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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 5

[Docket No. TTB–2012–0002; T.D. TTB–112; Ref: Notice No. 127]

RIN 1513–AB33

Amendment to the Standards of Identity for Distilled Spirits

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury Decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is amending the regulations setting forth the standards of identity for distilled spirits to include ''Cachaça'' as a type of rum and as a distinctive product of Brazil. This amendment follows requests received from the Government of Brazil and subsequent discussions with the Office of the United States Trade Representative.

DATES: *Effective Date:* April 11, 2013. Existing certificates of label approval that contain the term ''Cachaça'' and do not comply with the regulations in 27 CFR part 5 will be revoked by operation of regulation on August 26, 2013. Section 5.35a (27 CFR 5.35a) is effective from April 11, 2013 to February 25, 2015.

FOR FURTHER INFORMATION CONTACT: Kate M. Bresnahan, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200E, Washington, DC 20005; telephone 202–453–1039, Ext. 151.

SUPPLEMENTARY INFORMATION:

Background

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified in the United States Code at 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations relating to the packaging, marking, branding, labeling, and size and fill of containers of alcohol beverages that will prohibit consumer deception and provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law. Regulations implementing the provisions of section 105(e) as they relate to distilled spirits are set forth in part 5 of title 27 of the Code of Federal Regulations (27 CFR part 5).

Classes and Types of Spirits

The TTB labeling regulations require that the class and type of distilled spirits appear on the product's brand label (see 27 CFR 5.32(a)(2) and 5.35). Those regulations provide that the class and type must be stated in conformity with § 5.22 of the TTB regulations (27 CFR 5.22) if defined therein. Otherwise, the product must be designated in accordance with trade and consumer understanding thereof, or, if no such understanding exists, by a distinctive or fanciful name, and, in either case (with limited exceptions), followed by a truthful and adequate statement of composition (see 27 CFR 5.35).

Section 5.22 establishes standards of identity for distilled spirits products and categorizes these products according to various classes and types. As used in § 5.22, the term ''class'' refers to a general category of spirits, such as ''whisky'' or ''brandy.'' Currently, there are 12 different classes of distilled spirits recognized in § 5.22, including whisky, rum, and brandy. The term ''type'' refers to a subcategory within a class of spirits. For example, ''Cognac'' is a type of brandy, and ''Canadian whisky'' is a type of whisky.

Classification of Cachaça

''Cachaça'' is a term recognized by the Brazilian Government as a designation for a Brazilian distilled spirits product made from sugar cane. Currently, Cachaça products are generally classified as rum under TTB's labeling regulations. The standard of identity for rum is set forth in § 5.22(f) as an alcoholic distillate from the fermented juice of sugar cane, sugar cane syrup, sugar cane molasses, or other sugar cane by-products, produced at less than 190° proof in such manner that the distillate possesses the taste, aroma and characteristics generally attributed to rum, and bottled at not less than 80° proof; and also includes mixtures solely of such distillates. The above standard does not currently provide for any subcategories or ''types'' of rum.

By letter dated April 30, 2001, the Embassy of the Government of Brazil submitted a petition to TTB's predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), in which it requested that ATF amend its regulations to recognize ''Cachaça'' as a distinctive product of Brazil. After preliminary discussions with the Brazilian Embassy, no further action was taken with regard to the request.

In a second petition, dated March 6, 2006, the Brazilian Embassy asked TTB to amend its regulations to recognize Cachaça as a distinctive product of Brazil. Among other things, the Embassy noted Brazilian Decree No. 4851, of October 2, 2003, which defines ''Cachaça'' as ''the typical and exclusive designation of the sugar cane aguardente produced in Brazil, with an alcohol content of 38 to 48 percent by volume at 20 degrees Celsius, obtained from the distillation of the fermented must of sugar cane with specific sensory characteristics, to which up to six grams of sugar per liter may be added, expressed in terms of sucrose.''

In addition, following discussions between officials of Brazil and the Office of the United States Trade Representative (USTR), and after consultations between USTR and TTB, the United States Trade Representative and Brazil's Minister of Development, Industry, and Foreign Trade signed an agreement on April 9, 2012, setting out a procedure that could lead each party to recognize certain distinctive distilled spirits produced in the other party's territory, including Cachaça. The agreement provides in part that if, following the publication of a notice of proposed rulemaking, the United States publishes a final rule that provides,

among other things, that Cachaça is a type of rum that is a distinctive product of Brazil, then Brazil, within 30 days thereafter, will recognize Bourbon Whiskey and Tennessee Whiskey as distinctive products of the United States.

Besides the petition from the Brazilian Government and advice from USTR, TTB also received a number of essentially identical letters from private parties supporting the recognition of Cachaça as a distinctive type of distilled spirit.

Notice of Proposed Rulemaking and Comments Received

On April 30, 2012, TTB published in the **Federal Register** at 77 FR 25382 a notice of proposed rulemaking, Notice No. 127, which proposed to amend the regulations setting forth the standards of identity for distilled spirits contained in 27 CFR 5.22 to include Cachaça as a type of rum that is a distinctive product of Brazil. Specifically, TTB proposed amending § 5.22(f), which lays out the standard of identity for rum.

Under the proposed regulatory changes, Cachaça would be recognized as a type within the class designation ''rum'' that is a distinctive product of Brazil, manufactured in Brazil in compliance with the laws of Brazil regulating the manufacture of Cachaça for consumption in that country. Under the proposed rule, the product could simply be labeled as ''Cachaça'' without the term ''rum'' appearing on the label.

In Notice No. 127, TTB noted that the proposed type description would not include as ''Cachaça'' any spirits that use corn or corn syrup in the fermentation process. Some product labels currently include ''Cachaça'' as additional information or fanciful names for products that have been manufactured using a small quantity of corn or corn syrup in the fermentation process. Since these products were not distilled exclusively from sugar cane or sugar cane by-products, TTB has required that these products be labeled with distinctive or fanciful names, as well as statements of composition, in accordance with § 5.35. TTB has confirmed with the Brazilian Government that the Brazilian standard for Cachaça would not allow for the use of corn or corn syrup in the fermentation process.

TTB also noted that the Brazilian standard for Cachaça provides that Cachaça may contain up to six grams of added sugar per liter. The addition of sugar in this amount would not remove the product from the standard of identity for rum, pursuant to the provisions of 27 CFR 5.23. Accordingly, a Cachaça product, which is manufactured in Brazil in compliance with the laws of Brazil regulating the manufacture of Cachaça for consumption in that country, and which contains up to six grams of added sugar per liter, would fall within the standard of identity for rum. In Notice No. 127, TTB stated that the Brazilian standard allows products designated as Cachaça to have an alcohol content ranging from 38 to 48 percent alcohol by volume. TTB further noted that, since the standard of identity contained in the proposed rule identified Cachaça as a type of rum and the United States standard requires that rum must be bottled at not less than 40 percent alcohol by volume, or 80° proof, any ''Cachaça'' imported into the United States would have to conform to this minimum bottling proof requirement. A product that is bottled at below 40 percent alcohol by volume would fall outside the class and type designation. Depending on the way that such a product is manufactured, it may be labeled as a ''diluted Cachaça'' or a distilled spirits specialty product bearing a statement of composition.

In Notice No. 127, TTB sought comments on the proposed regulatory changes, and specifically requested comments on whether the proposed amendment would have an adverse impact on owners of U.S. trademarks. TTB also expressed specific interest in receiving comments on the extent to which distilled spirits labeled as Cachaça are produced outside Brazil in order to help determine whether Cachaça should be recognized as a distinctive product of Brazil.

During the comment period, TTB received a request from the European Union (EU) to extend the comment period ''in order to have time to analyze and prepare comments'' on the proposal. In response to this request, on June 29, 2012, TTB published in the **Federal Register** at 77 FR 38758 Notice No. 127A which extended the comment period for Notice No. 127 an additional 10 days. Accordingly, the comment period for the proposal outlined in Notice No. 127 closed on July 9, 2012.

TTB received a total of 13 responses to Notice No. 127, in addition to the request to extend the comment period (see comment 4 within Docket No. TTB–2012–0002 at ''Regulations.gov,'' *www.regulations.gov*). The 13 responses were received from industry and trade associations (6), consumers (3), businesses (2), the Government of Brazil, and the European Union.

Twelve of the commenters commented in support of TTB's proposal to recognize Cachaça as a distinctive product of Brazil in the United States. Eight of the commenters supported the regulatory proposal in Notice No. 127 without further change or clarification. Four expressed support for the regulatory proposal but also requested changes to or clarifications of the proposed regulatory text. The EU did not express support or opposition to the proposal, but suggested several changes to, and requested some clarification of, the proposed regulatory text. The requested changes and clarifications are discussed in detail below. None of the comments TTB received asserted that the proposed amendment would have an adverse impact on owners of U.S. trademarks or that any distilled spirits products labeled as Cachaça are produced outside Brazil. The four comments requesting changes to or clarifications of the proposed regulatory text and the EU comment are discussed in detail below.

Comments Concerning Flavored Cachaça

INOX North America (comment 2) supported TTB's proposal to amend the standards of identity for distilled spirits to include Cachaça as a distinctive type of rum, but asked that TTB consider an appropriate designation within the Cachaça subclass for flavored varieties of Cachaça, which contain natural or artificial flavors and have an alcohol content of 35 percent alcohol by volume. INOX North America stated that these products currently are sold legally in Brazil and that TTB has approved labels for three flavored Cachaça products.

With regard to flavored Cachaça and the comment submitted by INOX North America, the Brazilian Institute of Cachaça (comment 9) and the Government of Brazil (comment 11), stated that Brazilian law does not allow flavors to be added to Cachaça in Brazil. The Brazilian Institute of Cachaça asked TTB to carefully scrutinize labels for flavored distilled spirits specialty products that claim to be Cachaça or that refer to Cachaça in their fanciful names, as these labels may mislead consumers regarding the origin, identity, or characteristics of the products. The comment from the Brazilian Government urged TTB not to approve labels for flavored distilled spirits products referring to Cachaça, because they could mislead consumers regarding the origin, identity, or characteristics of the product.

TTB Response

According to the comment submitted by the Government of Brazil, Brazilian law does not authorize the use of a

''flavored Cachaça'' designation. Further, the use of such a designation is outside the scope of the proposed rule. Accordingly, TTB is not amending the regulations in § 5.22(f) in order to set forth a special category for ''flavored Cachaça'' as requested by the commenter.

TTB notes that the products described by INOX North America, which contain added flavors and have an alcohol content of 35 percent, would not meet the standard of identity proposed for Cachaça as a type of rum. However, the regulations in § 5.22 already contain a standard of identity for flavored rum. Under § 5.22(i), the standard of identity for ''flavored rum'' is rum ''to which have been added natural flavoring materials, with or without the addition of sugar, and bottled at not less than 60° proof''. Thus, products that are made by adding natural flavors to Cachaça, and which comply with the standards of section 5.22(i), may be designated as ''flavored rum.'' Products that do not meet the ''flavored rum'' standards may be labeled with distinctive or fanciful names in accordance with § 5.35. In such cases, the label would have to include a statement of composition that identified the base distilled spirits (if applicable, Cachaça) and the ingredients added to the product (such as ''natural and artificial flavors''). The designation ''Cachaça'' may not be used on such labels in a manner that creates the misleading impression that the final product is Cachaça, but it may be used to accurately designate the base distilled spirits.

Comment Concerning Aged Cachaça and Sweetened Cachaça

The EU (comment 12) asked for clarification on TTB's position concerning the labeling of ''Aged Cachaça'' and ''Sweetened Cachaça''. The EU stated that under Brazilian legislation, ''Aged Cachaça'' may be used on a label if the bottle contains a minimum of 50 percent Cachaça that has been aged for a year or longer, which differs from the U.S. provisions on statements of age. The EU also stated that in Brazil ''Sweetened Cachaça'' may contain a maximum of 30 grams of added sugar per liter, while in the United States the total addition of coloring, flavoring, or blending materials in distilled spirits products may not exceed 2½ percent by volume of the finished product.

TTB Response

Labels bearing a statement of age for Cachaça products being sold or distributed for consumption in the United States would have to comply with TTB regulations applicable to statements of age contained in 27 CFR 5.11 and 5.40(b). Section 5.11 contains the following definition of ''Age'': ''The period during which, after distillation and before bottling, distilled spirits have been stored in oak containers.'' Section 5.40(b) covers the use of statements of age on wine labels for rum, brandy, and Tequila. Section 5.40(b) states, in part, that age may, but need not, be stated on labels of rums, brandies, and Tequila. If age is stated, it shall be substantially as follows: ''____years old''; the blank to be filled in with the age of the youngest distilled spirits in the product.

The statement ''aged Cachaça'' would not comply with section 5.40(b), which requires such statements to specify the age of the youngest distilled spirits in the product. However, the statement could be used in conjunction with an age statement that complies with section 5.40(b) (such as ''___ years old''). A Cachaça or other rum that contains distilled spirits that have not been aged at all in oak containers would not be entitled to any age statement under TTB regulations, because § 5.40(b) requires age statements to be based on the age of the youngest distilled spirits in the product.

With regard to the question concerning labeling of products with the term ''Sweetened Cachaça,'' Brazilian law currently states that Cachaça that contains sugars in quantities above 6 and below 30 grams per liter shall be called ''Sweetened Cachaça''.

The applicable TTB regulation, 27 CFR 5.23(a)(2), generally allows for the addition of certain harmless coloring, flavoring, or blending materials, including sugar, to any class or type of distilled spirits, without a change in class or type, where the ingredients are not an essential component part of the particular distilled spirits to which added, but are customarily employed therein in accordance with established trade usage. However, the added coloring, flavoring, or blending materials must not total more than 2½ percent by volume of the finished product.

The Brazilian standard for ''Sweetened Cachaça'' is expressed in terms of grams of sugar per liter. Under the final rule, any Cachaça product containing more than 2½ percent by volume of added sugar would not be allowed to be labeled as Cachaça under § 5.22(f), because such a product would not meet the standards for the ''rum'' designation. If a product does not conform to any of the standards of identity set forth in § 5.22, it must be labeled in accordance with § 5.35. Under this provision, the product must be designated in accordance with trade and consumer understanding thereof, or, if no such understanding exists, by a distinctive or fanciful name, and, in either case (with limited exceptions), followed by a truthful and adequate statement of composition. Thus, consistent with § 5.35, a Cachaça product containing more than 2½ percent of added sugar by volume in the finished product could be labeled with a statement of composition such as ''Cachaça sweetened with sugar.'' If the product contains no more than 2½ percent by volume of added sugar but is no longer entitled to a ''Cachaça'' designation under Brazilian law because it contains more than 6 grams of sugar per liter, the product could still be labeled as ''rum'' under TTB regulations.

Comments Concerning the Regulatory Text

The Distilled Spirits Council of the United States (DISCUS) supported TTB's proposal to recognize Cachaça as a distinctive product of Brazil, but suggested a change to the regulatory text in proposed § 5.22(f)(1) (comment 7). The regulatory text proposed in Notice No. 127 stated that Cachaça must be ''manufactured in Brazil in compliance with the laws of Brazil regulating the manufacture of Cachaça *for consumption in that country''* (emphasis added). DISCUS commented that the highlighted language could inadvertently cause confusion as to whether a product that is produced in full conformity with Brazil's regulations governing the manufacture of Cachaça for consumption in Brazil and bottled at less than 40 percent alcohol by volume could be labeled and sold in the United States as ''Cachaça.'' DISCUS believes that removing the words ''for consumption in that country'' from proposed § 5.22(f)(1) would bring the proposed regulatory text into conformity with the U.S.–Brazil exchange of letters that occurred on April 9, 2012, and with TTB's intentions regarding the labeling of Cachaça bottled at less than 40 percent alcohol by volume.

DISCUS also noted that this change to the text would be consistent with TTB Notice No. 126, Standards of Identity for Pisco and Cognac, published in the **Federal Register** of March 27, 2012 (77 FR 18146).

The EU also recommended changes to the proposed regulatory text. The EU suggested that TTB reword proposed § 5.22(f)(1) as follows:

(1) ''Cachaça'' is a rum, as defined in 27 CFR Part 5[…], which is a distinctive product of Brazil manufactured in Brazil in compliance with the laws of Brazil regulating

the manufacture of Cachaça for consumption in that country. The word ''Cachaça'' may be spelled with or without the diacritic mark. This product may be labeled as ''Cachaça'' without the term ''rum'' on the label, provided that it complies with the standard of identity for rum as established in this section.

The EU asked that TTB rewrite the regulatory text in this way in order to specify that the labeling derogation for Cachaça will only apply to a product if that product conforms entirely with the U.S. definition of rum, and not only with regard to the minimum alcohol content.

TTB Response

TTB is not removing the phrase ''for consumption in that country'' from the regulatory text proposed in Notice No. 127. That phrase is similar to language in other type designations already in our regulations, including Scotch whisky (§ 5.22(b)(7)), Irish whisky (§ 5.22(b)(8)), and Canadian whisky (§ 5.22(b)(9)), and it is identical to the language found in the class designation for tequila (§ 5.22(g)). Removing that phrase from the regulatory language might suggest that the new regulatory text would have a meaning that is different from existing regulatory language regarding distilled spirits products that are distinctive products of a foreign country. TTB does not want to adopt language that might be interpreted as suggesting that the Brazilian laws governing the manufacture of Cachaça could provide different standards for products to be exported from those for products to be consumed within Brazil. As for the comparison to language used in Notice No. 126, TTB may consider these comments when drafting the final rule amending the standard of identity for Pisco brandy in § 5.22(d).

TTB is accepting the EU's suggestion to remove the words ''type of'' from the first sentence of the proposed regulatory text. TTB also will remove the word ''a'' before rum. TTB believes that these changes in language will conform the regulatory text to other type designations in § 5.22. Nonetheless, the final rule will still establish Cachaça as a type of rum.

TTB does not consider it necessary to include the rest of the EU's suggestions regarding the regulatory text in this final rule. As a type of rum, Cachaça must meet all the requirements for the rum class designation specified in § 5.22(f), as well as all of the Brazilian requirements for Cachaça, and TTB believes that further clarification of the proposed regulatory text in Notice No. 127 is unnecessary. As amended, the standards of identity will provide that Cachaça is a rum. Any product that is not entitled to a ''rum'' designation under § 5.22(f) will not be entitled to a ''Cachaça'' designation under § 5.22(f)(1).

TTB Finding

For the reasons stated above, TTB considers it appropriate to recognize ''Cachaça'' as a type within the class designation ''rum'' that is a distinctive product of Brazil, manufactured in Brazil in compliance with the laws of Brazil regulating the manufacture of Cachaça for consumption in that country. Therefore, TTB adopts the regulatory changes proposed in Notice No. 127, incorporating the modifications discussed above.

Effect on Existing Labels

Consistent with the proposed rule, distilled spirits for which corn or corn syrup has been used in the fermentation process would not meet the standard for ''Cachaça'' because they are not manufactured in compliance with the laws of Brazil regulating the manufacture of Cachaça for consumption in that country, and because they do not comply with the standard for ''rum'' under section 5.22. Such products would instead continue to be labeled with distinctive or fanciful names, as well as statements of composition, in accordance with § 5.35. Because the base distilled spirits used in such a product are not entitled to be designated as ''Cachaça'' under the final rule, the use of the term ''Cachaça'' as a fanciful name or in a statement of composition would similarly be prohibited. Thus, any labels for such products that include the term ''Cachaça'' would be revoked by operation of regulation.

The use of the term ''Cachaça'' as additional information on labels of products that are currently designated as ''rum'' or ''Brazilian rum'' will continue to be allowed as long as the products in question meet the new regulatory standards for designation as ''Cachaça.'' Once the final rule goes into effect, such products may be designated as ''Cachaça'' without the use of the designation ''rum'' on the label.

Labels containing the term ''Cachaça'' that do not comply with the new regulatory language contained in § 5.22(f) will be revoked by operation of regulation under the provisions of 27 CFR 13.51 and 13.72. Section 13.51 provides that TTB will not individually notify all holders of certificates of label approval that their approvals have been revoked if the revocation occurs by operation of regulation. Moreover, in such cases, it is the responsibility of the certificate holder to voluntarily surrender all certificates that are no longer in compliance.

Section 13.72 provides that revocations by operation of regulation become effective on the effective date of the change in the regulation with which the label does not comply, or, if a separate label compliance date is given, on that date. TTB believes that only a small number of industry members have labels that will be revoked by operation of this final rule. In order to minimize any adverse effect on industry members who have noncompliant labels, TTB is adding a label compliance provision to the regulation that allows the continued use of previously approved ''Cachaça'' labels for 180 days from the date that the final rule is published in the **Federal Register**. Accordingly, under the terms of this final rule, noncompliant labels will not be revoked by operation of law until August 26, 2013. This document includes the transition period provisions in the codified regulations at a new § 5.35a for ease of reference, but provides for the expiration of this provision after 2 years, because industry members will no longer have a need to refer to this temporary transition rule after that time.

