics are prescribed and used—an effort that could save tens of thousands of lives in the next few years alone. Last year, I signed an Executive Order to implement measures aimed at detecting, preventing, and controlling illnesses caused by antibiotic-resistant infections here at home and across the globe. This action will help stem the emergence and proliferation of bacteria resistant to antibiotics and ensure the continued availability of effective treatments for bacterial infections. This Order also directed the development of a Government-wide, 5-year *National Action Plan for Combating Antibiotic-Resistant Bacteria,* which is designed to accelerate actions to address urgent and serious drug-resistant threats that can affect all people. The plan enhances our efforts to slow the spread of resistant bacterial infections, strengthens our work to combat resistance, advances the ways we identify and characterize resistant bacteria, supports the research and development of new diagnostic tests and treatments, and bolsters collaboration with international partners to create a coordinated system for international surveillance. To build on this comprehensive effort, we convened a White House Forum on Antibiotic Stewardship earlier this year, bringing together health, business, academic, and agricultural leaders to promote the responsible use of antibiotics in humans and animals. By ensuring antibiotics are used carefully and only when needed, we can help safeguard the health of our people and people around the world.

The United States has the ability to lead a new era in health care. Antibiotic stewardship in science and medicine requires working with global partners,

and it demands that we provide the tools and resources necessary for individuals to use antibiotics safely and effectively. Throughout this week, let us rededicate our attention toward the effects of the misuse and overuse of antibiotics, and let us reaffirm our support for those striving to combat antibiotic-resistant bacteria.

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 November 16 through November 22, 2015, as Get Smart About Antibiotics Week. I call upon the scientific community, medical professionals, educators, businesses, industry leaders, and all Americans to observe this week by promoting the responsible use of antibiotics and raising awareness of the dangers inherent to their misuse and overuse.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of November, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2015–29628
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Billing code 3295–F6–P

Presidential Documents

Proclamation 9368 of November 13, 2015

America Recycles Day, 2015

By the President of the United States of America

A Proclamation

Every American has a role to play in preserving our planet for future generations. Being good stewards of our environment and protecting our natural resources are imperative tasks for ensuring our children and grandchildren live in a clean and sustainable world, and recycling is a pivotal way each of us can do our part. Today, we acknowledge the importance of reusing materials and reducing consumption, and we recognize that a recycling bin may often be a better alternative to a garbage can.

Each year, as much energy is saved recycling and composting as is consumed by 10 million American households. Over one-third of everything we throw away is recycled or composted, but many items that could be recycled end up in landfills instead. Recycling paper, plastic, glass, batteries, and other reusable items can have tremendous effects on the land we live on, the water we drink, and the air we breathe. It also helps reduce waste, conserve our natural resources, generate well-paying jobs in the recycling and manufacturing industries, and lessen the amount of harmful emissions that contribute to climate change.

Recycling is one way all people can join in the effort of maintaining a sustainable society. Reusing goods and reducing consumption, in addition to donating old or unwanted materials, can have significant impacts on the earth, as well. Individuals and families can help by recycling at home, setting up their own compost piles, choosing to purchase products made from recycled resources, and learning of the many products that can be recycled. Businesses can work to reduce their overall waste and establish recycling programs. And States and local governments can do their part to make recycling easier for consumers by taking simple steps like standardizing the color of recycling bins in public places and effectively communicating recycling policies to residents.

Communities across America must continue promoting activities that encourage people to recycle and to conserve so we do not take for granted today the world our children will inherit tomorrow. We owe it to them to leave behind a stable, secure planet, and that begins with preserving the natural blessings of our Nation. On this day, let us work to fulfill our obligation to our next generation by safeguarding our resources and working with our friends, family, and neighbors to protect the world we share.

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 November 15, 2015, as America Recycles Day. I call upon the people of the United States to observe this day with appropriate programs and activities, and I encourage all Americans to continue their reducing, reusing, and recycling efforts throughout the year.

IN WITNESS WHEREOF, I have hereunto set my hand this thirteenth day of November, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

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