Regulatory Flexibility Act

TTB certifies that these regulations will not have a significant economic impact on a substantial number of small entities. The final rule amends the standards of identity for rum at 27 CFR 5.22(f) and does not impose any new reporting, recordkeeping, or other administrative requirement. TTB did not receive any comments indicating that products made outside of Brazil were currently using the designation ''Cachaça'', and we believe that only a small number of labels will be noncompliant with the new regulation. The final rule allows the continued use of noncompliant labels for a 180-day period in order to allow sufficient time for necessary labeling changes. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

Drafting Information

Kate M. Bresnahan of the Regulations and Rulings Division prepared this final rule.

List of Subjects in 27 CFR Part 5

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, and Packaging and containers.

Amendments to the Regulations

For the reasons discussed in the preamble, TTB amends 27 CFR, chapter I, part 5, as follows:

PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS

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

Authority: 26 U.S.C. 5301, 7805, 27 U.S.C. 205.

■ 2. Amend § 5.22 by revising paragraph (f) to read as follows:

§ 5.22 The standards of identity.

* * * * *

(f) *Class 6; rum.* ''Rum'' is an alcoholic distillate from the fermented juice of sugar cane, sugar cane syrup, sugar cane molasses, or other sugar cane by-products, produced at less than 190° proof in such manner that the distillate possesses the taste, aroma, and characteristics generally attributed to rum, and bottled at not less than 80° proof; and also includes mixtures solely of such distillates.

(1) ''Cachaça'' is rum that is a distinctive product of Brazil, manufactured in Brazil in compliance with the laws of Brazil regulating the manufacture of Cachaça for consumption in that country. The word ''Cachaça'' may be spelled with or without the diacritic mark (*i.e.,* ''Cachaça'' or ''Cachaca'').

(2) [Reserved]

* * * * *

■ 3. Add new § 5.35a to read as follows:

§ 5.35a Transition period for labels containing the term ''Cachaça.''

Holders of certificates of label approval issued prior to April 11, 2013 for labels that contain the term ''Cachaça'' in a manner that does not comply with the labeling requirements contained in part 5 of this title may continue to use those certificates until August 26, 2013, at which time those certificates shall be revoked by operation of regulation.

Signed: November 30, 2012.

John J. Manfreda,

Administrator.

Approved: December 13, 2012.

Timothy E. Skud,

Deputy Assistant Secretary, Tax, Trade, and Tariff Policy.

[FR Doc. 2013–04242 Filed 2–22–13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0986]

RIN 1625–AA00

Safety Zone for Ice Conditions; Baltimore Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule with request for comments.

SUMMARY: The Coast Guard is establishing a temporary safety zone in all navigable waters of the Captain of the Port Baltimore Zone. The temporary safety zone restricts vessels from transiting the zone during the effective period, unless authorized by the Captain of the Port Baltimore or his designated representative. This safety zone is necessary to protect mariners from the hazards associated with ice in the navigable waterways.

DATES: This rule has been enforced with actual notice from January 26, 2013, until February 25, 2013. This rule is effective in the **Federal Register** on February 25, 2013 until April 15, 2013, unless cancelled earlier by the Captain of the Port.

ADDRESSES: Documents mentioned in this preamble are part of Docket Number USCG–2012–0986. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Open Docket Folder'' on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may submit comments, identified by docket number, using any one of the following methods:

(1) *Federal eRulemaking Portal: http://www.regulations.gov.*

(2) *Fax:* (202) 493–2251.

(3) *Mail or Delivery:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Deliveries accepted between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays. The telephone number is 202–366–9329.

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for further instructions on submitting comments. To avoid duplication, please use only one of these three methods.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Ronald L. Houck, Sector Baltimore Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided.

1. Submitting Comments

If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online at *http://www.regulations.gov*, or by fax, mail, or hand delivery, but please use only one of these means. If you submit a comment online, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an email address, or a

telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on ''Submit a Comment'' on the line associated with this rulemaking.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

2. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

3. Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

4. Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one, using one of the methods specified under **ADDRESSES**. Please explain why you believe a public meeting would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

B. Regulatory History and Information

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. Publishing an NPRM would be contrary to the safety zone's intended objectives since immediate action is necessary to protect persons and vessels against the hazards associated with ice on navigable waters. Such hazards include vessels becoming beset or dragged off course, sinking or grounding, and creating hazards to navigation.

For similar reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Due to the need for immediate action, the restriction of vessel traffic is necessary to protect life, property and the environment. Therefore, a 30-day notice is impracticable. Delaying the effective date would be contrary to the safety zone's intended objectives of protecting persons and vessels from becoming beset or dragged off course, sinking or grounding, and creating hazards to navigation.

C. Basis and Purpose

During an average or severe winter, frozen waterways present numerous hazards to vessels. Ice in a waterway may hamper a vessel's ability to maneuver, and could cause visual aids to navigation to be submerged, destroyed or moved off station. Ice abrasions and ice pressure could also compromise a vessel's watertight integrity, and non-steel hulled vessels would be exposed to a greater risk of hull breach.

When ice conditions develop to a point where vessel operations become unsafe, it becomes necessary to impose operating restrictions to ensure the safe navigation of vessels. A safety zone is a tool available to the Captain of the Port (COTP) to restrict and manage vessel movement when hazardous conditions exist. The COTP Baltimore is establishing a safety zone within all navigable waters of the COTP Baltimore Zone. This safety zone will restrict certain vessels meeting certain conditions specified from entering the navigable waters included within the COTP Baltimore Zone. Those vessels prohibited from entering the safety zone will be specified via broadcast notice to mariners and marine safety information bulletins.

Ice generally begins to form in the Upper Chesapeake Bay and its tributaries, including the C & D Canal, in late December or early January. During an average or severe winter, ice in navigable waters can become a serious problem, requiring the use of federal, state and private ice breaking resources. The Commander, Coast Guard Sector Baltimore will use his COTP authority to promote vessel safety in ice-congested waters and the continuation of waterborne commerce throughout the cold weather months.

Ice fields in the Upper Chesapeake Bay and its tributaries move with prevailing winds and currents. Heavy ice buildups can occur in the C & D Canal, from Town Point Wharf to Reedy Point. Other areas that are commonly affected by high volumes of ice are: the Elk River, Susquehanna River, Patapsco River, Nanticoke River, Wicomico River, Tangier Sound, Pocomoke River and Sound, and the Potomac River. Once ice buildup begins it can affect the transit of large ocean-going vessels. This regulation is intended to mitigate the threat ice in the COTP Baltimore Zone poses to the maritime public.

D. Discussion of the Interim Rule

A safety zone is being established encompassing the COTP Baltimore Zone, as described in 33 CFR 3.25–15. The COTP Baltimore anticipates only having to enforce certain parts of the regulated area at certain times. The purpose of this regulation is to promote maritime safety and to protect mariners transiting the area from the potential hazards due to ice conditions that become a threat to navigation. The COTP Baltimore will notify the maritime community, via marine broadcasts, of the location and thickness of the ice as well as the ability of vessels to transit through the safety zone depending on the prevailing ice conditions. Prevailing ice conditions will be categorized as Condition One, Condition Two, or Condition Three.

Ice Condition One is an emergency condition in which ice has largely covered the regulated area. Under these conditions, convoys may be required and restrictions based on shaft horsepower and a vessel's planned transit may be imposed by the COTP on certain vessels seeking to enter the safety zone.

Ice Condition Two is an alert condition in which at least 2 inches of ice begins to form in the regulated area. The COTP Baltimore may impose

restrictions, including but not limited to, those based on shaft horsepower and hull type restrictions for certain vessels seeking to enter the safety zone.

Ice Condition Three is a readiness condition in which weather conditions are favorable for the formation of ice in the regulated area. Daily reports for the Coast Guard Stations and commercial vessels are monitored, and no limitations for vessels seeking to enter the zone based on vessel traffic, hull type or shaft horsepower are anticipated.

This rule has been enforced with actual notice since January 26, 2013 and it will be enforced until April 15, 2013, unless sooner terminated by the COTP Baltimore.

E. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. Although this regulation could hinder or prevent traffic from transiting the COTP Baltimore Zone, the effect of this regulation will not be significant because there is little vessel traffic associated with recreational boating and commercial fishing during the effective period.

2. 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 Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to operate, transit or anchor in the regulated area, from January 26, 2013 until April 15, 2013. This safety zone will not have a significant economic impact on a substantial number of small entities due to a lack of seasonal vessel traffic associated with recreational boating and commercial fishing during the effective period. Although the safety zone will apply to the entire COTP Baltimore Zone, the Captain of the Port Baltimore anticipates only having to enforce certain parts of the regulated area at certain times. Traffic will be allowed to pass through the zone with the permission of the COTP Baltimore. Also, the COTP Baltimore will notify the maritime community, via marine broadcasts, of the location and thickness of the ice, as well as the ability of vessels to transit through the safety zone.

3. Assistance for Small Entities

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

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

4. 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).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. 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.

7. 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.

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children From Environmental Health Risks

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

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

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations

That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. 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 determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishing a temporary safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–0986 to read as follows:

§ 165.T05–0986 Safety Zone for Ice Conditions; Baltimore Captain of the Port Zone.

(a) *Regulated Area.* The following area is a safety zone: The navigable waters of the Captain of the Port Baltimore Zone, as described in 33 CFR 3.25–15.

(b) *Regulations.* The general safety zone regulations found in 33 CFR 165.23 apply to the safety zone created by this temporary section, § 165.T05.0986.

(1) All vessels and persons are prohibited from entering into or moving within the safety zone unless they meet the requirements set forth by the Captain of the Port (COTP) Baltimore for the prevailing ice conditions. Requirements for entry during periods when the safety zone is enforced will be described via Marine Safety Radio Broadcast on VHF–FM marine band radio, channel 22A (157.1 MHZ). Requirements may include, but are not limited to, the use of convoys, restrictions on shaft horsepower, and hull type restrictions, dependent on the prevailing ice conditions and vessel type.

(2) Persons desiring to transit in the safety zone not meeting the requirements established by the COTP Baltimore must contact the COTP Baltimore or his designated representative at telephone number 410–576–2693 or on VHF–FM channel 16 (156.8 MHZ) to seek permission prior to transiting the area. If permission is granted, all persons and vessels shall comply with the instructions of the COTP Baltimore or his designated representative.

(3) The Coast Guard vessels enforcing this safety zone can be contacted on VHF–FM marine band radio channel 16 (156.8 MHZ). Upon being hailed by a U.S. Coast Guard vessel, or other Federal, State, or local agency vessel operating under the authority of the COTP Baltimore, by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed. The COTP Baltimore and his designated representatives can be contacted at telephone number 410–576–2693.

(4) The COTP Baltimore or his designated representative will notify the public of any changes in the status of this safety zone by Marine Safety Radio Broadcast on VHF–FM marine band radio channel 22A (157.1 MHZ).

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

Captain of the Port Baltimore means the Commander, U.S. Coast Guard Sector Baltimore, Maryland.

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

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

(f) *Enforcement period.* This section will be enforced from January 26, 2013 until April 15, 2013.

Dated: January 26, 2013.

Kevin C. Kiefer,

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

[FR Doc. 2013–04010 Filed 2–22–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2012–0903]

RIN 1625–AA00

Safety Zone; Seafair Blue Angels Air Show Performance, Seattle, WA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The U.S. Coast Guard is amending the Seafair Blue Angels Air Show Performance safety zone on the waters of Lake Washington, Seattle, WA. This action is necessary to safeguard participants and spectators from the safety hazards associated with the Seafair Blue Angels Air Show Performance, which include low flying high speed aircraft, and will do so by prohibiting entry into the safety zone unless authorized by the Captain of the Port (COTP), Puget Sound or a Designated Representative.

DATES: This rule is effective March 27, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2012–0903]. To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email ENS Nathaniel P. Clinger; Waterways Management Division, Coast Guard Sector Puget Sound; Coast Guard; telephone 206–217–6045, email *SectorPugetSoundWWM@uscg.mil.* If you have questions on viewing or

submitting material to the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR **Federal Register**
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

On July 30, 2012, a Temporary Final Rule (TFR), Safety Zone; Seafair Blue Angels Air Show Performance, Seattle, WA, was published. The TFR increased the size of the preexisting safety zone. On October 15, 2012, an NPRM, Safety Zone, Seafair Blue Angels Air Show Performance, Seattle, WA, was published. The Coast Guard received 2 comments pertaining to the NPRM, submitted via regulations.gov, and received 0 requests for public meeting. The comments received were in favor of the rule outlined in the NPRM and therefore no changes were made to the rule.

B. Basis and Purpose

The Coast Guard is amending this safety zone to ensure the safety of the maritime public and participants during the Seattle Blue Angels Air Show. The size of the safety zone in 33 CFR 165.1319 has been determined to be inadequate to accommodate the anticipated flight pattern of the Blue Angels. This rule extends the northern boundary line of the existing regulation northward by 500 yards, and updates coordinates to provide a zone of adequate size.

C. Discussion of Comments, Changes and the Final Rule

The Coast Guard received 2 comments with regard to the preceding NPRM of this Final Rule. Both comments supported the decision to increase the safety zone size of the rule to ensure adequate safety of the maritime public and participants during the Air Show. As a result no changes were made to the rule.

As described in 69 FR 35249–01, the Coast Guard established a final rule for the annual Blue Angels Air Show Performance. The purpose of this rule is to protect the public from dangers including excessive noise and falling objects from any potential accidents caused by these low-flying military aircraft. The regulation contained in 33 CFR 165.1319 encompasses ''all waters of Lake Washington, Washington State, enclosed by the following points: Near the termination of Roanoke Way 47°35′44″ N, 122°14′47″ W; thence to 47°35′48″ N, 122°15′45″ W; thence to 47°36′02.1″ N, 122°15′50.2″ W; thence to 47°35′56.6″ N, 122°16′29.2″ W; thence to 47°35′42″ N, 122°16′24″ W; thence to the east side of the entrance to the west highrise of the Interstate 90 bridge; thence westerly along the south side of the bridge to the shoreline on the western terminus of the bridge; thence southerly along the shoreline to Andrews Bay at 47°33′06″ N, 122°15′32″ W; thence northeast along the shoreline of Bailey Peninsula to its northeast point at 47°33′44″ N, 122°15′04″ W; thence easterly along the east-west line drawn tangent to Bailey Peninsula; thence northerly along the shore of Mercer Island to the point of origin. [Datum: NAD 1983]''

However, the participating aircraft have a flight pattern that will extend past the northern boundary of the regulation in 33 CFR 156.1319. As such, an extension is necessary in order to protect the maritime public and participants.

This rule amends the Seafair Blue Angels Air Show Performance Safety Zone, extending the northern boundary starting at point 47°36′17.28″ N, 122°16′49.44″ W; thence west to point 47°36′17.28″ N, 122°16′58.56″ W; thence south along the shoreline to point 47°35′25.44″ N, 122°17′9.48″ W; thence east along the I–90 bridge to point 47°35′23.16″ N, 122°15′17.1″ W; thence north east along the shoreline to point 47°35′45.3″ N, 122°14′49.44″ W; thence north back to the point of origin.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. The Coast Guard bases this finding on the fact that the safety zone will be in place for a limited period of time and vessel traffic will be able to transit around the safety zone. Maritime traffic may also request permission to transit through the zone from the (COTP), Puget Sound or a Designated Representative.

2. 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 rule. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which may be small entities: the owners and operators of vessels intending to operate in the waters covered by the safety zone while it is in effect. The rule would not have a significant economic impact on a substantial number of small entities because the safety zone would be in place for limited periods of time and maritime traffic would still be able to transit around the safety zone. Maritime traffic may also request permission to transit through the zone from the COTP, Puget Sound or a Designated Representative.

3. Assistance for Small Entities

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

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

4. 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).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

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

7. 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.

8. Taking of Private Property

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

9. Civil Justice Reform

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

10. Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

11. Indian Tribal Governments

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

12. Energy Effects

This action is not a ''significant energy action'' under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. 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 determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves the amendment of a safety zone. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1

■ 2. Amend § 165.1319 to revise paragraph (b) to read as follows:

§ 165.1319 Safety Zone Regulations; Seafair Blue Angels Air Show Performance, Seattle, WA.

* * * * *

(b) *Location.* The following is a safety zone: All waters of Lake Washington encompassed by the following points: 47°36′17.28″ N, 122°14′49.44″ W; thence west to point 47°36′17.28″ N, 122°16′58.56″ W; thence south along the shoreline to Andrews Bay at point 47°33′04.62″ N, 122°15′32.46″ W; thence northeast along the shoreline of Bailey Peninsula to its northeast point at 47°33′44.98″ N, 122°15′03.48″ W; thence easterly to point 47°33′43.98″ N, 122°13′51.36″ W on Mercer Island; thence northerly along the shore of Mercer Island to point 47°35′45.12″ N, 122°14′49.44″ W; thence north back to the point of origin.

* * * * *

Dated: February 9, 2013.

S.J. Ferguson,

Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.

[FR Doc. 2013–04218 Filed 2–22–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 61

RIN 2900–AN81

VA Homeless Providers Grant and Per Diem Program

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, with changes, the proposed rule to amend the Department of Veterans Affairs (VA) regulations concerning VA's Homeless Providers Grant and Per Diem Program (Program). This rulemaking updates and improves the clarity of these regulations, and implements and authorizes new VA policies.

DATES: *Effective Date:* This final rule is effective March 27, 2013.

FOR FURTHER INFORMATION CONTACT: Guy Liedke, VA Homeless Providers Grant and Per Diem Program Office, 10770 N. 46th Street, Suite C–200, Tampa, FL 33617; (877) 332–0334. (This is a toll-free number.)

SUPPLEMENTARY INFORMATION: Pursuant to 38 U.S.C. 501, 2001, 2011, 2012,

2061, and 2064, the VA Homeless Providers Grant and Per Diem Program provides capital grants and per diem payments to public or nonprofit private entities that assist homeless veterans by helping to ensure the availability of supportive housing and service centers to furnish outreach, rehabilitative services, vocational counseling and training, and supportive housing. The regulations governing this program are located at title 38, Code of Federal Regulations, part 61.

In a document published in the **Federal Register** on March 1, 2012 (77 FR 12698), VA proposed to amend its regulations concerning the VA Homeless Providers Grant and Per Diem Program which are found in 38 CFR part 61.

Discussion of Comments

We provided a 60-day comment period and received two comments. One comment was supportive of the proposed definition of ''supportive housing.'' We appreciate the comment and have not made any changes based on it. Another comment was received from a health care interest group, which recommended changes to the proposed rule. A discussion of these recommendations follows.

The commenter stated that the definition of supportive housing should be amended to specifically include ''medical respite care.'' Medical respite care, as defined by the commenter, provides short term access to a bed to an individual who is recuperating from an acute injury or illness. The commenter noted that homeless adults are hospitalized more frequently than the general population, and the lack of a stable home environment following discharge negatively affects clinical outcomes. The commenter recommended changing the term ''respite'' to ''medical respite'' in the definition of supportive housing in § 61.1 to avoid confusion between what the commenter referred to as ''caregiver respite'' and ''medical respite.'' In addition, the commenter recommended incorporating into the final rule the definition of ''medical respite services'' used by the Health Resources and Services Administration (HRSA). Additionally, the commenter recommended revising the definition of supportive services to include such medical respite services that are delivered in settings other than those included in the definition of supportive housing.

Under § 61.1, ''supportive housing'' is defined in relevant part as housing that is designed to ''[p]rovide specific medical treatment such as detoxification, *respite,* or hospice treatments.'' (Emphasis added.) The word ''respite'' is used in the definition of ''supportive housing'' as being an example of ''specific medical treatment.'' The commenter suggested that the term ''respite'' is ambiguous and can somehow be confused with respite care provided to veterans with caregivers. We make no changes based on this comment because there is no meaningful difference between these types of respite care.

The commenter appears to misunderstand the nature of respite care provided through VA's caregiver benefits program under 38 CFR part 71. The commenter attempts to distinguish ''caregiver respite'' from part 61 ''respite'' care, but the distinction cannot be drawn in the manner described by the commenter. ''Caregiver respite'' is medical care provided to veterans who have caregivers as part of the medical benefits package, found at 38 CFR 17.38(a)(1)(ix), as further delineated under 38 CFR 71.25(d), 71.40(a)(4), and 71.40(c)(2). As a medical benefit, this respite care, too, could be referred to as ''medical respite care''—just like the type of respite services discussed by the commenter. It is identical in all meaningful respects to the type of care that the commenter refers to as ''medical respite services''—it is short-term medical care and case management provided to an individual who is unable to care for him/herself. In short, any distinction between ''caregiver respite'' and respite care provided under part 61 could not be made based on the insertion of the word ''medical'' before ''respite.'' The only clear distinction is that respite care provided to veterans with caregivers is not necessarily provided in an emergent situation, and we see no reason to limit respite care provided under part 61 to respite care provided in an emergent situation.

We also note that under 38 CFR 62.33(a)(2)(i), respite care is an authorized supportive service under VA's Supportive Services for Veteran Families (SSVF) program, which may be provided by SSVF grantees who are providing health care services to veteran families who recently became homeless or who are at risk of becoming homeless. There has been no confusion among SSVF grantees that such respite care may only be provided to a veteran with a caregiver, and we likewise see no potential for confusion in § 61.1. Indeed, we might create ambiguity where there currently is none if we were to refer in § 61.1 to ''medical respite care'' and in § 62.33 to ''respite care'' when both regulations describe the same medical service. Therefore, § 61.1 should not be revised to differentiate between ''caregiver respite'' and respite care provided to a homeless, seriously ill veteran.

The commenter recommended incorporating the HRSA definition of ''medical respite'' into the final rule. The HRSA definition defines ''medical respite services'' in part as ''short term medical care and case management provided to persons (generally homeless) recovering from an acute illness or injury, whose conditions would be exacerbated by living on the street, in a shelter or other unsuitable places.'' We decline to do so because, as noted above, respite care is already identified as medical care in the context of the medical benefits package, and as a type of care appropriate for homeless veterans under SSVF. In addition, the definition proposed by the commenter, by its express terms, includes persons who may not be homeless. The statutory authority for the VA Homeless Providers Grant and Per Diem Program extends only to a veteran who is homeless as that term is defined in section 103(a) of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11302(a)).

The commenter urged us to revise the definition of supportive services, noting that medical respite services may be delivered in settings other than those included in the definition of ''supportive housing.'' The VA Homeless Providers Grant and Per Diem Program was authorized by Congress in 1992 under Public Law 102–590, which gave VA authority to provide financial support to nonprofit organizations and state and local governments to establish programs to assist the homeless veteran population. Two program parameters set by statute have remained constant since the inception of this program: (1) Providing support services in the context of housing for homeless veterans; and (2) doing so via capital grants to eligible organizations, or per diem payments to entities that are either receiving or are eligible to receive capital grants. 38 U.S.C. 2011 and 2012. These criteria reflect VA's goal to provide homeless veterans a safe and stable environment with needed services, as well as ensuring that entities providing services have sufficient resources to maintain those services. Providing medical respite as a standalone support service separate and apart from offering supportive housing to homeless veterans is not within the purview of this program.

Although we make no changes based on the comments, we do assure the commenter that care meeting the HRSA definition of medical respite services

could be provided as a supportive service to homeless veterans under the VA Homeless Providers Grant and Per Diem Program, so long as the provider and the care meet the other part 61 requirements for either a capital or per diem grant. We recognize the importance of such care to the recovery of homeless veterans from emergent medical crises, and we do not believe that our regulations bar, or even discourage, the provision of such care by grantees.

The commenter also urged VA to conduct research to determine the number of detoxification programs that are based out of housing before publishing its final rule. The commenter states that many detoxification programs are based out of clinical settings rather than housing settings, and that by limiting the VA Homeless Providers Grant and Per Diem Program to those detoxification programs based out of housing, VA may be limiting access in many communities. In 2010, VA announced its goal to eliminate veteran homelessness within 5 years. The VA Homeless Providers Grant and Per Diem Program is one of several programs focused on achieving that goal, and it provides funding for supportive services through housing, not clinical, settings. Other VA programs, such as VA's Health Care for Homeless Veterans (HCHV) Program (implemented under 38 CFR part 63) does focus on the substance abuse issues of homeless veterans. It offers outreach, exams, treatment, referrals, and case management to veterans who are homeless and dealing with mental health issues, including substance use. Other related VA programs that offer services to homeless veterans include VA's Substance Use Disorder Treatment Enhancement Initiative as well as Veteran Justice Outreach. The scope of the VA Homeless Providers Grant and Per Diem Program does not include funding for detoxification treatment in other venues, but homeless veterans may receive that treatment through other VA programs.

The final issues raised by the commenter focused on operational requirements for grantees. The commenter stated that the current requirement for grantee compliance with the Life Safety Code of the National Fire Protection Association (NFPA) prevents some potential grantees from participating in the VA Homeless Providers Grant and Per Diem Program. The specific example cited by the commenter was a local program that was prevented from collaborating with VA because it was unable to comply with code requirements for a sprinkler system throughout its facility. The commenter stated that VA should assist programs by providing grants to help medical respite programs meet operational requirements. In addition, the commenter suggests that VA develop alternative policies relative to operational requirements that are more flexible and reflect a balance between safety and no care at all.

Section 2011(b)(5) of title 38, United States Code, states that the eligibility criteria for entities eligible to receive grants shall include provisions to ensure that the entity receiving a grant meets fire and safety requirements established by VA, including applicable state and local requirements as well as fire and safety requirements applicable under the Life Safety Code of the NFPA or such other comparable fire and safety requirements as VA may specify. Similar requirements for per diem only payments are found in 38 U.S.C. 2012(c). We interpret these provisions to require that grantees meet fire and safety requirements as a prerequisite to receiving a grant award. Providing grants to assist programs in meeting fire and safety requirements could result in situations where an applicant receives a grant to upgrade a structure to meet fire and safety requirements, and thereafter does not meet the other criteria for receiving a grant to provide services to homeless veterans.

The safety of veterans receiving services directly from VA or through grantees is of paramount importance. Fire and safety requirements that are applicable across VA ensure that homeless veterans receiving services from a grantee are protected to the same degree regardless of location. We believe this rule strikes the correct balance and do not make any changes based on this comment.

61.67

In proposed § 61.67(b), we had proposed to revise the amount of grant money VA will seek to recover on a prorated basis where the grant recipient ceases to provide services for which the grant was made or withdraws from the Program prior to the expiration of the applicable period of operation. This was reflected in a chart showing the correlation between grant amounts and years of operation, which is necessary to apply the formula for grant recovery described in proposed paragraph (b). We had proposed to extend the periods of operation from the existing range of 7 to 20 years to a range of 20 to 40 years, and to change the grant amount relating to periods of years within that proposed 20- to 40-year period. At the time the proposed rule was published, we believed these revisions would better reflect industry standards for both accounting and real estate methodologies for calculating depreciation and asset worth.

Since this proposed change in the recovery provisions was published, VA has increased funding to programs that focus on moving veterans to permanent housing. We believe it is reasonable to conclude that although transitional housing will always be needed, demand for transitional housing will decline as homeless veterans move into permanent housing. In December 2011, VA announced that the number of homeless veterans had decreased by 12 percent and that between 2009 and 2011 VA and the Department of Housing and Urban Development had successfully housed a total of 33,597 veterans in permanent, supportive housing with dedicated case managers and access to high-quality VA health care. In its first 6 months of operation, the SSVF provided services to over 15,000 participants. To date, over 80 percent of those discharged from SSVF have been placed in or saved their permanent housing.

Based on the successful transition of so many veterans to permanent housing, we now believe that there is less of a need to extend the operational period for grants awarded under this program. The VA Homeless Providers Grant and Per Diem Program specifically provides for the homeless veteran population, and the purpose of the extended recovery period was to require a longer-term period of operation for grantee programs. We now believe that lengthening the time of operation for our grantees could hamper their continued viability, as transitional housing beds may not be filled, decreasing grantee per diem income. Further, grantees would have to wait longer to convert from providing existing transitional housing to providing permanent housing (which is beyond the scope of this program), since the conversion can be accomplished only after the original grant obligations have been met. By continuing to use the current rather than the proposed recovery period, grantees could convert earlier thereby keeping their organizations viable while continuing to serve veterans. Therefore, we are not amending § 61.67(b) at this time.

In addition, we have included in this final rule changes to part 61 mandated by the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012, Public Law 112–154. This law was enacted following publication of the proposed rule. Title III of this Public Law impacts this final rule by expanding the definition of homeless

veterans with special needs to include individuals, regardless of gender, who have care of minor dependents; allowing special needs grant and per diem recipients to provide services directly to a dependent of a homeless veteran with special needs who is under the care of that homeless veteran; and clarifying grant eligibility for certain nonprofit organizations. This final rule differs from the proposed rule as necessary to reflect those changes. Because we are repeating the statutory language in the regulations without substantive change, additional notice and comment rulemaking is not required. We made the following changes:

61.14

New paragraph (d) states that VA may not reject an application solely on the basis that the entity proposes to use funding from other private or public sources, if the entity demonstrates that a private nonprofit organization will provide oversight and site control for the project. ''Private nonprofit organization'' is further defined.

61.40

VA provides special need grants to public or nonprofit private entities that will create or provide supportive housing and services, which they would not otherwise create or provide, for certain special need homeless veteran populations. In paragraph (a), we expand the covered special need homeless veteran populations to include male homeless veterans with minor children.

New paragraph (c) states that recipients of special needs grants under this section may use amounts under the grant to provide services directly to a dependent of a homeless veteran with special needs who is under the care of that homeless veteran while the veteran receives services from the grant recipient.

61.41

Paragraphs (b) and (c) of this section are revised to match special needs grant application requirements related to changes in § 61.40.

In this final rule we also correct some minor, nonsubstantive typographical errors. Based on the rationale set forth in the proposed rule and in this document, VA is adopting the provisions of the proposed rule as a final rule, except as to the changes noted above.

Effect of Rulemaking

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

Paperwork Reduction Act

This final rule at §§ 61.62(f) and 61.80(c) contains new collections of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). On March 1, 2012, in a proposed rule published in the **Federal Register**, we requested public comments on the new collections of information. We received no comments. Therefore, we make no changes to these collections.

The Office of Management and Budget (OMB) has approved the new information collection requirements associated with this final rule and assigned OMB Control Number 2900–0554. We are adding a parenthetical statement after the authority citations to the sections in part 61 for which new collections have been approved so that the control number is displayed for each new collection.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will directly affect only those entities that choose to participate in the VA Homeless Providers Grant and Per Diem Program. Small entity applicants would not be affected to a greater extent than large entity applicants. Small entities must elect to participate, and it is considered a benefit to those who choose to apply. To the extent this rule would have any impact on small entities, it would not have an impact on a substantial number of small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Orders 12866 and 13563

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

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits and 64.024, VA Homeless Providers Grant and Per Diem Program.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of

the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on February 14, 2013, for publication.

List of Subjects in 38 CFR Part 61

Administrative practice and procedure, Alcohol abuse, Alcoholism, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Mental health programs, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Dated: February 20, 2013.

Robert C. McFetridge,

Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 61 is revised to read as follows:

PART 61—VA HOMELESS PROVIDERS GRANT AND PER DIEM PROGRAM

Sec.

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61.82 Participant fees for supportive housing.

Authority: 38 U.S.C. 501, 2001, 2002, 2011, 2012, 2061, 2064.

Subpart A—General Provisions

§ 61.0 Purpose.

This part implements the VA Homeless Providers Grant and Per Diem Program which consists of the following components: capital grants, per diem, special need capital and non-capital grants, and technical assistance grants.

(Authority: 38 U.S.C. 501, 2001, 2002, 2011, 2012, 2061, 2064)

§ 61.1 Definitions.

For purposes of this part:

Area or community means a political subdivision or contiguous political subdivisions (such as a precinct, ward, borough, city, county, State, Congressional district, etc.) with a separately identifiable population of homeless veterans.

Capital grant means a grant for construction, renovation, or acquisition of a facility, or a grant for acquisition of a van.

Capital lease is defined by § 61.4.

Chronically mentally ill means a condition of schizophrenia or major affective disorder (including bipolar disorder) or post-traumatic stress disorder (PTSD), based on a diagnosis from a licensed mental health professional, with at least one documented hospitalization for this condition sometime in the last 2 years or with documentation of a formal assessment on a standardized scale of any serious symptomatology or serious impairment in the areas of work, family relations, thinking, or mood.

Default means a determination by VA that an awardee has materially failed to comply with the terms and conditions of an award.

Fixed site means a physical structure that under normal conditions is not capable of readily being moved from one location to another location.

Frail elderly means 65 years of age or older with one or more chronic health problems and limitations in performing one or more activities of daily living (such as bathing, toileting, transferring from bed to chair, etc.).

Homeless has the meaning given that term in section 103 of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11302(a)).

New construction means building a structure where none existed, or building an addition to an existing structure that increases the floor area by more than 100 percent.

Nonprofit organization means a private organization, no part of the net earnings of which may inure to the benefit of any member, founder, contributor, or individual. The organization must be recognized as a section 501(c)(3) or 501(c)(19) nonprofit organization by the United States Internal Revenue Service, and meet all of the following criteria:

(1) Have a voluntary board;

(2) Have a functioning accounting system that is operated in accordance with generally accepted accounting principles, or designate an entity to maintain such a functioning accounting system; and

(3) Practice nondiscrimination in the provision of supportive housing and supportive services assistance.

Notice of Fund Availability (NOFA) means a notice published in the **Federal Register** in accordance with § 61.60.

Operating costs means expenses incurred in operating supportive housing, supportive services or service centers with respect to:

(1) Administration (including staff salaries; costs associated with accounting for the use of grant funds, preparing reports for submission to VA, obtaining program audits, and securing accreditation; and similar costs related to administering the grant after the award), maintenance, repair and security for the supportive housing;

(2) Van costs or building rent (except under capital leases), e.g., fuel, insurance, utilities, furnishings, and equipment;

(3) Conducting on-going assessments of supportive services provided for and needed by participants and the availability of such services; and

(4) Other costs associated with operating the supportive housing.

Operational means a program for which all VA inspection requirements under this part have been met and an activation document has been issued by the VA National GPD Program.

Outpatient health services means outpatient health care, outpatient mental health services, outpatient

alcohol and/or substance abuse services, and case management.

Participant means a person receiving services based on a grant or per diem provided under this part.

Participant agreement means any written or implied agreement between a grant recipient agency and a program participant that outlines the requirements for program compliance, participant or service delivery.

Project means all activities that define the parameters of the purpose of the grant.

Public entity means any of the following:

(1) A county, municipality, city, town, township, local public authority (including any public and Indian housing agency under the United States Housing Act of 1937), school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under state law), any other regional or interstate government entity, or any agency or instrumentality of a local government; or

(2) The governing body or a governmental agency of any Indian tribe, band, nation, or other organized group or community (including any Native village as defined in section 3 of the Alaska Native Claims Settlement Act, 85 Stat 688) certified by the Secretary of the Interior as eligible for the special programs and services provided by the Bureau of Indian Affairs.

Recipient means the entity whose employer or taxpayer identification number is on the Application for Federal Assistance (SF 424) and is consequently responsible to comply with all terms and conditions of the award. For the purpose of this part the terms ''grantee,'' ''recipient,'' and ''awardee'' are synonymous and interchangeable.

Rehabilitation means the improvement or repair of an existing structure. Rehabilitation does not include minor or routine repairs.

State means any of the several states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a state exclusive of local governments. The term does not include any public and Indian housing agency under United States Housing Act of 1937.

Supportive housing means housing with supportive services provided for homeless veterans that:

(1) Is not shelter care, other emergent housing, or housing designed to be permanent or long term (more than 24 months), with no requirement to move; and

(2) Is designed to either:

(i) Facilitate the movement of homeless veterans to permanent housing within a period that is not less than 90 days and does not exceed 24 months, subject to § 61.80; or

(ii) Provide specific medical treatment such as detoxification, respite, or hospice treatments that are used as step-up or step-down programs within that specific project's continuum.

Supportive services has the meaning assigned to it under § 61.2.

Terminally ill means a prognosis of 9 months or less to live, based on a written medical diagnosis from a physician.

Total project cost means the sum of all costs incurred by a recipient for the acquisition, rehabilitation, and new construction of a facility, or van(s), identified in a grant application.

VA means the Department of Veterans Affairs.

VA National GPD Program refers to the VA Homeless Providers Grant and Per Diem Program.

Veteran means a person who served in the active military, naval, or air service, and who was discharged or released there from under conditions other than dishonorable.

(Authority: 38 U.S.C. 501, 2002, 2011, 2012, 2061, 2064)

§ 61.2 Supportive services—general.

(a) Recipients must design supportive services. Such services must provide appropriate assistance, or aid participants in obtaining appropriate assistance, to address the needs of homeless veterans. The following are examples of supportive services:

(1) Outreach activities;

(2) Providing food, nutritional advice, counseling, health care, mental health treatment, alcohol and other substance abuse services, case management services;

(3) Establishing and operating child care services for dependents of homeless veterans;

(4) Providing supervision and security arrangements necessary for the protection of residents of supportive housing and for homeless veterans using supportive housing or services;

(5) Assistance in obtaining permanent housing;

(6) Education, employment counseling and assistance, and job training;

(7) Assistance in obtaining other Federal, State and local assistance available for such residents including mental health benefits, employment counseling and assistance, veterans' benefits, medical assistance, and income support assistance; and

(8) Providing housing assistance, legal assistance, advocacy, transportation, and other services essential for achieving and maintaining independent living.

(b) Supportive services do not include inpatient acute hospital care.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061)

§ 61.3 Notice of Fund Availability.

When funds are made available for a grant or per diem award under this part, VA will publish a Notice of Fund Availability in the **Federal Register**. The notice will:

(a) Give the location for obtaining application packages;

(b) Specify the date, time, and place for submitting completed applications;

(c) State the estimated amount and type of funding available; and

(d) State any priorities for or exclusions from funding to meet the statutory mandate of 38 U.S.C. 2011, to ensure that awards do not result in the duplication of ongoing services and to reflect the maximum extent practicable appropriate geographic dispersion and an appropriate balance between urban and nonurban locations.

(e) Provide other information necessary for the application process, such as the grant period, where applicable.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061, 2064)

§ 61.4 Definition of capital lease.

A capital lease, for purposes of this part, means a conditional sales contract that either:

(a) Will be in effect for all of the period of recovery listed in § 61.67(b); or

(b) That satisfies one of the following criteria:

(1) The lease transfers ownership to the lessee at the expiration of the lease term.

(2) The lease contains a bargain purchase option.

(3) The present value of lease payments that are applied to the purchase are equal to or greater than 90 percent of the fair market value of the asset.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061, 2064)

Subpart B—Capital Grants

§ 61.10 Capital grants—general.

(a) Subject to the availability of appropriations provided for such purpose, VA will provide capital grants to public or nonprofit private entities so they can assist homeless veterans by helping to ensure the availability of

supportive housing and service centers to furnish outreach, rehabilitative services, and vocational counseling and training. Specifically, VA provides capital grants for up to 65 percent of the cost to:

(1) Construct structures and purchase the underlying land to establish new supportive housing facilities or service centers, or to expand existing supportive housing facilities or service centers;

(2) Acquire structures to establish new supportive housing facilities or service centers, or to expand existing supportive housing facilities or service centers;

(3) Renovate existing structures to establish new supportive housing facilities or service centers, or to expand existing supportive housing facilities or service centers; and

(4) Procure a van in accordance with § 61.18, Capital grants for vans.

(b) Capital grants may not be used for acquiring buildings located on VA-owned property. However, capital grants may be awarded for construction, expansion, or renovation of buildings located on VA-owned property.

(Authority: 38 U.S.C. 501, 2011)

§ 61.11 Capital grants—application packages.

(a) *General.* To apply for a capital grant, an applicant must obtain from, complete, and submit to VA a capital grant application package within the time period established in the Notice of Fund Availability.

(b) *Content of application.* The capital grant application package will require the following:

(1) Site description, site design, and site cost estimates.

(2) Documentation supporting:

(i) Eligibility to receive a capital grant under this part;

(ii) Matching funds committed to the project;

(iii) A proposed operating budget and cost sharing;

(iv) Supportive services committed to the project;

(v) The applicant's authority to control the site and meet appropriate zoning laws; and

(vi) The boundaries of the area or community that would be served.

(3) If capital grant funds would be used for acquisition or rehabilitation, documentation demonstrating that the costs associated with acquisition or rehabilitation are less than the costs associated with new construction.

(4) If capital grant funds would be used for new construction, documentation demonstrating that the costs associated with new construction are less than the costs associated with rehabilitation of an existing building, that there is a lack of available appropriate units that could be rehabilitated at a cost less than new construction, and that new construction is less costly than acquisition of an existing building (for purposes of this cost comparison, costs associated with rehabilitation or new construction may include the cost of real property acquisition).

(5) If proposed construction includes demolition:

(i) A demolition plan that describes the extent and cost of existing site features to be removed, stored, or relocated; and

(ii) Information establishing that the proposed construction is either in the same location as the building to be demolished or that the demolition is inextricably linked to the design of the construction project. Without such information, the cost of demolition cannot be included in the cost of construction.

(6) If the applicant is a state, comments or recommendations by appropriate state (and area wide) clearinghouses pursuant to E.O. 12372 (3 CFR, 1982 Comp., p. 197).

(7) A statement from the applicant that all of the following are true:

(i) The project will furnish to veterans the level of care for which such application is made, and services provided will meet the requirements of this part.

(ii) The applicant will continue to operate the project until the expiration of the period during which VA could seek full recovery under § 61.67.

(iii) Title to the site will vest solely in the applicant and the applicant will insure the site to the same extent they would insure a site bought with their own funds.

(iv) Adequate financial support will be available for the completion of the project.

(v) The applicant will keep records and submit reports as VA may reasonably require, within the time frames required, and, upon demand, allow VA access to the records upon which such information is based.

(vi) The applicant will state that no more than 25 percent of the grant-awarded beds are occupied by non-veterans.

(c) *Multiple capital grant applications.* Subject to § 61.12(i), applicants may apply for more than one capital grant.

(Authority: 38 U.S.C. 501, 2011)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554).

§ 61.12 Capital grant application packages—threshold requirements.

The following threshold requirements for a capital grant application must be met, or the application will be rejected before being rated under § 61.13:

(a) The application package must meet all of the following criteria:

(1) Be on the correct application form.

(2) Be completed in all parts, including all information requested in the Notice of Fund Availability and application package.

(3) Include a signed Application for Federal Assistance (SF 424) that contains the Employer Identification Number or Taxpayer Identification Number (EIN/TIN) that corresponds to the applicant's Internal Revenue Service (IRS) 501(c)(3) or (19) determination letter. All applicants must provide such an IRS determination letter, which includes their EIN/TIN. Applicants that apply under a group EIN/TIN must be identified by the parent EIN/TIN as a member or sub-unit of the parent EIN/TIN and provide supporting documentation.

(4) Be submitted before the deadline established in the Notice of Fund Availability.

(b) The applicant must be a public or nonprofit private entity at the time of application.

(c) The activities for which assistance is requested must be eligible for funding under this part.

(d) The applicant must demonstrate that adequate financial support will be available to carry out the project for which the capital grant is sought, consistent with the plans, specifications, and schedule submitted by the applicant.

(e) The application must demonstrate compliance with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (URA) (42 U.S.C. 4601–4655).

(f) The applicant must agree to comply with the requirements of this part and demonstrate the capacity to do so.

(g) The applicant must not have an outstanding obligation to VA that is in arrears, or have an overdue or unsatisfactory response to an audit.

(h) The applicant must not have been notified by VA as being in default.

(i) The applicant, during the 5 years preceding the date of the application, must not have done any of the following:

(1) Had more than two grants awarded under this part that remain in development;

(2) Failed to establish two previous awarded grant projects under this part; or

(3) Had a previous grant or per diem project awarded under this part terminated or transferred to another eligible entity for failure to comply with the terms and conditions of the award.

(Authority: 38 U.S.C. 501, 2011)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554).

§ 61.13 Capital grant application packages—rating criteria.

(a) *General.* Applicants that meet the threshold requirements in § 61.12 will be rated using the selection criteria listed in this section. To be eligible for a capital grant, an applicant must receive at least 750 points (out of a possible 1000) and must receive points under each of the following paragraphs (b), (c), (d), (e), (f), and (g) of this section.

(b) *Project plan.* VA will award up to 300 points based on the demonstration and quality of the following:

(1) The selection of the proposed housing in light of the population to be served.

(2) The process used for deciding which veterans are appropriate for admission.

(3) How, when, and by whom the progress of participants toward meeting their individual goals will be monitored, evaluated, and documented.

(4) The role program participants will have in operating and maintaining the housing.

(5) The responsibilities the applicant, sponsors, or contractors will have in operating and maintaining the housing.

(6) The supportive services that will be provided and by whom to help participants achieve residential stability, increase skill level and/or income, and become involved in making life decisions that will increase self-determination.

(7) The measureable objectives that will be used to determine success of the supportive services.

(8) How the success of the program will be evaluated on an ongoing basis.

(9) How the nutritional needs of veterans will be met.

(10) How the agency will ensure a clean and sober environment.

(11) How participants will be assisted in assimilating into the community through access to neighborhood facilities, activities, and services.

(12) How the proposed project will be implemented in a timely fashion.

(13) How permanent affordable housing will be identified and made known to participants upon leaving the supportive housing.

(14) How participants will be provided necessary follow-up services.

(15) The description of program policies regarding participant agreements, rent, and fees.

(c) *Outreach to persons on streets and in shelters.* VA will award up to 100 points based on:

(1) The agency's outreach plan to serve homeless veterans living in places not ordinarily meant for human habitation (e.g., streets, parks, abandoned buildings, automobiles, under bridges, in transportation facilities) and those who reside in emergency shelters; and

(2) The likelihood that proposed plans for outreach and selection of participants will result in these populations being served.

(d) *Ability of applicant to develop and operate a project.* VA will award up to 200 points based on the extent to which the application demonstrates the necessary staff and organizational experience to complete and operate the proposed project, based on the following:

(1) Staffing plan for the project that reflects the appropriate professional staff, both administrative and clinical;

(2) Experience of staff, if staff not yet hired, position descriptions and expectations of time to hire;

(3) Amount of time each staff position is dedicated to the project, and in what capacity;

(4) Applicant's previous experience assessing and providing for the housing needs of homeless veterans;

(5) Applicant's previous experience assessing and providing supportive services for homeless veterans;

(6) Applicant's previous experience assessing supportive service resources and entitlement benefits;

(7) Applicant's previous experience with evaluating the progress of both individual participants and overall program effectiveness using quality and performance data to make changes;

(8) Applicant's previous experience operating housing for homeless individuals;

(9) Overall agency organizational overview (org. chart); and

(10) Historical documentation of past performance both with VA and non-VA projects, including those from other Federal, state and local agencies and audits by private or public entities.

(e) *Need.* VA will award up to 150 points based on the extent to which the applicant demonstrates:

(1) Substantial unmet needs, particularly among the target population living in places not ordinarily meant for human habitation such as the streets, emergency shelters, based on reliable data from surveys of homeless populations or other reports or data gathering mechanisms that directly support claims made; and

(2) An understanding of the homeless population to be served and its unmet housing and supportive service needs.

(f) *Completion confidence.* VA will award up to 50 points based on the review panel's confidence that the applicant has effectively demonstrated the supportive housing or service center project will be completed as described in the application. VA may use historical program documents of past performance both VA and non-VA, including those from other Federal, state and local agencies as well as audits by private or public entities in determining confidence scores.

(g) *Coordination with other programs.* VA will award up to 200 points based on the extent to which applicants demonstrate that they have coordinated with Federal, state, local, private and other entities serving homeless persons in the planning and operation of the project. Such entities may include shelter transitional housing, health care, or social service providers; providers funded through Federal initiatives; local planning coalitions or provider associations; or other program providers relevant to the needs of homeless veterans in the local community. Applicants are required to demonstrate that they have coordinated with the VA medical care facility of jurisdiction and/or VA Regional Office of jurisdiction in their area. VA will award up to 50 points of the 200 points based on the extent to which commitments to provide supportive services are documented at the time of application. Up to 150 points of the 200 points will be given to the extent applicants demonstrate that:

(1) They are part of an ongoing community-wide planning process within the framework described above which is designed to share information on available resources and reduce duplication among programs that serve homeless veterans;

(2) They have consulted directly with the closest VA Medical Center and other providers within the framework described above regarding coordination of services for project participants; and

(3) They have coordinated with the closest VA Medical Center their plan to assure access to health care, case management, and other care services.

(Authority: 38 U.S.C. 501, 2011)

§ 61.14 Capital grants—selection of grantees.

(a) Applicants will first be grouped in categories according to the funding priorities set forth in the NOFA, if any. Applicants will then be ranked, within their respective funding category if applicable. The highest-ranked applications for which funding is available, within highest priority funding category if applicable, will be conditionally selected to receive a capital grant in accordance with their ranked order, as determined under § 61.13. If funding priorities have been established and funds are still available after selection of those applicants in the highest priority group VA will continue to conditionally select applicants in lower priority categories in accordance with the selection method set forth in this paragraph subject to available funding.

(b) In the event of a tie between applicants, VA will use the score from § 61.13(g) to determine the ranking. If the score from § 61.13(g) is also tied, VA will use the score from § 61.13(d) to determine the ranking.

(c) VA may reject an application where the project is not cost effective based on the cost and number of new supportive housing beds made available—or based on the cost, amount, and types of supportive services made available—when compared to other supportive housing or services projects, and when adjusted for high cost areas. For those applications that VA believes not to be cost-effective VA will;

(1) Reduce the award; or

(2) Not select the application for funding.

(d) VA may not reject an application solely on the basis that the entity proposes to use funding from other private or public sources, if the entity demonstrates that a private nonprofit organization will provide oversight and site control for the project. In this section ''private nonprofit organization'' means one of the following:

(1) An incorporated private institution, organization, or foundation—

(i) That has received, or has temporary clearance to receive, tax-exempt status under paragraph (2), (3), or (19) of section 501(c) of the Internal Revenue Code of 1986;

(ii) For which no part of the net earnings of the institution, organization, or foundation inures to the benefit of any member, founder, or contributor of the institution, organization, or foundation; and

(iii) That VA determines is financially responsible.

(2) A for-profit limited partnership or limited liability company, the sole general partner or manager of which is an organization that is described by paragraph (d)(1) of this section.

(3) A corporation wholly owned and controlled by an organization that is described by paragraph (d)(1) of this section.

(e) In the case of a previously awarded project that can no longer provide services and or housing and the recipient agency has decided to withdraw or the project has been terminated for failure to comply with the terms and conditions of the award; VA may transfer a capital grant or non-capital grant to another eligible entity in the same geographical area without competition, in order to prevent a loss of capacity of services and housing to homeless veterans. The new entity must meet all of the requirements to which the original grantee was subject. In the case of a capital grant transfer the new grantee will only be entitled to the funding that remains from the original capital obligation and remains responsible for all commitments made by the original grantee.

(Authority: 38 U.S.C. 501, 2011)

§ 61.15 Capital grants—obtaining additional information and awarding capital grants.

(a) Each applicant who has been conditionally selected for a capital grant will be requested by VA to submit additional documentation or information as necessary, including:

(1) Any additional information necessary to show that the project is feasible, including a plan from an architect, contractor, or other building professional who provides estimated costs for the proposed design;

(2) Documentation showing the sources of funding for the project and firm financing commitments for the matching requirements described in § 61.16;

(3) Documentation establishing site control described in § 61.17;

(4) Documentation establishing compliance with the National Historic Preservation Act (16 U.S.C. 470);

(5) Information necessary for VA to ensure compliance both with Uniform Federal Accessibility Standards (UFAS) and the Americans with Disabilities Act Accessibility Guidelines;

(6) Documentation establishing compliance with local and state zoning codes;

(7) Documentation in the form of one set of design development (35 percent completion) drawings demonstrating compliance with local codes, state codes, and the current Life Safety Code of the National Fire Protection Association.

(8) Information necessary for VA to ensure compliance with the provisions of the National Environmental Policy Act (42 U.S.C. 4321 et seq.);

(9) A site survey performed by a licensed land surveyor; and

(10) Such other documentation as specified by VA in writing or verbally to the applicant to confirm or clarify information provided in the application.

(b) Items requested under paragraph (a) of this section must be received by VA in acceptable form within the time frame established in accordance with the Notice of Fund Availability.

(c) Following receipt of the additional information in acceptable form, VA will execute an agreement and make payments to the grant recipient in accordance with § 61.61 and other applicable provisions of this part.

(Authority: 38 U.S.C. 501, 2011)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554)

§ 61.16 Matching funds for capital grants.

(a) VA cannot award a capital grant for more than 65 percent of the total allowable costs of the project. The grantee must provide funding (''matching funding'') for the remaining 35 percent of the total cost, using non-federal funds. VA requires that applicants provide documentation of all costs related to the project including those that are not allowable under OMB Circular A–122 as codified at 2 CFR part 230. Allowable costs means those related to the portion (percentage) of the property that would be used to provide supportive housing and services under this part.

(b) Capital grants may include application costs, including site surveys, architectural, and engineering fees, but may not include relocation costs or developer's fees.

(c) *Documentation of matching funds.* The matching funds described in paragraph (a) of this section must be documented as follows; no other format will be accepted as evidence of a firm commitment of matching funds:

(1) Donations must be on the donor's letterhead, signed and dated.

(2) The applicant's own cash must be committed on the applicant's letterhead, signed, and dated.

(3) No conditions may be placed on the matching funds other than the organization's receipt of the capital grant.

(4) Funds must be committed to the same activity as the capital grant application (i.e., acquisition, renovation,

new construction, or a van), and must not relate to operating costs or services.

(5) The value of matching funds must be for a cost that is included in the calculation of the total project cost, thereby decreasing the total expenditures of the grantee.

(d) *Van applications.* The requirements of this section also apply to applications for a capital grant for a van under § 61.18.

(Authority: 38 U.S.C. 501, 2011)

§ 61.17 Site control for capital grants.

(a) In order to receive a capital grant for supportive housing or a fixed site service center, an applicant must demonstrate site control. Site control must be demonstrated through a deed or an executed contract of sale, or a capital lease, which assigns control or ownership to the entity whose Federal employer or taxpayer identification number is on the Application for Federal Assistance (SF424), unless one of the following apply:

(1) VA gives written permission for an alternate assignment. VA will permit alternate assignments except when:

(i) The alternate assignment is to a for-profit entity which is neither controlled by the applicant or by the applicant's parent organization or the entity is controlled by the applicant's parent organization which is a for-profit entity; or

(ii) VA has a reasonable concern that the assignment may provide an economic or monetary benefit to the assignee other than the benefit that would have inured to the applicant had the applicant not made the alternate assignment.

(2) The site is in a building or on land owned by VA, and the applicant has an agreement with VA for site control.

(b) A capital grant recipient may change the site to a new site meeting the requirements of this part subject to VA approval under § 61.62. However, the recipient is responsible for and must demonstrate ability to provide for any additional costs resulting from the change in site.

(c) If site control is not demonstrated within 1 year after execution of an agreement under § 61.61, the grantee may request a reasonable extension from the VA national GPD office, or the grant may be terminated. VA will authorize an extension request if the grantee was not at fault for being unable to exercise site control and the lack of site control does not affect the grantee's ability to complete the project.

(Authority: 38 U.S.C. 501, 2011)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554)

§ 61.18 Capital grants for vans.

(a) *General.* A capital grant may be used to procure one or more vans, as stated in a NOFA, to provide transportation or outreach for the purpose of providing supportive services. The grant may cover the purchase price, sales taxes, and title and licensing fees. Title to the van must vest solely in the applicant, and the applicant must insure the van to the same extent they would insure a van bought with their own funds.

(b) *Who can apply for a van.* VA will only award vans to applicants who currently have an operational grant under this part, or in conjunction with a new application.

(c) *Application packages for van(s).* In order to receive a van, the application must demonstrate the following:

(1) Clear need for the van(s);

(2) Specific use of the van(s);

(3) Frequency of use of the van(s);

(4) Qualifications of the van driver(s);

(5) Training of the van driver(s);

(6) Type of van(s) to be obtained; and

(7) Adequate financial support will be available for the completion of the project or for the purchase and maintenance, repair, and operation of the van(s).

(d) *Rating criteria.* Applications will be scored using the selection criteria listed in this section. To be eligible for a van grant, an applicant must receive at least 80 points (out of a possible 100) of this section.

(1) *Need.* VA will award up to 60 points based on the extent to which the applicant demonstrates a substantial unmet need for transportation due to:

(i) Lack of alternative public transportation,

(ii) Project location,

(iii) Expired life use of current van, or

(iv) Special disabled individual transportation.

(2) *Activity.* VA will award up to 20 points based on the extent to which the applicant demonstrates:

(i) Frequency of use,

(ii) Type of use, and

(iii) Type of van, e.g., whether there is a justification for a van with a wheelchair lift or other modifications.

(3) *Operator qualification.* VA will award up to 20 points based on the extent to which the applicant demonstrates a job description for the van operator that details:

(i) Requirements of the position, and

(ii) Training that will be provided to the driver.

(Authority: 38 U.S.C. 501, 2011)

§ 61.19 Transfer of capital grants.

In the case of a previously awarded project that can no longer provide services and/or housing and the recipient agency has decided to withdraw or the project has been terminated for failure to comply with the terms and conditions of the award, VA may transfer a capital grant or non-capital grant to another eligible entity in the same geographical area without competition, in order to prevent a loss of capacity of services and housing to homeless veterans. The new entity must meet all of the requirements to which the original grantee was subject. In the case of a capital grant transfer the new grantee will only be entitled to the funding that remains from the original capital obligation and remains responsible for all commitments made by the original grantee.

(Authority: 38 U.S.C. 501, 2011)

Subpart C—Per Diem Payments

§ 61.30 Per diem—general.

(a) *General.* VA may provide per diem funds to offset operating costs for a program of supportive housing or services. VA may provide:

(1) Per diem funds to capital grant recipients; or

(2) Per diem only (PDO) funds to entities eligible to receive a capital grant, if the entity established a program of supportive housing or services after November 10, 1992.

(b) *Capital grant recipients.* Capital grant recipients may request per diem funds after completion of a project funded by a capital grant and a site inspection under § 61.80 to ensure that the grantee is capable of providing supportive services.

(c) *Per diem only applicants.* PDO awards to entities eligible to receive a capital grant must provide supportive housing or services to the homeless veteran population within 180 days after the date on the notification of award letter, or VA will terminate the PDO payments.

(Authority: 38 U.S.C. 501, 2012)

§ 61.31 Per diem—application packages.

(a) *Capital grant recipient.* To apply for per diem, a capital grant recipient need only indicate the intent to receive per diem on the capital grant application or may separately request per diem by submitting to VA a written statement requesting per diem.

(b) *Non-capital-grant recipient (per diem only).* To apply for per diem only, a non-capital grant applicant must obtain from VA a non-capital grant application package and submit to VA the information called for in the

application package within the time period established in the Notice of Fund Availability. The application package includes exhibits to be prepared and submitted as part of the application process, including:

(1) Documentation on eligibility to receive per diem under this part;

(2) Documentation on operating budget and cost sharing;

(3) Documentation on supportive services committed to the project;

(4) Comments or recommendations by appropriate state (and area wide) clearinghouses pursuant to E.O. 12372 (3 CFR, 1982 Comp., p. 197), if the applicant is a state; and

(5) Reasonable assurances with respect to receipt of per diem under this part that:

(i) The project will be used principally to furnish to veterans the level of care for which such application is made; that not more than 25 percent of participants at any one time will be non-veterans; and that such services will meet the requirements of this part;

(ii) Adequate financial support will be available for the per diem program; and

(iii) The recipient will keep records and submit reports as VA may reasonably require, within the time frames required; and give VA, upon demand, access to the records upon which such information is based.

(Authority: 38 U.S.C. 501, 2012)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554)

§ 61.32 Per diem application packages—rating criteria.

(a) *Conditional selection.* Application packages for per diem only (i.e., from non-capital grant applicants) in response to a Notice of Fund Availability (NOFA) will be reviewed and grouped in categories according to the funding priorities set forth in the NOFA, if any. Such applications will then be ranked within their respective funding category according to scores achieved only if the applicant scores at least 750 cumulative points out of a possible 1000 from each of the following paragraphs: (b), (c), (d), (e), (f), and (g) of § 61.13. The highest-ranked applications for which funding is available, within highest funding priority category if applicable, will be conditionally selected for eligibility to receive per diem payments or special need payment in accordance with their ranked order. If funding priorities have been established and funds are still available after selection of those applicants in the highest priority group, VA will continue to conditionally select applicants in lower priority categories in accordance with the selection method set forth in this paragraph subject to available funding. Conditional selectees will be subsequently awarded per diem, if they otherwise meet the requirements of this part, including passing the inspection required by § 61.80.

(b) *Ranking applications.* In the event of a tie between applicants, VA will use the score from § 61.13(g) to determine the ranking. Note: Capital grant recipients are not required to be ranked; however, continuation of per diem payments to capital grant recipients will be subject to limitations set forth in § 61.33.

(c) *Executing per diem agreements.* VA will execute per diem agreements with an applicant whose per diem application was conditionally selected under this section using the same procedures applicable to a capital grant under § 61.15.

(Authority: 38 U.S.C. 501, 2012)

§ 61.33 Payment of per diem.

(a) *General.* VA will pay per diem to the recipient for those homeless veterans:

(1) Who VA referred to the recipient; or

(2) For whom VA authorized the provision of supportive housing or supportive service.

(b) *Rate of payments for individual veterans.* The rate of per diem for each veteran in supportive housing shall be the lesser of:

(1) The daily cost of care estimated by the per diem recipient minus other sources of payments to the per diem recipient for furnishing services to homeless veterans that the per diem recipient certifies to be correct (other sources include payments and grants from other departments and agencies of the United States, from departments of local and State governments, from private entities or organizations, and from program participants); or

(2) The current VA state home program per diem rate for domiciliary care, as set by the Secretary under 38 U.S.C. 1741(a)(1).

(c) *Rate of payments for service centers.* The per diem amount for service centers shall be ⅛ of the lesser of the amount in paragraph (b)(1) or (b)(2) of this section, per hour, not to exceed 8 hours in any day.

(d) *Continuing payments.* Recipients may continue to receive per diem only so long as funding is available, they continue to provide the supportive services described in their application, and they continue to meet the applicable ongoing requirements of this part. For non-capital grant recipients of per diem only, funds will be paid to the highest-ranked applicants, within the highest-funding priority category if applicable, in descending order until funds are expended. Generally, payments will continue for the time frame specified in the Notice of Fund Availability. When necessary due to funding limitations, VA will reduce the rate of per diem.

(e) *Retroactive payments.* Per diem may be paid retroactively for services provided not more than 3 days before VA approval is given or where, through no fault of the recipient, per diem payments should have been made but were not made.

(f) *Payments for absent veterans.* VA will pay per diem for up to, and not more than, 72 consecutive hours (scheduled or unscheduled) of absence.

(g) *Supportive housing limitation.* VA will not pay per diem for supportive housing for any homeless veteran who has had three or more episodes (admission and discharge for each episode) of supportive housing services paid for under this part. VA may waive this limitation if the services offered are different from those previously provided and may lead to a successful outcome.

(h) *Veterans receiving supportive housing and services.* VA will not pay per diem for both supportive housing and supportive services provided to the same veteran by the same per diem recipient.

(i) At the time of receipt, a per diem recipient must report to VA all other sources of income for the project for which per diem was awarded. The report provides a basis for adjustments to the per diem payment under paragraph (b)(1) of this section.

(Authority: 38 U.S.C. 501, 2012)

Subpart D—Special Need Grants

§ 61.40 Special need grants—general.

(a) VA provides special need grants to public or nonprofit private entities that will create or provide supportive housing and services, which they would not otherwise create or provide, for the following special need homeless veteran populations:

(1) Women;

(2) Frail elderly;

(3) Terminally ill;

(4) Chronically mentally ill; or

(5) Individuals who have care of minor dependents.

(b) Applicants must submit an application package for a capital or non-capital grant, which will be processed by the VA National GPD Program in accordance with this part; however, to be eligible for a capital special need

grant, an applicant must receive at least 800 points (out of a possible 1000) and must receive points under each of the following paragraphs: (b), (c), (d), (e), (f), and (g) of § 61.13. Non-capital special need grants are rated in the same manner as non-capital grant applications under § 61.32.

(c) A recipient of a grant under paragraph (a) of this section may use amounts under the grant to provide services directly to a dependent of a homeless veteran with special needs who is under the care of such homeless veteran while such homeless veteran receives services from the grant recipient under this section.

(d) The following sections apply to special need grants: §§ 61.61 through 61.67, § 61.80, and § 61.82.

(Authority: 38 U.S.C. 501, 2061)

§ 61.41 Special need grants—application packages and threshold requirements.

(a) *Applications.* To apply for a special need grant, an applicant must obtain, complete, and submit to VA a special need capital grant or special need per diem only application package within the time period established in the Notice of Fund Availability. A special need grant application must meet the same threshold requirements applicable to a capital grant under § 61.12.

(b) *Additional requirement.* In addition to the requirements of § 61.11, applicants must describe how they will address the needs of one or more of the homeless veteran populations identified in paragraphs (c) through (g) of this section.

(c) *Women.* Applications must show how the program design will:

(1) Ensure transportation for women, especially for health care and educational needs; and

(2) Address safety and security issues including segregation from other program participants if deemed appropriate.

(d) *Individuals who have care of minor dependents.* Applications must show how the program design will:

(1) Ensure transportation for individuals who have care of minor dependents, and their children, especially for health care and educational needs;

(2) Provide directly or offer referrals for adequate and safe child care;

(3) Ensure children's health care needs are met, especially age-appropriate wellness visits and immunizations; and

(4) Address safety and security issues including segregation from other program participants if deemed appropriate.

(e) *Frail elderly.* Applications must show how the program design will:

(1) Ensure the safety of the residents in the facility to include preventing harm and exploitation;

(2) Ensure opportunities to keep residents mentally and physically agile to the fullest extent through the incorporation of structured activities, physical activity, and plans for social engagement within the program and in the community;

(3) Provide opportunities for participants to address life transitional issues and separation and/or loss issues;

(4) Provide access to walkers, grippers, or other assistance devices necessary for optimal functioning;

(5) Ensure adequate supervision, including supervision of medication and monitoring of medication compliance; and

(6) Provide opportunities for participants either directly or through referral for other services particularly relevant for the frail elderly, including services or programs addressing emotional, social, spiritual, and generative needs.

(f) *Terminally ill.* Applications must show how the program design will:

(1) Help participants address life-transition and life-end issues;

(2) Ensure that participants are afforded timely access to hospice services;

(3) Provide opportunities for participants to engage in ''tasks of dying,'' or activities of ''getting things in order'' or other therapeutic actions that help resolve end of life issues and enable transition and closure;

(4) Ensure adequate supervision including supervision of medication and monitoring of medication compliance; and

(5) Provide opportunities for participants either directly or through referral for other services particularly relevant for terminally ill such as legal counsel and pain management.

(g) *Chronically mentally ill.* Applications must show how the program design will:

(1) Help participants join in and engage with the community;

(2) Facilitate reintegration with the community and provide services that may optimize reintegration such as life-skills education, recreational activities, and follow up case management;

(3) Ensure that participants have opportunities and services for re-establishing relationships with family;

(4) Ensure adequate supervision, including supervision of medication and monitoring of medication compliance; and

(5) Provide opportunities for participants, either directly or through referral, to obtain other services particularly relevant for a chronically mentally ill population, such as vocational development, benefits management, fiduciary or money management services, medication compliance, and medication education.

(Authority: 38 U.S.C. 501, 2061)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554).

§ 61.44 Awarding special need grants and payment of special need per diem.

(a) For those applicants selected for a special need grant, VA will execute an agreement and make payments to the grantee under § 61.61.

(b) Capital grantee selectees who successfully complete the capital portion of their grant, or non-capital grantee selectees who successfully pass VA inspection, will be eligible for a special need per diem payment to defray the operational cost of the project. Special need per diem payment will be the lesser of:

(1) 100 percent of the daily cost of care estimated by the special need recipient for furnishing services to homeless veterans with special need that the special need recipient certifies to be correct, minus any other sources of income; or

(2) Two times the current VA State Home Program per diem rate for domiciliary care.

(c) Special need awards are subject to funds availability, the recipient meeting the performance goals as stated in the grant application, statutory and regulatory requirements, and annual inspections.

(d) Special need capital grantees are not eligible for per diem payment under § 61.33, as the special need per diem payment covers the cost of care.

(Authority: 38 U.S.C. 501, 2061)

Subpart E—Technical Assistance Grants

§ 61.50 Technical assistance grants—general.

(a) *General.* VA provides technical assistance grants to entities or organizations with expertise in preparing grant applications relating to the provision of assistance for homeless veterans. The recipients must use the grants to provide technical assistance to nonprofit organizations with experience in providing assistance to homeless veterans in order to help such groups apply for grants under this part, or from any other source, for addressing the needs of homeless veterans. Current recipients of any grant under this part

(other than a technical assistance grant), or their sub-recipients, are ineligible for technical assistance grants.

(b) *Allowable activities.* Technical assistance grant recipients may use grant funds for the following activities:

(1) Group or individual ''how-to'' grant writing seminars, providing instructions on applying for a grant. Topics must include:

(i) Determining eligibility;

(ii) Matching the awarding agency's grant mission to the applicant agency's strengths;

(iii) Meeting the specific grant outcome requirements;

(iv) Creating measurable goals and objectives for grants;

(v) Relating clear and concise grant project planning;

(vi) Ensuring appropriate grant project staffing; and

(vii) Demonstrating the applicant's abilities.

(2) Creation and dissemination of ''how-to'' grant writing materials, i.e., compact disks, booklets, web pages or other media specifically designed to facilitate and instruct applicants in the completion of grant applications.

(3) Group or individual seminars, providing instructions on the legal obligations associated with grant applications. Topics must include:

(i) Office of Management and Budget (OMB) grant management circulars and forms, 2 CFR parts 215, 225, 230;

(ii) Federal funding match and fund separation requirements; and

(iii) Property and equipment disposition.

(4) Telephone, video conferencing or email with potential grant applicants that specifically address grant application questions.

(c) *Unallowable activities.* Technical assistance grant recipients may not use grant funds for the following activities:

(1) Meetings, consortia, or any similar activity that does not assist community agencies in seeking grants to aid homeless veterans.

(2) Referral of individual veterans to agencies for benefits, housing, medical assistance, or social services.

(3) Lobbying.

(Authority: 38 U.S.C. 501 and 2064)

§ 61.51 Technical assistance grants—application packages.

(a) To apply for a technical assistance grant, an applicant must obtain from VA, complete, and submit to VA a technical assistance grant application package within the time period established in the Notice of Fund Availability.

(b) The technical assistance grant application package will require the following:

(1) Documentation on eligibility to receive a technical assistance grant under this part;

(2) A description of technical assistance that would be provided (see § 61.50);

(3) Documentation concerning the estimated operating costs and operating budget for the technical assistance program for which the grant is sought;

(4) Documentation concerning expertise in preparing grant applications;

(5) Documentation of resources committed to the provision of technical expertise;

(6) Comments or recommendations by appropriate state (and area wide) clearinghouses pursuant to E.O. 12372 (3 CFR, 1982 Comp., p. 197), if the applicant is a state; and

(7) Reasonable assurances that:

(i) The recipient will provide adequate financial and administrative support for providing the services set forth in the technical assistance grant application, and will actually provide such services; and

(ii) The recipient will keep records and timely submit reports as required by VA, and will give VA, on demand, access to the records upon which such reports are based.

(Authority: 38 U.S.C. 501, 2064)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554)

§ 61.52 Technical assistance grant application packages—threshold requirements.

The following threshold requirements for a technical assistance grant must be met, or the application will be rejected before being rated under § 61.53:

(a) The application must be complete and submitted on the correct form and in the time period established in the Notice of Fund Availability;

(b) The applicant must establish expertise in preparing grant applications;

(c) The activities for which assistance is requested must be eligible for funding under this part;

(d) The applicant must demonstrate that adequate financial support will be available to carry out the project for which the grant is sought, consistent with the plans, specifications and schedule submitted by the applicant;

(e) The applicant must not have an outstanding obligation to VA that is in arrears, or have an overdue or unsatisfactory response to an audit; and

(f) The applicant must not have been notified by VA as being in default.

(Authority: 38 U.S.C. 501, 2064)

§ 61.53 Technical assistance grant application packages—rating criteria.

(a) *General.* Applicants that meet the threshold requirements in § 61.52 will then be rated using the selection criteria listed in paragraphs (b) and (c) of this section. To be eligible for a technical assistance grant, an applicant must receive at least 600 points (out of a possible 800).

(b) *Quality of the technical assistance.* VA will award up to 400 points based on the following:

(1) How the recipients of technical training will increase their skill level regarding the completion of applications;

(2) How the recipients of technical training will learn to find grant opportunities in a timely manner;

(3) How the technical assistance provided will be monitored and evaluated and changes made, if needed; and

(4) How the proposed technical assistance programs will be implemented in a timely fashion.

(c) *Ability of applicant to demonstrate expertise in preparing grant applications and to develop and operate a technical assistance program.* VA will award up to 400 points based on the extent to which the application demonstrates all of the following:

(1) Ability to find grants available for addressing the needs of homeless veterans.

(2) Ability to find and offer technical assistance to entities eligible for such assistance.

(3) Ability to administer a technical assistance program.

(4) Ability to provide grant technical assistance.

(5) Ability to evaluate the overall effectiveness of the technical assistance program and to make adjustments, if necessary, based on those evaluations.

(6) Past performance. VA may use historical documents of past performance from both VA and non-VA, including those from other Federal, state and local agencies and audits by private or public entities in scoring technical assistance applications.

(Authority: 38 U.S.C. 501, 2064)

§ 61.54 Awarding technical assistance grants.

(a) Applicants will first be grouped in categories according to the funding priorities set forth in the NOFA, if any. Applicants will then be ranked within their respective funding category, if applicable. The highest-ranked applications for which funding is available, within highest priority funding category if applicable, will be

selected to receive a technical assistance grant in accordance with their ranked order, as determined under § 61.53. If funding priorities have been established and funds are still available after selection of those applicants in the highest priority group, VA will continue to conditionally select applicants in lower priority categories in accordance with the selection method set forth in this paragraph subject to available funding.

(b) In the event of a tie between applicants, VA will use the score from § 61.53(c) to determine the ranking.

(c) For those applicants selected to receive a technical assistance grant, VA will execute an agreement and make payments to the grant recipient in accordance with § 61.61.

(d) The amount of the technical assistance grant will be the estimated total operational cost of the technical assistance over the life of the technical assistance grant award as specified in the technical assistance grant agreement. Payments may be made for no more than the period specified in the Notice of Fund Availability.

(e) VA will not pay for sustenance or lodging for the nonprofit community participants or attendees at training conferences offered by technical assistance grant recipients; however, the grantee may use grant funds to recover such expenses.

(Authority: 38 U.S.C. 501, 2064)

§ 61.55 Technical assistance reports.

Each technical assistance grantee must submit to VA a quarterly report describing the activities for which the technical assistance grant funds were used, including the type and amount of technical assistance provided and the number of nonprofit community-based groups served.

(Authority: 38 U.S.C. 501, 2064)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554)

Subpart F—Awards, Monitoring, and Enforcement of Agreements

§ 61.61 Agreement and funding actions.

(a) *Agreement.* When VA selects an applicant for grant or per diem award under this part, VA will incorporate the requirements of this part into an agreement to be executed by VA and the applicant. VA will enforce the agreement through such action as may be appropriate, including temporarily withholding cash payments pending correction of a deficiency. Appropriate actions include actions in accordance with the VA common grant rules at 38 CFR parts 43 and 49 and the OMB Circulars, including those cited in § 61.66.

(b) *Obligating funds.* Upon execution of the agreement, VA will obligate funds to cover the amount of the approved grant/per diem, subject to the availability of funding. Payments will be for services rendered, contingent on submission of documentation in the form of invoices or purchase agreements and inspections, as VA deems necessary. VA will make payments on its own schedule to reimburse for amounts expended. Except for increases in the rate of per diem, VA will not increase the amount obligated for assistance under this part after the initial obligation of funds.

(c) *Deobligating funds.* VA may deobligate all or parts of funds obligated under this part:

(1) If the actual total cost for assistance is less than the total cost stated in the application; or

(2) If the recipient fails to comply with the requirements of this part.

(d) *Deobligation procedure.* Before deobligating funds under this section, VA will issue a notice of intent to terminate payments. The recipient will have 30 days to submit documentation demonstrating why payments should not be terminated. After review of any such documentation, VA will issue a final decision concerning termination of payment.

(e) *Other government funds.* No funds provided under this part may be used to replace Federal, state or local funds previously used, or designated for use, to assist homeless veterans.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061, 2064)

§ 61.62 Program changes.

(a) Except as provided in paragraphs (b) through (d) of this section, a recipient may not make any significant changes to a project for which a grant has been awarded without prior written approval from the VA National Grant and Per Diem Program Office. Significant changes include, but are not limited to, a change in the recipient, a change in the project site (including relocating, adding an annex, a branch, or other expansion), additions or deletions of activities, shifts of funds from one approved type of activity to another, and a change in the category of participants to be served.

(b) Recipients of grants involving both construction and non-construction projects must receive prior written approval from the VA National Grant and Per Diem Program Office for cumulative transfers among direct cost categories which exceed or are expected to exceed 10 percent of the current total approved budget.

(c) Recipients of grants for projects involving both construction and non-construction who are state or local governments must receive prior written approval from the VA National Grant and Per Diem Program Office for any budget revision which would transfer funds between non-construction and construction categories.

(d) Approval for changes is contingent upon the application ranking remaining high enough after the approved change to have been competitively selected for funding in the year the application was selected.

(e) Any changes to an approved program must be fully documented in the recipient's records.

(f) Recipients must inform the VA National Grant and Per Diem Program Office in writing of any key position and address changes in/of their organization within 30 days of the change, i.e., new executive director or chief financial officer, permanent change of address for corporate communications.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061, 2064)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554).

§ 61.63 Procedural error.

If an application would have been selected but for a procedural error committed by VA, VA may reconsider that application in the next funding round. A new application will not be required for this purpose so long as there is no material change in the information.

(Authority: 38 U.S.C. 501)

§ 61.64 Religious organizations.

(a) Organizations that are religious or faith-based are eligible, on the same basis as any other organization, to participate in VA programs under this part. In the selection of service providers, neither the Federal Government nor a state or local government receiving funds under this part shall discriminate for or against an organization on the basis of the organization's religious character or affiliation.

(b)(1) No organization may use direct financial assistance from VA under this part to pay for any of the following:

(i) Inherently religious activities such as, religious worship, instruction, or proselytization; or

(ii) Equipment or supplies to be used for any of those activities.

(2) For purposes of this section, ''indirect financial assistance'' means Federal assistance in which a service provider receives program funds through a voucher, certificate, agreement or other form of disbursement, as a result of the independent and private choices of individual beneficiaries. ''Direct financial assistance'' means Federal aid in the form of a grant, contract, or cooperative agreement where the independent choices of individual beneficiaries do not determine which organizations receive program funds.

(c) Organizations that engage in inherently religious activities, such as worship, religious instruction, or proselytization, must offer those services separately in time or location from any programs or services funded with direct financial assistance from VA, and participation in any of the organization's inherently religious activities must be voluntary for the beneficiaries of a program or service funded by direct financial assistance from VA.

(d) A religious organization that participates in VA programs under this part will retain its independence from Federal, state, or local governments and may continue to carry out its mission, including the definition, practice and expression of its religious beliefs, provided that it does not use direct financial assistance from VA under this part to support any inherently religious activities, such as worship, religious instruction, or proselytization. Among other things, faith-based organizations may use space in their facilities to provide VA-funded services under this part, without removing religious art, icons, scripture, or other religious symbols. In addition, a VA-funded religious organization retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members and otherwise govern itself on a religious basis, and include religious reference in its organization's mission statements and other governing documents.

(e) An organization that participates in a VA program under this part shall not, in providing direct program assistance, discriminate against a program beneficiary or prospective program beneficiary regarding housing, supportive services, or technical assistance, on the basis of religion or religious belief.

(f) If a state or local government voluntarily contributes its own funds to supplement Federally funded activities, the state or local government has the option to segregate the Federal funds or commingle them. However, if the funds are commingled, this provision applies to all of the commingled funds.

(g) To the extent otherwise permitted by Federal law, the restrictions on inherently religious activities set forth in this section do not apply where VA funds are provided to religious organizations through indirect assistance as a result of a genuine and independent private choice of a beneficiary, provided the religious organizations otherwise satisfy the requirements of this part. A religious organization may receive such funds as the result of a beneficiary's genuine and independent choice if, for example, a beneficiary redeems a voucher, coupon, or certificate, allowing the beneficiary to direct where funds are to be paid, or a similar funding mechanism provided to that beneficiary and designed to give that beneficiary a choice among providers.

(Authority: 38 U.S.C. 501)

§ 61.65 Inspections.

VA may inspect the facility and records of any applicant or recipient when necessary to determine compliance with this part or an agreement under § 61.61. The authority to inspect does not authorize VA to manage or control the applicant or recipient.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061, 2064)

§ 61.66 Financial management.

(a) All recipients must comply with applicable requirements of the Single Audit Act Amendments of 1996, as implemented by OMB Circular A–133 and codified at 38 CFR part 41.

(b) All entities receiving assistance under this part must use a financial management system that follows generally accepted accounting principles and meets the requirements set forth under OMB Circular A–102, Subpart C, section 20, codified at 38 CFR 43.20, for state and local government recipients, or under OMB Circular A–110, Subpart C, section 21, codified at 38 CFR 49.21 for nonprofit recipients. All recipients must implement the requirements of the appropriate OMB Circular for Cost-Principles (A–87 or A–122 codified at 2 CFR parts 225 and 230, respectively) for determining costs reimbursable under all awards issued under this part.

(Authority: 38 U.S.C. 501)

§ 61.67 Recovery provisions.

(a) *Full recovery of capital grants.* VA may recover from the grant recipient all of the grant amounts provided for the project if, after 3 years after the date of an award of a capital grant, the grant recipient has withdrawn from the VA Homeless Providers Grant and Per Diem Program (Program), does not establish the project for which the grant was made, or has established the project for which the grant was made but has not passed final inspection. Where a recipient has no control over causes for delays in implementing a project, VA may extend the 3-year period, as appropriate. VA may obligate any recovered funds without fiscal year limitation.

(b) *Prorated (partial) recovery of capital grants.* If a capital grant recipient is not subject to recovery under paragraph (a) of this section, VA will seek recovery of the grant amount on a prorated basis where the grant recipient ceases to provide services for which the grant was made or withdraws from the Program prior to the expiration of the applicable period of operation, which period shall begin on the date shown on the activation document produced by the VA National GPD Program. In cases where capital grant recipients have chosen not to receive per diem payments, the applicable period of operation shall begin on the date the VA Medical Center Director approved placement at the project site as shown on the inspection documents. The amount to be recaptured equals the total amount of the grant, multiplied by the fraction resulting from using the number of years the recipient was not operational as the numerator, and using the number of years of operation required under the following chart as the denominator.

Grant amount (dollars in thousands)	Years of operation
0–250	7
251–500	8
501–750	9
751–1,000	10
1,001–1,250	11
1,251–1,500	12
1,501–1,750	13
1,751–2,000	14
2,001–2,250	15
2,251–2,500	16
2,501–2,750	17
2,751–3,000	18
Over 3,000	20

(c) *Disposition of real property for capital grantees.* In addition to being subject to recovery under paragraphs (a) and (b) of this section, capital grantees are subject to real property disposition

as required by 38 CFR 49.32 when the grantee no longer is providing services through a grant awarded under this part.

(d) *Recovery of per diem and non-capital grants.* VA will seek to recover from the recipient of per diem, a special need non-capital grant, or a technical assistance grant any funds that are not used in accordance with the requirements of this part.

(e) *Notice.* Before VA takes action to recover funds, VA will issue to the recipient a notice of intent to recover funds. The recipient will then have 30 days to submit documentation demonstrating why funds should not be recovered. After review of any such documentation, VA will issue a decision regarding whether action will be taken to recover funds.

(f) *Vans.* All recovery provisions will apply to vans with the exception of the period of time for recovery. The period of time for recovery will be 7 years. Disposition provisions of 38 CFR 49.34 apply to vans. Grantees are required to notify the VA National Grant and Per Diem Program Office for disposition of any van funded under this part.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061, 2064)

§ 61.80 General operation requirements for supportive housing and service centers.

(a) Supportive housing and service centers for which assistance is provided under this part must comply with the requirements of the current edition of the Life Safety Code of the National Fire Protection Association and all applicable state and local housing codes, licensing requirements, fire and safety requirements, and any other requirements in the jurisdiction in which the project is located regarding the condition of the structure and the operation of the supportive housing or service centers. Note: All facilities are to be protected throughout by an approved automatic sprinkler system unless a facility is specifically exempted under the Life Safety Code.

(b) Except for such variations as are proposed by the recipient that would not affect compliance with paragraph (a) of this section and are approved by VA, supportive housing must meet the following requirements:

(1) The structures must be structurally sound so as not to pose any threat to the health and safety of the occupants and so as to protect the residents from the elements;

(2) Entry and exit locations to the structure must be capable of being utilized without unauthorized use of other private properties, and must provide alternate means of egress in case of fire;

(3) Buildings constructed or altered with Federal assistance must also be accessible to the disabled, as required by § 502 of the Americans with Disabilities Act, referred to as the Architectural Barriers Act;

(4) Each resident must be afforded appropriate space and security for themselves and their belongings, including an acceptable place to sleep that is in compliance with all applicable local, state, and federal requirements;

(5) Every room or space must be provided with natural or mechanical ventilation and the structures must be free of pollutants in the air at levels that threaten the health of residents;

(6) The water supply must be free from contamination;

(7) Residents must have access to sufficient sanitary facilities that are in proper operating condition, that may be used in privacy, and that are adequate for personal cleanliness and the disposal of human waste;

(8) The housing must have adequate heating and/or cooling facilities in proper operating condition;

(9) The housing must have adequate natural or artificial illumination to permit normal indoor activities and to support the health and safety of residents and sufficient electrical sources must be provided to permit use of essential electrical appliances while assuring safety from fire;

(10) All food preparation areas must contain suitable space and equipment to store, prepare, and serve food in a sanitary manner;

(11) The housing and any equipment must be maintained in a sanitary manner;

(12) The residents with disabilities must be provided meals or meal preparation facilities must be available;

(13) Residential supervision from a paid staff member, volunteer, or senior resident participant must be provided 24 hours per day, 7 days per week and for those times that a volunteer or senior resident participant is providing residential supervision a paid staff member must be on call for emergencies 24 hours a day 7 days a week (all supervision must be provided by individuals with sufficient knowledge for the position); and

(14) Residents must be provided a clean and sober environment that is free from illicit drug use or from alcohol use that: could threaten the health and/or safety of the residents or staff; hinders the peaceful enjoyment of the premises; or jeopardizes completion of the grantee's project goals and objectives. Those supportive housing or service centers that provide medical or social detox at the same site as the supportive housing or service must ensure that those residents in detox are clearly separated from the general residential population.

(c) Each recipient of assistance under this part must conduct an ongoing assessment of the supportive services needed by the residents of the project and the availability of such services, and make adjustments as appropriate. The recipient will provide evidence of this ongoing assessment to VA regarding the plan described in their grant application to include meeting their performance goals. This information will be incorporated into the annual inspection. Grantees must submit during the grant agreement period to VA, a quarterly technical performance report. A quarterly report must be filed once during each quarter and no later than January 30, April 30, July 30, and October 30. The report may be in any acceptable business format and must include the following information:

(1) A comparison of actual accomplishments to established goals for the reporting period and response to any findings related to monitoring efforts. This comparison will be on the same level of detail as specified in the program approved in the grant document. It will address quantifiable as well as non-quantifiable goals.

(2) If established goals have not been met, provide a detailed narrative explanation and an explanation of the corrective action(s) which will be taken, as well as a timetable for accomplishment of the corrective action(s).

(3) Other pertinent information, including a description of grant-related activities occurring during the report period. This may include personnel activity (hiring-training), community orientation/awareness activity, programmatic activity (job development). Also identify administrative and programmatic problems, which may affect performance and proposed solutions.

(4) The quarterly technical performance report will be submitted to the VA National GPD Program Liaison assigned to the project, with each quarterly report being a cumulative report for the entire calendar year. All pages of the reporting documents should have the appropriate grant number and signature, where appropriate. VA National GPD Program Liaisons will file the report and corrective actions in the administrative file for the grant.

(5) Between scheduled reporting dates, the recipient will also immediately inform the VA National GPD Program Liaison of any significant

developments affecting the recipient's ability to accomplish the work. VA National GPD Program Liaisons will provide grantees with necessary technical assistance, when and where appropriate as problems arise.

(6) For each goal or objective listed in the grant application, grantees will be allowed a 15 percent deviation of each goal or objective. If the deviation is greater than 15 percent in any one goal or objective, a corrective action plan must be submitted to the VA National GPD Program Liaison. Failure to meet goals and objectives may result in withholding of placement, withholding of payment, suspension of payment and termination as outlined in this part or other applicable Federal statutes if the goal or objective would impact the program's ability to provide a successful outcome for veterans.

(7) Corrective Action(s): When necessary, the grantee will automatically initiate a Corrective Action Plan (CAP). A CAP will be required if, on a quarterly basis, actual grant accomplishments vary by a margin of +/−15 percent or more from the planned goals and objectives. Please note that this is a general rule of thumb, and in some cases +/−15 percent deviations are beneficial to the program such as more placements into employment or training than planned, less cost per placement than planned, higher average wage at placement than planned, etc.

(8) All +/−15 percent deviations from the planned goals that have a negative impact on the grantee's ability to accomplish planned goals must be fully explained in the grantee's quarterly technical report and a CAP is to be initiated, developed, and submitted by the grantee to the VA Liaison for approval.

(9) The CAP must identify the activity or expenditure source which has the +/−15 percent deviation, describe the reason(s) for the variance, provide specific proposed corrective action(s), and a timetable for accomplishment of the corrective action. The plan may include an intent to modify the grant when appropriate.

(10) The CAP will be submitted as an addendum to the quarterly technical report. After receipt of the CAP, the VA National GPD Program Liaison will send a letter to the grantee indicating that the CAP is approved or disapproved. If disapproved, VA Liaison will make beneficial suggestions to improve the proposed CAP and request resubmission until CAP is satisfactory to both parties.

(d) A homeless veteran may remain in supportive housing for which assistance is provided under this part for a period no longer than 24 months, except that a veteran may stay longer, if permanent housing for the veteran has not been located or if the veteran requires additional time to prepare for independent living. However, at any given time, no more than one-half of the veterans at such supportive housing facility may have resided at the facility for periods longer than 24 months.

(e) Each recipient of assistance under this part must provide for the consultation and participation of not less than one homeless veteran or formerly homeless veteran on the board of directors or an equivalent policymaking entity of the recipient, to the extent that such entity considers and makes policies and decisions regarding any project provided under this part. This requirement may be waived if an applicant, despite a good faith effort to comply, is unable to meet it and presents a plan, subject to VA approval, to otherwise consult with homeless or formerly homeless veterans in considering and making such policies and decisions.

(f) Each recipient of assistance under this part must, to the maximum extent practicable, involve homeless veterans and families, through employment, volunteer services, or otherwise, in constructing, rehabilitating, maintaining, and operating the project and in providing supportive services for the project.

(g) Each recipient of assistance under this part shall establish procedures for fiscal control and fund accounting to ensure proper disbursement and accounting of assistance received under this part.

(h) The recipient of assistance under this part that provides family violence prevention or treatment services must establish and implement procedures to ensure:

(1) The confidentiality of records pertaining to any individual provided services, and

(2) The confidentially of the address or location where the services are provided.

(i) Each recipient of assistance under this part must maintain the confidentiality of records kept on homeless veterans receiving services.

(j) VA may disapprove use of outpatient health services provided through the recipient if VA determines that such services are of unacceptable quality. Further, VA will not pay per diem where the Department concludes that services furnished by the recipient are unacceptable.

(k) A service center for homeless veterans shall provide services to homeless veterans for a minimum of 40 hours per week over a minimum of 5 days per week, as well as provide services on an as-needed, unscheduled basis. The calculation of average hours shall include travel time for mobile service centers. In addition:

(1) Space in a service center shall be made available as mutually agreeable for use by VA staff and other appropriate agencies and organizations to assist homeless veterans;

(2) A service center shall be equipped to provide, or assist in providing, health care, mental health services, hygiene facilities, benefits and employment counseling, meals, and transportation assistance;

(3) A service center shall provide other services as VA determines necessary based on the need for services otherwise not available in the geographic area; and

(4) A service center may be equipped and staffed to provide, or to assist in providing, job training and job placement services (including job readiness, job counseling, and literacy and skills training), as well as any outreach and case management services that may be necessary to meet the requirements of this paragraph.

(l) Fixed site service centers will prominently post at or near the entrance to the service center their hours of operation and contacts in case of emergencies. Mobile service centers must take some action reasonably calculated to provide in advance a tentative schedule of visits (e.g., newspapers, fliers, public service announcements on television or radio). The schedule should include but is not limited to:

(1) The region of operation;

(2) Times of operation;

(3) Expected services to be provided; and

(4) Contacts for specific information and changes.

(m) Each recipient that provides housing and services must have a written disaster plan that has been coordinated with the emergency management entity responsible for the locality in which the project exists. The plan must encompass natural and man-made disasters.

(n) The recipient will inform within 24 hours its VA liaison of any sentinel events occurring within the program (i.e., drug overdose, death, injury).

(o) The grantee, or sub-grantee, will provide appropriate orientation and training to staff to enable them to provide quality services that are appropriate to homeless veteran or homeless special need veteran population.

(p) The grantee will maintain systematic participant enrollment information and participant tracking records designed to facilitate the uniform compilation and analysis of programmatic data necessary for verification of veteran status and case management, reporting, monitoring, and evaluation purposes.

(q) The grantee will also document in each participant record at a minimum:

(1) Family status.

(2) Verification of veteran status (DD214, Department of Veterans Affairs confirmation report and/or identification card).

(3) Education, employment history, and marketable skills/licenses/credentials.

(4) An Individual Service Plan (ISP) for each individual participant will be maintained in the participant case management record which contains the following:

(i) An assessment of barriers, service needs, as well as strengths; and

(ii) Specific services and referrals planned and benefits to be achieved as a result of program participation.

(5) Duration and outcome of supportive service.

(6) The grantee must verify service outcomes each calendar year quarter through the participant and provide documentation of this verification in the participant case management files.

(r) The grantee will ensure that no more than 25 percent of the grant awarded beds are occupied by non-veterans, or VA may take actions as appropriate to decrease the beds, grant amounts, or terminate the grant and seek recapture in the case of capital funding. To calculate the occupancy rate, divide the actual number of bed days of care for veterans eligible to reside in the project, by the total number of possible bed days of care (the previous 180 days from the most current 6 month period).

(Authority: 38 U.S.C. 501, 2011, 2012, 2061)

(The Office of Management and Budget has approved the information collection requirements in this section under control number 2900–0554).

§ 61.81 Outreach activities.

Recipients of capital grants and per diem relating to supportive housing or service centers must use their best efforts to ensure that eligible hard-to-reach veterans are found, engaged, and provided assistance. To achieve this goal, recipients may search for homeless veterans at places such as shelters, soup kitchens, parks, bus or train stations, and the streets. Outreach particularly should be directed toward veterans who have a nighttime residence that is an emergency shelter or a public or private place not ordinarily used as a regular sleeping accommodation for human beings (e.g., cars, streets, or parks).

(Authority: 38 U.S.C. 501, 2011, 2012, 2061)

§ 61.82 Participant fees for supportive housing.

(a) Each participant of supportive housing may be required to pay a participant fee in an amount determined by the recipient, except that such participant fee may not exceed 30 percent of the participant's monthly income after deducting medical expenses, child care expenses, court ordered child support payments, or other court ordered payments; nor may it exceed the program's set maximum rate or the HUD Fair Market Rent for that type of housing and its location, whichever is less. The participant fee determination and collection process/procedures should be documented in the grant recipient's operating procedures to ensure consistency, fairness, and accuracy of fees collected. The participant's monthly income includes all income earned by or paid to the participant.

(b) Retroactive benefit payments from any source to program participants, for the purpose of this part, may be considered income in the month received and therefore may be used in calculating the participant fee for that month.

(c) Participant fees may be used for costs of operating the supportive housing or to assist supportive housing residents' move to permanent housing, and must have a therapeutic benefit.

(d) In addition to a participant fee, recipients may charge residents reasonable fees for extracurricular services and activities (extracurricular fee) that participants are not required to receive under the terms of the grant award, are not paid for by VA per diem, or provided by VA. Extracurricular fees must be voluntary on the part of the participant.

(e) In projects funded under this part where participants sign agreements, VA treats the costs associated with participant eviction to be as unallowable.

(f) Use of participant agreements.

(1) Participant agreements must be between the grant recipient of record and the program participant.

(2) Participant agreements must be part of a therapeutic plan to increase self-determination and responsibility.

(3) Participant agreements must include a clause that allows program participants the ability to break the lease or program agreement without penalty for medical or clinical necessity.

(4) Participant agreements may not be used to exclude homeless veterans with little or no income from the program.

(5) Participant agreements and conditions must be fully disclosed to potential participants and acknowledged in writing by both parties.

(Authority: 38 U.S.C. 501, 2011, 2012, 2061)

[FR Doc. 2013–04222 Filed 2–22–13; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 64

RIN 2900–AO35

Grants for the Rural Veterans Coordination Pilot (RVCP)

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as a final rule, without change, the proposal to establish a pilot program known as the Rural Veterans Coordination Pilot (RVCP). The RVCP will provide grants to eligible community-based organizations and local and State government entities to be used by these organizations and entities to assist veterans and their families who are transitioning from military service to civilian life in rural or underserved communities. VA will use information obtained through the pilot program to evaluate the effectiveness of using community-based organizations and local and State government entities to improve the provision of services to transitioning veterans and their families. Five RVCP grants will be awarded for a 2-year period in discrete locations pursuant to a Notice of Funds Availability (NOFA) to be published in the **Federal Register**.

DATES: *Effective Date:* This final rule is effective March 27, 2013.

FOR FURTHER INFORMATION CONTACT: Karen Malebranche, Veterans Health Administration, Office of Interagency Health Affairs (10P5), 810 Vermont Avenue NW., Washington, DC 20420, telephone (202) 461–6001. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On May 5, 2010, the President signed into law the Caregivers and Veterans Omnibus Health Services Act of 2010 (2010 Act), Public Law 111–163. Section 506(a) of the 2010 Act, codified at 38 U.S.C. 523 note, requires VA to establish a pilot

program to assess the feasibility and advisability of using community-based organizations and local and State government entities to assist veterans and their families who are transitioning from military service to civilian life in rural or underserved communities. In addition, section 506(c)(2) of the 2010 Act instructs VA to carry out the program in five locations to be selected by the Secretary of Veterans Affairs. In a document published in the **Federal Register** on July 18, 2012 (77 FR 42230), VA proposed regulations to establish the RVCP to meet the requirements of section 506(a). We provided a 60-day comment period, which ended on September 17, 2012, during which we received four comments from members of the general public.

The first commenter indicated support for the pilot and commented on the need for monitoring to ensure the success of the program. VA appreciates this comment and assures the commenter that the program will be carefully monitored and assessed. We do not make any changes to the regulation based on this comment.

A second commenter asked whether five locations will be sufficient to carry out the purpose of the pilot and whether outreach can be provided to veterans and their families to inform them about the availability of RVCP to help them get to VA for their appointments.

VA is limited by the express language of the 2010 Act to using five locations for the RVCP. Section 506(c)(1) of the 2010 Act specifically states that ''the pilot program shall be carried out at five locations selected by the Secretary for purposes of the pilot program.'' Therefore, we cannot expand the RVCP beyond five locations.

Regarding the commenter's concerns about outreach, outreach is one of the four permissible uses of RVCP funds, and this is reflected in § 64.6(a)(4), which authorizes grantees to provide, develop or deploy strategies to reach transitioning veterans and their families. Therefore, we do not make any changes based on this comment.

A third commenter echoed the issue raised in the previous comment regarding the reliance on five sites and stated that ''[t]here is an extreme need for this pilot and I congratulate those who are putting forth the effort to make this happen. I reviewed the 'underserved' areas defined within my state of Florida, more specifically in and around the Jacksonville area and found that there are areas designated as underserved within the metro area. With that said, I would have to agree with a commented concern: if five service grants would provide the overall benefit and or statistical data in which the grants are seeking to obtain?'' VA agrees that there are significant populations in metropolitan areas that meet the definition of ''underserved'' as set out in the proposed rule. That definition incorporates three of the four types of areas that VA must consider in selecting locations for an RVCP grant, as set forth in section 506(c)(2) of the 2010 Act. The fourth type of area that VA must consider in choosing the five locations is rural areas. See Public Law 111–163, Sec. 506(c)(2)(A). In the proposed regulations, we did not limit locations to rural areas; under § 64.10(b)(3), applicants for grants must show that the proposed project location qualifies either as a rural area or as having an underserved community. Scoring and selection criteria in § 64.12(a)(6) weigh these considerations equally. Therefore, we do not make any changes to the regulation based on this comment.

The final commenter asked that VA ''explicitly incorporate universities as eligible entities for this grant.'' VA has defined an ''eligible entity'' for the RVCP grant as a ''community-based organization or a local or State government entity.'' A local or State operated educational institution would be included under this definition. We do not believe it is necessary to revise the rule to state this expressly. The commenter has not indicated language in the rule that could mislead the public into believing that such institutions are excluded, and VA will not exclude them. Therefore, we do not make any changes based on this comment.

Based on the rationale set forth in the **SUPPLEMENTARY INFORMATION** to the proposed rule and in this final rule, VA is adopting the proposed rule as a final rule without any change.

Effect of Rulemaking

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

Paperwork Reduction Act

Although this rule contains provisions constituting collections of information, at 38 CFR 64.10, under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521), no new or proposed revised collections of information are associated with this final rule. The information collection requirements for § 64.10 are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control numbers 4040–0003, 4040–0004, 4040–0006, 4040–0007, 4040–0008, 4040–0009, and 4040–0010. The reports required under § 64.16 will be collected only from the five award recipients and, therefore, do not constitute a collection of information as defined in section 3502(3)(A)(i) of the Paperwork Reduction Act of 1995.

Executive Orders 12866 and 13563

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

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action, and it has been determined not to be a significant regulatory action under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule does not have a significant economic impact on a substantial number of small entities as

they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. There will be no negative economic impact on any of the eligible entities because the grantees will not be required to provide matching funds to obtain the maximum grant allowance. This pilot grant program will not impact a substantial number of small entities because only five non-renewable grants will be awarded. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates

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

Catalog of Federal Domestic Assistance

At this time there are no Catalog of Federal Domestic Assistance numbers and titles for the program affected by this regulation. Catalog of Federal Domestic Assistance numbers and titles will be obtained when the program is established on the Grants.gov Web site.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on January 23, 2013, for publication.

List of Subjects in 38 CFR Part 64

Administrative practice and procedure, Disability benefits, Claims, Government contracts, Grant programs—health, Grant programs—veterans, Health care, Health records, Reporting and recordkeeping requirements, Veterans.

Dated: February 20, 2013.

Robert C. McFetridge,

Director of Regulation Policy and Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons stated in the preamble, VA amends 38 CFR chapter I by adding part 64 to read as follows:

PART 64—GRANTS FOR THE RURAL VETERANS COORDINATION PILOT (RVCP)

Sec.

64.0 Purpose and scope.
64.2 Definitions.
64.4 RVCP grants—general.
64.6 Permissible uses of RVCP grants.
64.8 Notice of Funds Availability (NOFA).
64.10 Application.
64.12 Scoring and selection.
64.14 RVCP grant agreement.
64.16 Reporting.
64.18 Recovery of funds.

Authority: 38 U.S.C. 501, 523 *note.*

§ 64.0 Purpose and scope.

(a) *Purpose.* The Rural Veterans Coordination Pilot (RVCP) program implements the requirements of section 506 of the Caregivers and Veterans Omnibus Health Services Act of 2010 to provide grants to community-based organizations and local and State government entities to assist veterans who are transitioning from military service to civilian life in rural or underserved communities and families of such veterans.

(b) *Scope.* This part applies only to the administration of the RVCP, unless specifically provided otherwise.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.2 Definitions.

For the purpose of this part and any Notice of Funds Availability issued under this part:

Applicant means an eligible entity that submits an application for an RVCP grant as announced in a Notice of Funds Availability.

Community-based organization means a group that represents a community or a significant segment of a community and is engaged in meeting community needs.

Eligible entity means a community-based organization or local or State government entity. An eligible entity will be identified as the legal entity whose employer identification number is on the Application for Federal Assistance (SF 424), even if only a particular component of the broader entity is applying for the RVCP grant.

Grantee means recipient of an RVCP grant.

Limited access to health care means residing in an area identified by the Health Resources and Services Administration of the U.S. Department of Health and Human Services as ''medically underserved'' or having a ''medically underserved population.''

Local government means a county, municipality, city, town, township, or regional government or its components.

Minority group member means an individual who is Asian American; Black; Hispanic; Native American (including American Indian, Alaskan Native, and Native Hawaiian); or Pacific-Islander American.

Notice of Funds Availability (NOFA) means a Notice published by VA in the **Federal Register** alerting eligible entities of the availability of RVCP grants and containing important information about the RVCP grant application process in accordance with § 64.8.

Participant means a veteran or a member of a veteran's family who receives services for which an RVCP grant is awarded.

Rural means an area classified as ''rural'' by the U.S. Census Bureau.

Rural Veterans Coordination Pilot (RVCP) refers to the pilot grant program authorized by section 506 of the Caregivers and Veterans Omnibus Health Services Act of 2010.

State government means any of the fifty States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State government.

Underserved communities are areas that meet one or more of the following criteria:

(1) Have a high proportion of minority group representation;

(2) Have a high proportion of individuals who have limited access to health care; or

(3) Have no active duty military installation that is reasonably accessible to the community.

VA means the U.S. Department of Veterans Affairs.

Veteran means a person who served in active military, naval, or air service, who was discharged or released under conditions other than dishonorable.

Veteran who is transitioning from military service to civilian life means a veteran who is separating from active military, naval, or air service in the Armed Forces to return to life as a civilian and such veteran's date of discharge or release from active military, naval, or air service was not more than 2 years prior to the date on which the RVCP grant was awarded.

Veteran's family means those individuals who reside with the veteran in the veteran's primary residence. These individuals include a parent, a spouse, a child, a step-family member, an extended family member, and individuals who reside in the home with the veteran but are not a member of the family of the veteran.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.4 RVCP grants—general.

(a) VA will award five RVCP grants to eligible entities as defined in § 64.2.

(b) An eligible entity may receive only one RVCP grant, and only one RVCP grant will be awarded in any one pilot project location (see § 64.12(a)(6)).

(c) RVCP grants will be awarded for a maximum period of 2 years, beginning on the date on which the RVCP grants are awarded. They will not be extended or renewable.

(d) A grantee will not be required to provide matching funds as a condition of receiving an RVCP grant.

(e) No participant will be charged a fee for services provided by the grantee or be required to participate in other activities sponsored by the grantee as a condition of receiving services for which the RVCP grant is made.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.6 Permissible uses of RVCP grants.

(a) Grantees must maximize the use of RVCP grants by ensuring that at least 90 percent of funds awarded are used to provide services designed to aid in the adjustment to civilian life in one or more of the following areas:

(1) *Increasing coordination of health care and benefits for veterans.* Examples include, but are not limited to, identifying sources of community, local, State, and Federal health care and benefits; obtaining necessary applications and assisting veterans in the preparation of applications for such care and benefits; and identifying and eliminating barriers to receiving identified benefits.

(2) *Increasing availability of high quality medical and mental health services.* Examples include, but are not limited to, increasing availability of or access to insurance or low- or no-cost public or private health care, including out-patient care, preventive care, hospital care, nursing home care, rehabilitative care, case management, respite care, and home care; providing assistance in accessing or using telehealth services; transporting veterans to medical facilities or transporting medical or mental health providers to veterans; and providing assistance in obtaining necessary pharmaceuticals, supplies, equipment, devices, appliances, and assistive technology.

(3) *Providing assistance to families of transitioning veterans.* Examples include, but are not limited to, helping obtain medical insurance for family members; helping the family obtain suitable housing; providing job-search assistance or removing barriers for family members seeking employment; assisting the family in identifying and applying to appropriate schools and/or child care programs; securing learning aids such as textbooks, computers and laboratory supplies; and obtaining personal financial and legal services.

(4) *Outreach to veterans and families.* Examples include, but are not limited to, the provision, development or deployment of various media tools (e.g., Internet, television, radio, flyers, posters, etc.), activity days, program booths, or other strategies to reach transitioning veterans and their families in the target community and assist them with their transition from military service to civilian life. Outreach services may be provided directly by the RVCP grantee or the grantee may engage the outreach services of another entity using RVCP funds.

(b) Grantees may use up to 10 percent of the RVCP grant for indirect costs, i.e., the expenses of doing business that are not readily identified with a particular grant but are necessary for the general operation of the grantee organization and the conduct of activities it performs.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.8 Notice of Funds Availability (NOFA).

When funds are available for RVCP grants, VA will publish a NOFA in the **Federal Register** and in Grants.gov (*http://www.grants.gov*). The NOFA will identify:

(a) The location for obtaining RVCP grant applications, including the specific forms that will be required;

(b) The date, time, and place for submitting completed RVCP grant applications;

(c) The estimated total amount of funds available and the maximum funds available to a single grantee;

(d) The minimum number of total points and points per category that an applicant must receive to be considered for a grant and information regarding the scoring process;

(e) Any timeframes and manner for payments under the RVCP grant; and

(f) Other information necessary for the RVCP grant application process, as determined by VA, including contact information for the office that will oversee the RVCP within VA.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.10 Application.

(a) To apply for an RVCP grant, eligible entities must submit to VA a complete application package. Applications will be accepted only through Grants.gov (*http://www.grants.gov*).

(b) A complete RVCP grant application package includes the following:

(1) A description of the services to be provided and which of the permissible uses for RVCP grants outlined in § 64.6(a) the services are intended to fulfill.

(2) A description, with supporting documentation, of the need for the proposed project in the proposed location, including an estimate, with supporting documentation, of the number of veterans and families that will be provided services by the applicant.

(3) A description, with supporting documentation, of how the proposed project location qualifies as a rural or an underserved community, as defined in this part.

(4) Documentation evidencing the applicant's experience in providing the proposed services, particularly to veterans and their families.

(5) Evidence of a clear, realistic, and measurable program of self-evaluation and monitoring, including a documented commitment to remediate any identified noncompliance.

(6) Documentation of the ability of the applicant to administer the project, including plans to:

(i) Continuously assess and adapt to the needs of participants for services under the RVCP grant;

(ii) Coordinate and customize the provision of services to the identified needs of the participants;

(iii) Comply with and implement the requirements of this part throughout the term of the RVCP grant; and

(iv) Complete and submit timely reports of RVCP grant activities.

(7) A description of any assistance received from or any consultations with VA or Veterans Service Organizations in the development of the proposal being submitted.

(8) Any additional information deemed appropriate by VA and set forth in the NOFA.

(Authority: 38 U.S.C. 501, 523 note)

(The Office of Management and Budget has approved the information collection provisions in this section under control numbers 4040–0003, 4040–0004, 4040–0006, 4040–0007, 4040–0008, 4040–0009, and 4040–0010.)

§ 64.12 Scoring and selection.

(a) *Scoring.* VA will score only complete applications received from eligible entities by the established deadline. Applications will be scored using the following criteria:

(1) *Background, organizational history, qualifications, and past performance (maximum 10 points).* Applicant documents a relevant history of successfully providing the type of

services proposed in the RVCP grant application, particularly in the location it plans to serve and/or to veterans and their families.

(2) *Need for pilot project (maximum 10 points).* Applicant demonstrates the need for the pilot project among veterans and their families in the proposed project location, and provides evidence of the applicant's understanding of the unique needs of veterans and their families in the location to be served.

(3) *Pilot project concept, innovation, and ability to meet VA's objectives (maximum 40 points).* Application shows appropriate concept, size, and scope of the project; provides realistic estimates of time, staffing, and material needs to implement the project; and details the project's ability to enhance the overall services provided, while presenting realistic plans to reduce duplication of benefits and services already in place. Application must describe a comprehensive and well-developed plan to meet one or more of the permissible uses set out in § 64.6.

(4) *Pilot project evaluation and monitoring (maximum 10 points).* Self-evaluation and monitoring strategy provided in application is reasonable and expected to meet requirements of § 64.10(b)(5).

(5) *Organizational finances (maximum 10 points).* Applicant provides documentation that it is financially stable, has not defaulted on financial obligations, has adequate financial and operational controls in place to assure the proper use of RVCP grants, and presents a plan for using RVCP grants that is cost effective and efficient.

(6) *Pilot project location (maximum 20 points).* Applicant documents how the proposed project location meets the definition of rural or underserved communities in this part.

(b) *Selection of grantees.* All complete applications will be scored using the criteria in paragraph (a) and ranked in order from highest to lowest total score. VA will rank all applications that receive at least the minimum number of points indicated in the NOFA. VA will award one RVCP grant to the highest scoring application. VA will award RVCP grants to each successive application, ranked by total score, provided the applicant has not been awarded an RVCP grant for a higher scoring application and the proposed project is not in the same project location as any previously awarded RVCP grant.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.14 RVCP grant agreement.

(a) VA will draft an RVCP grant agreement to be executed by VA and the grantee.

(b) The RVCP grant agreement will provide that the grantee agrees to:

(1) Operate the project in accordance with this part and the terms of the agreement;

(2) Abide by the following additional requirements:

(i) Community-based organizations are subject to the Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations under 38 CFR part 49, as well as to OMB Circular A–122, Cost Principles for Non-Profit Organizations, codified at 2 CFR part 230, and 2 CFR parts 25 and 170, if applicable.

(ii) Local and State government entities are subject to the Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments under 38 CFR part 43, as well as to OMB Circular A–87, Cost Principles for State, Local, and Indian Tribal Governments, and 2 CFR parts 25 and 170, if applicable.

(3) Comply with such other terms and conditions, including recordkeeping and reports for project monitoring and evaluation purposes, as VA may establish for purposes of carrying out the RVCP in an effective and efficient manner and as described in the NOFA; and

(4) Provide any necessary additional information that is requested by VA in the manner and timeframe specified by VA.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.16 Reporting.

(a) *Quarterly reports.* All grantees must submit to VA quarterly reports based on the Federal fiscal year, which include the following information:

(1) Record of time and resources expended in outreach activities, and the methods used;

(2) The number of participants served, including demographics of this population;

(3) Types of assistance provided;

(4) A full accounting of RVCP grant funds received from VA and used or unused during the quarter; and

(5) Results of routine monitoring and any project variations.

(b) *Submission of reports.* Reports must be submitted to VA no later than 15 calendar days after the close of each Federal fiscal quarter.

(c) *Additional reports.* VA may request additional reports to allow VA to fully assess project accountability and effectiveness.

(Authority: 38 U.S.C. 501, 523 note)

§ 64.18 Recovery of funds.

(a) *Recovery of funds.* VA may terminate a grant agreement with any RVCP grantee that does not comply with the terms of the RVCP agreement. VA may recover from the grantee any funds that are not used in accordance with a RVCP grant agreement. If VA decides to recover funds, VA will issue to the grantee a notice of intent to recover RVCP grant funds, and the grantee will then have 30 days beginning from the date of the notice to submit documentation demonstrating why the RVCP grant funds should not be recovered. If the RVCP grantee does not respond or if the grantee responds but VA determines the documentation is insufficient to establish compliance, VA will make a final determination as to whether action to recover the RVCP grant funds will be taken.

(b) *Prohibition of further grants.* When VA determines action will be taken to recover grant funds from a grantee, the grantee will be prohibited from receiving any further RVCP grant funds for the duration of the pilot program.

(Authority: 38 U.S.C. 501, 523 *note*)

[FR Doc. 2013–04277 Filed 2–22–13; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 70

[Docket No. CDC–2012–0016]

RIN 0920–AA22

Control of Communicable Diseases: Interstate; Scope and Definitions

AGENCY: Centers for Disease Control and Prevention (HHS/CDC), Department of Health and Human Services (HHS).

ACTION: Confirmation of effective date of Direct Final Rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is publishing this document to confirm the effective date of the Direct Final Rule (DFR), published on December 26, 2012 (77 FR 75880).

DATES: The Direct Final Rule published at 77 FR 75880, December 26, 2012, becomes effective on February 25, 2013.

FOR FURTHER INFORMATION CONTACT: For questions concerning this notice: Ashley A. Marrone, JD, Centers for Disease

Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION: On December 26, 2012, HHS/CDC published a Direct Final Rule (DFR) amending 42 CFR part 70 to update the Scope and Definitions for that part (77 FR 75880). On the same date, HHS/CDC simultaneously published a companion Notice of Proposed Rulemaking (NPRM) that proposed identical updates to the Scope and Definitions (77 FR 75936). In both documents, HHS/CDC indicated that if we did not receive any significant adverse comments on the direct final rule by January 25, 2013, we would publish a document in the **Federal Register** withdrawing the NPRM and confirming the effective date of the direct final rule within 30 days after the end of the comment period. HHS/CDC received one public comment that was not a significant, adverse comment, but rather, was in support of the companion NPRM. Because HHS/CDC did not receive any significant adverse comments to the NPRM within the specified comment period, we have published a document to withdraw the NPRM in this issue of the **Federal Register**. Therefore, consistent with the Direct Final Rule, the amendments to 42 CFR part 70 become effective on February 25, 2013 (77 FR 75880).

Dated: February 13, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–04137 Filed 2–22–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2012–0017]

RIN 0920–AA12

Control of Communicable Diseases: Foreign; Scope and Definitions

AGENCY: Centers for Disease Control and Prevention (HHS/CDC), Department of Health and Human Services (HHS).

ACTION: Confirmation of effective date of direct final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is publishing this document to confirm the effective date of the Direct Final Rule (DFR), published on December 26, 2012 (77 FR 75939).

DATES: The Direct Final Rule published at 77 FR 75939, December, 26, 2012, becomes effective on February 25, 2013.

FOR FURTHER INFORMATION CONTACT: For questions concerning this notice: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION: On December 26, 2012, HHS/CDC published a Direct Final Rule (DFR) amending 42 CFR part 71 to update the Scope and Definitions for that part (77 FR 75885). On the same date, HHS/CDC simultaneously published a companion Notice of Proposed Rulemaking (NPRM) that proposed identical updates to the Scope and Definitions (77 FR 75939). In both documents, HHS/CDC indicated that if we did not receive any significant adverse comments on the direct final rule by January 25, 2013, we would publish a document in the **Federal Register** withdrawing the NPRM and confirming the effective date of the direct final rule within 30 days after the end of the comment period. HHS/CDC received two comments to the companion NPRM. One comment pertained to food safety that raised issues unrelated to the companion NPRM and appears to have been submitted in error. The second comment was a general comment on immigration and was outside the scope of this rulemaking. HHS/CDC did not consider this comment to be a significant, adverse comment because it did not raise any issues that were relevant to the subject matter under consideration. Because HHS/CDC did not receive any relevant significant adverse comments within the specified comment period, we have published a notice to withdrawal the NPRM in this issue of the **Federal Register**. Therefore, consistent with the Direct Final Rule the amendments to 42 CFR part 71 become effective on February 25, 2013 (77 FR 75885).

Dated: February 13, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–04136 Filed 2–22–13; 8:45 am]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 12–225; RM–11668; DA 13–92]

Radio Broadcasting Services; Greenup, IL

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document the Audio Division, at the request of Word Power, Inc., allots a first local service to Greenup, Illinois, and reserves Channel *230A at Greenup for noncommercial educational use. A staff engineering analysis confirms that Channel *230A at Greenup would provide a first and/or second NCE radio service to 67.5 percent (21,149 persons) of the total population of 31,338 persons. Channel *230A can be allotted to Greenup consistent with the distance separation requirements of Section 73.207 of the Commission's rules with a site restriction 4.6 kilometers (2.9 miles) southwest of the community. The reference coordinates for Channel *230A are 39–12–38 NL and 88–11–15 WL.

DATES: Effective March 11, 2013.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* adopted January 24, 2013, and released January 25, 2013. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY–A257, 445 Twelfth Street SW., Washington, DC 20554. This document may also be purchased from the Commission's duplicating contractors, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or via email *www.BCPIWEB.com.* This document does not contain proposed information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104–13. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336 and 339.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Illinois, is amended by adding Greenup, Channel *230A.

[FR Doc. 2013–04169 Filed 2–22–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 544

[Docket No. NHTSA–2013–0024]

Insurer Reporting Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule repeals NHTSA's regulation requiring motor vehicle insurers to submit information on the number of thefts and recoveries of insured vehicles and actions taken by the insurer to deter or reduce motor vehicle theft. NHTSA is repealing this regulation because the agency's only available statutory authority to require insurers to submit this information was removed by the Motor Vehicle and Highway Safety Improvement Act of 2012 (Mariah's Act) (incorporated into the Moving Ahead for Progress in the 21st Century Act (MAP–21)). Given that NHTSA no longer has the authority to require insurers to submit this information and thus has no discretion to take any action other than rescinding the regulation, the agency did not issue a notice of proposed rulemaking (NPRM) prior to this final rule. Under those circumstances, public comment to the rulemaking is unnecessary.

The repeal of the authority to maintain and enforce the insurer reporting requirements reduced the paperwork burden on the public by 13,375 hours and reduced the cost to the government in collecting the information by $64,000.

DATES: *Effective date:* This final rule is effective February 25, 2013. *Petitions for reconsideration:* Petitions for reconsideration of this final rule must be received not later than April 11, 2013.

ADDRESSES: Any petitions for reconsideration should refer to the docket number of this document and be submitted to: Administrator, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., West Building, Ground Floor, Docket Room W12–140, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, 1200 New Jersey Avenue SE., Washington, DC 20590, by electronic mail to *Carlita.Ballard@dot.gov.* Ms. Ballard's telephone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to 49 U.S.C. 33112, *Insurer Reports and Information,* NHTSA issued a regulation requiring certain passenger motor vehicle insurers to file an annual report with the agency. Each insurer is required to report information about thefts and recoveries of motor vehicles, the rating rules used by the insurer to establish premiums for comprehensive coverage, the actions taken by the insurer to reduce such premiums, and the actions taken by the insurer to reduce or deter theft. This statute also gives NHTSA the discretion to exempt small insurers from the reporting requirements if the agency finds that such an exemption will not significantly affect the validity or usefulness of the information in the reports, either nationally or on a state-by-state basis.

In order to carry out 49 U.S.C. 33112, NHTSA promulgated 49 CFR part 544, *Insurer Reporting Requirements,* which requires insurers to submit information about the make, model, and year of all vehicle thefts, the make, model, and year of all vehicle recoveries, whether the vehicle was recovered in whole or in part, the dollar amount of the insurer's claims paid out due to theft, the rating rules used by the insurer to establish premiums for comprehensive coverage, the actions taken by the insurer to reduce such premiums, and the actions taken by the insurer to reduce or deter theft. The following insurers are subject to the reporting requirements:

(1) Issuers of motor vehicle insurance policies whose total premiums account for 1 percent or more of the total premiums of motor vehicle insurance issued within the United States;

(2) issuers of motor vehicle insurance policies whose premiums account for 10 percent or more of total premiums written within any one state; and

(3) rental and leasing companies with a fleet of 20 or more vehicles not covered by theft insurance policies issued by insurers of motor vehicles, other than any governmental entity.

This final rule repeals Part 544 because 49 U.S.C. 33112, which gives the agency the authority to require insurers to submit information about motor vehicle thefts, was repealed by Mariah's Act.[1] Apart from 49 U.S.C. 33112, the agency does not have any statutory authority on which it could rely to require insurers to submit the information required under Part 544. NHTSA has the authority under 49 U.S.C. 32303, *Insurance Information,* to require insurers to submit accident claim information about physical damage, repair costs, and personal injury but that statute does not provide the agency with the authority to collect information from insurers about motor vehicle thefts. Furthermore, 49 U.S.C. 33102, *Theft Prevention Standard for High Theft Lines,* states that NHTSA's general authority to issue theft prevention standards does not authorize the agency to require any person to keep records or make reports related to motor vehicle thefts unless the agency has express statutory authority to do so. NHTSA has statutory authority to issue motor vehicle safety standards, recall defective and noncompliant vehicles, ensure that imported vehicles comply with Federal motor vehicle safety standards, issue bumper standards, prevent odometer fraud, issue fuel economy standards and issue theft prevention standards. None of the statutory provisions that authorize those activities give NHTSA the authority to continue to require insurers to submit information about motor vehicle thefts. Because the statute authorizing NHTSA to require insurers to report information about motor vehicle thefts has been repealed and the agency does not have any other basis to require insurers to submit this information, we are issuing this final rule to repeal Part 544.

The effective date of this final rule is the date of publication. However, Part 544 ceased to be enforceable on October 1, 2012, the effective date of the provision in Mariah's Act removing the

[1] Public Law 112–141.

agency's authority to require insurers to submit this information.

II. Public Comment

NHTSA did not issue an NPRM prior to this final rule. While the Administrative Procedure Act requires that agencies publish a general NPRM in the **Federal Register** prior to issuing a final rule, an agency is not required to publish an NPRM if the agency is able to make and makes a good cause finding that notice and public comment is ''impracticable, unnecessary, or contrary to the public interest.'' [2] Because NHTSA no longer has the authority to require insurers to submit information on thefts under Part 544, we cannot enforce those provisions and must repeal them. Given that the agency has no discretion as to the outcome of this rulemaking, public comment on it is unnecessary.

III. Regulatory Notices and Analyses

A. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

NHTSA has considered the impact of this rulemaking action under Executive Order 12866, Executive Order 13563, and the DOT's regulatory policies and procedures. This final rule was not reviewed by the Office of Management and Budget (OMB) under E.O. 12866, ''Regulatory Planning and Review.'' It is not considered to be significant under E.O. 12866 or the Department's regulatory policies and procedures.

This final rule repeals regulations requiring motor vehicle insurers to submit certain information about vehicle thefts. The repeal of the authority to maintain and enforce the insurer reporting requirements reduced the paperwork burden on the public by 13,375 hours and reduces the cost to the government in collecting the information by $64,000. Because there are not any costs or savings associated with this rulemaking, we have not prepared a separate economic analysis for this rulemaking.

B. Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, 5 U.S.C. 60l et seq., NHTSA has evaluated the effects of this action on small entities. I hereby certify that this rule would not have a significant impact on a substantial number of small entities. The final rule would affect motor vehicle insurers, but the entities that qualify as small businesses would not be significantly affected by this rulemaking because the agency is repealing existing requirements that these entities submit information on motor vehicle thefts to the agency.

C. Executive Order 13132

NHTSA has examined today's rule pursuant to Executive Order 13132 (64 FR 43255, August 10, 1999) and concluded that no additional consultation with States, local governments or their representatives is mandated beyond the rulemaking process. The agency has concluded that the rulemaking would not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The final rule would 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.'' Because this final rule is repealing existing requirements, this final rule will not preempt any state law.

D. National Environmental Policy Act

NHTSA has analyzed this final rule for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action will not have any significant impact on the quality of the human environment.

E. Paperwork Reduction Act

Under the procedures established by the Paperwork Reduction Act of 1995, a person is not required to respond to a collection of information by a Federal agency unless the collection displays a valid OMB control number. The repeal of the authority to maintain and enforce the insurer reporting requirements reduced the paperwork burden on the public by 13,375 hours and reduced the cost to the government in collecting the information by $64,000.

F. National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' This Final Rule does not adopt any voluntary consensus standards because this rulemaking repeals existing requirements.

G. Civil Justice Reform

With respect to the review of the promulgation of a new regulation, section 3(b) of Executive Order 12988, ''Civil Justice Reform'' (61 FR 4729, February 7, 1996) requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect; (2) clearly specifies the effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct, while promoting simplification and burden reduction; (4) clearly 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. This document is consistent with that requirement.

Pursuant to this Order, NHTSA notes as follows. The preemptive effect of this final rule is discussed above. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). This final rule would not result in expenditures by State, local or tribal governments, in the aggregate, or by the private sector in excess of $100 million annually.

I. Executive Order 13211

Executive Order 13211 (66 FR 28355, May 18, 2001) applies to any rulemaking that: (1) Is determined to be economically significant as defined under E.O. 12866, and is likely to have a significantly adverse effect on the supply of, distribution of, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. This rulemaking is not subject to E.O. 13211.

J. Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified

[2] 5 U.S.C. 553.

Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

List of Subjects in 49 CFR Part 544

Imports, Motor vehicle safety, Motor vehicles, Tires, Reporting and recordkeeping requirements.

In consideration of the foregoing, under the authority of Sec. 31313, Public Law 112–141, NHTSA amends 49 CFR Chapter V as set forth below:

PART 544—[REMOVED AND RESERVED]

■ 1. Part 544 is removed and reserved.

Issued in Washington, DC on February 13, 2013 under authority delegated in 49 CFR 1.95.

David L. Strickland,

Administrator.

[FR Doc. 2013–04300 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 121022572–3075–02]

RIN 0648–XC318

Fisheries of the Northeastern United States; Atlantic Herring Fishery; Adjustment to 2013 Annual Catch Limits

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

ACTION: Final rule.

SUMMARY: This action reduces the Atlantic herring 2013 sub-annual catch limits in herring management area 1A to account for catch overages in 2011, and to prevent overfishing.

DATES: This rule is effective from March 27, 2013 through December 31, 2013.

ADDRESSES: Copies of supporting documents, the 2010–2012 Herring Specifications and Amendment 4 to the Herring Fishery Management Plan (FMP) are available from: John K. Bullard, Northeast Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. This document is also accessible via the Internet at *http://www.nero.noaa.gov.* NMFS prepared a Final Regulatory Flexibility Analysis (FRFA), which is contained in the Classification section of this rule. Copies of the FRFA and the Small Entity Compliance Guide are available from: John K. Bullard, Regional Administrator, National Marine Fisheries Service, Northeast Region, 55 Great Republic Drive, Gloucester, MA 01930–2276, or via the internet at *http://www.nero.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Lindsey Feldman, Fishery Management Specialist, 978–675–2179, fax 978–281–9135.

SUPPLEMENTARY INFORMATION:

Background

The New England Fishery Management Council (Council) developed herring specifications for 2010–2012, which were approved by NMFS on August 12, 2010 (75 FR 48874). The Herring FMP divides the stock-wide herring ACL (91,200 mt) among three management areas, one of which has two sub-areas. Area 1 is located in the Gulf of Maine (GOM) and consists of an inshore section (Area 1A) and an offshore section (Area 1B). Area 2 is located in the coastal waters between Massachusetts and North Carolina, and Area 3 is on Georges Bank (GB). Each management area has its own sub-ACL to allow greater control of the fishing mortality on each stock component. The management area sub-ACLs established for 2010–2012 were: 26,546 mt for Area 1A, 4,362 mt for Area 1B, 22,146 mt for Area 2, and 38,146 mt for Area 3.

Amendment 4 to the Herring FMP (Amendment 4) (76 FR 11373, March 2, 2011) revised the specification-setting process, bringing the Herring FMP into compliance with ACL and accountability measure (AM) requirements of the Magnuson-Stevens Fishery Conservation and Management Act (MSA). Under the FMP, if NMFS determines catch will reach 95 percent of the sub-ACL allocated to a management area or seasonal period, then NMFS prohibits vessels from fishing for, possessing, catching, transferring, or landing more than 2,000 lb (907.2 kg) of herring per trip from that area or seasonal period. This AM slows catch to prevent or minimize catch in excess of a management area or seasonal period sub-ACL. As a way to account for ACL overages in the herring fishery, Amendment 4 also established an AM that provided for overage deductions. If the catch of herring in any given management area in any given fishing year exceeds any sub-ACL, the overage will subsequently be deducted from the corresponding management area sub-ACL in a subsequent fishing year. A range of additional AMs are currently being considered as a part of the 2013–2015 specifications process. Until then, the current AMs, including the overage deduction addressed in this rule, are still in place.

Final Adjustment to the 2013 Annual Catch Limits

The 2011 Atlantic herring fishing year began on January 1, 2011, and ended on December 31, 2011. Based on dealer, VTR, and observer data, 2011 herring catch exceeded the sub-ACL in Area 1A by 1,425 mt. There were no sub-ACL overages in the other herring management areas. Therefore, NMFS is required to deduct the Area 1A overage in 2011 from the 2013 Area 1A sub-ACL. At the time of this final rule, the Atlantic herring 2013 specifications have not yet been finalized. The 2013–2015 herring specifications are currently in development and will not be effective prior to the 2013 herring fishing year, which begins on January 1, 2013.

The Council's Scientific and Statistical Committee (SSC) met on September 13, 2012, and again on November 19, 2012, and recommended herring acceptable biological catch (ABC) levels for 2013–2015. The Council expects to take final action at its January meeting, and a proposed and final rule for the 2013–2015 herring specifications will follow. Although the 2013 herring specifications will not be in place on January 1, 2013, the regulations at § 648.200(d) include a provision that allows the previous years' specifications to roll over to the following year(s) when new specifications are delayed past the start of the fishing year. Therefore, in accordance with regulations at § 648.201(a)(3), this action deducts the 1,425-mt 2011 overage in Area 1A from the 2013 Area 1A sub-ACL. Since the 2012 herring specifications will be in place on January 1, 2013, this action adjusts the rolled over sub-ACL in Area 1A until the 2013–2015 specifications are finalized. As a result, NMFS is revising the sub-ACL for Area 1A from 26,546 mt to 25,121 mt (a reduction of 1,425 mt). When the 2013 specifications are finalized, NMFS will deduct the 1,425-mt overage from the final 2013 Area 1A sub-ACL.

Comments and Responses

NMFS received five comment letters on the proposed rule for this action from the following: The Cape Cod Commercial Hook Fishermen's Association (CCCHFA); Coalition for the Atlantic Herring Fishery's Orderly, Informed, and Responsible Long-Term Development (CHOIR); the Conservation

Law Foundation (CLF) and Earthjustice, both on behalf of the Herring Alliance; and a member of the public.

Comment 1: CCCHFA, CHOIR, CLF, and the member of the public commented in support of adjusting the 2013 Herring sub-ACL in Area 1A to account for catch overages in 2011.

Response: NMFS agrees and is adjusting the 2013 Area 1A sub-ACL to account for 2011 Area 1A sub-ACL catch overages in this final rule.

Comment 2: CCCHFA, Earthjustice, and CHOIR commented that the catch overage of 1,425 mt in Area 1A indicates that the current monitoring, reporting methods, and AMs in the Atlantic herring FMP are not sufficient to prevent sub-ACL overages.

Response: The comment on NMFS's ability to adequately monitor catch in the herring fishery, and comments on the reporting methods and AMs in the Herring FMP are beyond the scope of this rulemaking, which simply implements the AM currently required under the Herring FMP. Nevertheless, NMFS believes the current reporting and monitoring methods and AMs are sufficient to adequately monitor the fishery on a real-time basis. However, NMFS recognizes the difficulties in monitoring high volume fisheries, such as the herring fishery, in which the fleet catches and lands large volumes of fish in a very short period of time. We currently monitor the herring quota using a combination of daily VMS reporting, weekly VTR reporting, and weekly dealer reporting. We recognize that VMS catch reports may be overestimate catch, and that data errors in catch reports, late reporting, or non-compliance have been a challenge to monitor the fishery in real-time. While we believe that the current reporting and monitoring methods are sufficient to adequately monitor this fishery on a real-time basis, it is imperative that vessels and dealers report catch and landings consistently and accurately. We are currently planning outreach meetings with the Atlantic herring industry to discuss ways to improve the accuracy of catch reporting to improve the timing of management area closures. In addition, for the 2013–2015 herring specifications, the Council is considering a range of AMs to better ensure that herring catch does not exceed management area sub-ACLs. Moreover, under the National Standard Guidelines at 50 CFR 600.310(g)(3), if herring fishery exceeds the stockwide herring ACL, the stock's ACLs and AMs may be reexamined.

Comment 3: Earthjustice and CHOIR commented that NMFS should modify the overage deduction AM so that NMFS deducts any sub-ACL overages from the following year's sub-ACL, instead of from the 2nd fishing year after the overage. CHOIR noted that waiting until two years after the catch overage to account for any sub-ACL overages could have a significant impact on the herring resource.

Response: Like Comment 2, this comment on adjusting the AMs is beyond the scope of this rulemaking, which NMFS is implementing under the limited authority under the Herring FMP. AMs must be adjusted through a Council action, such as the 2013–2015 specifications or a future framework or amendment. This action is an inseason adjustment to the herring ACL. Because this is not a framework adjustment or amendment.

Furthermore, there is no evidence that accounting for sub-ACL overages in the year after determining the total catch has a significant adverse impact on the herring resource. For example, there is no evidence that a single year delay versus an immediate deduction the year following an overage affects the reproductive potential of the stock. Herring is a relatively long-lived species (over 10 years) and the fishery harvests multiple year classes. These characteristics suggest that the herring stock may withstand a single year delay in overage deductions. Moreover, the herring stock is neither overfished nor subject to overfishing at this time.

Comment 4: Earthjustice criticized NMFS' discard accounting methodology for the herring fishery. Earthjustice believes that discards coded as ''fish not known (fish nk)'' contain substantial amounts of herring, which should have been included in the amount of Atlantic herring caught during the 2011 fishing year. In referenced prior comments, Earthjustice argues that counting ''fish nk'' as herring catch would change the amount of the overage and overage deduction. When calculating a herring discard estimate, they recommended that NMFS assume all ''fish nk'' discarded from limited access herring vessels are Atlantic herring and that the fleet-wide estimate of discarded ''fish nk'' should be added to the discard estimate of herring to calculate total herring discards in 2011.

Response: NMFS calculated 2011 herring discards consistent with how it calculated discards in 2010, as recommended by the Herring Plan Development Team (PDT). Herring discards are estimated by dividing the amount of observed herring discards (labeled ''herring'' and ''herring not known (herring nk'') in observer haul logs) by the amount of all observed fish landed. NMFS then multiplies that discard ratio by the amount of all fish landed for each trip to calculate total amount of herring discards in 2011. If an observer verifies that fish are Atlantic herring, they code those fish as ''herring'' and if the observer identifies the fish as a type of herring but cannot verify species of herring, the observer codes those fish as ''herring nk.'' Only in the instance where an observer cannot verify species identification on discarded catch, does the observer code that discard event as ''fish nk.'' When developing the discard methodology, the Herring PDT concurred that NMFS should calculate the discard estimate for the herring based on the amount of observed ''herring'' and ''herring nk'' and that it should not include discards coded as ''fish nk.''

NMFS does not believe it is appropriate to count discards coded as 'fish nk' as Atlantic herring. Including 'fish nk' discards in determining the amount of an overage would likely overstate the overage. 'Fish nk' consists of a mix of multiple species and is not limited to Atlantic herring. And while excluding 'fish nk' discards would likely understate the overage, any understatement would be an extremely small percentage of the sub-ACL for Area 1A. Total 'fish nk' discards for the Atlantic herring fishery in 2011 are estimated at 510 mt, equaling less than 1 percent of the 26,546 mt quota in Area 1A, and only a portion of those total discards occurred in Area 1A. Given these facts, we believe that when choosing between including all or including none of the 'fish nk' discards, the better course is to not include 'fish nk' discards.

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 Atlantic Herring FMP, other provisions of the MSA, and other applicable law.

NMFS completed the National Environmental Policy Act analysis to support this action in Amendment 4 (76 FR 11373, March 2, 2011).

This final rule has been determined to be not significant for purposes of Executive Order 12866. This final rule does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act.

NMFS, pursuant to section 604 of the Regulatory Flexibility Act, has prepared a FRFA, included in the preamble of this final rule. The FRFA describes the economic impact that this final rule, along with other non-preferred alternatives, will have on small entities.

The FRFA incorporates the economic impacts and analysis summaries in the IRFA, a summary of the significant issues, if any, raised by the public in response to the IRFA, and NMFS' responses to those comments. A copy of the IRFA, the RIR, and the EA are available upon request (see **ADDRESSES**).

Statement of Objective and Need

In 2011, there was a herring catch limit overage in herring management area 1A equal to 1,425 mt. In accordance with regulations at § 648.201(a)(3), this action deducts the 2011 management Area 1A overage from the 2013 management Area 1A catch limits. Since the 2013 specifications will not be finalized by January 1, 2013, and the 2012 specifications will be in place at the start of the herring fishing year, this action revises the rolled over sub-ACL for Area 1A for 2013 from 26,546 mt to 25,121 mt to account for 2011 the catch overage. When NMFS finalizes the 2013 herring specifications, it will deduct the 1,425 mt from the final 2013 Area 1A sub-ACL.

A Summary of the Significant Issues Raised by the Public Comments in Response to the IRFA, a Summary of the Assessment of the Agency of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments

There were no issues related to the IRFA raised in public comments.

Description and Estimate of Number of Small Entities To Which the Rule Will Apply

All participants in the herring fishery are small entities as defined by the SBA under the Regulatory Flexibility Act, as none grossed more than $4 million annually, so there would be no disproportionate economic impacts on small entities. In 2011, 93 vessels were issued limited access herring permits, and 2,149 were issued open access herring permits.

Total herring revenue in 2011 equaled approximately $22.4 million for limited access vessels, and $43,000 for open access vessels. NMFS estimates the reduced sub-ACL in Areas 1A to equal approximately $400,000 in lost revenue for the fishery in 2013. While this action reduces the amount of fish available for harvest, both the fishery-wide and individual-vessel economic effects are anticipated to be minimal, because the reduction overall and per vessel is relatively minor, as compared with the fishery's overall revenue, and because it only affects one of the herring management areas.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action. In addition, there are no Federal rules that duplicate, overlap, or conflict with this rule.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impacts on Small Entities Consistent With the Stated Objectives of Applicable Statutes, Including a Statement of the Factual, Policy, and Legal Reasons for Selecting the Alternative Adopted in the Final Rule and Why Each One of the Other Significant Alternatives to the Rule Considered by the Agency Which Affect the Impact on Small Entities Was Rejected

Amendment 4 analyzed the effects of deducting ACL/sub-ACL overages from the subsequent corresponding ACL/sub-ACL. During a year when the fishery exceeds the ACL/sub-ACL, fishery participants may benefit economically from higher catch. In the subsequent year, when NMFS deducts the amount of the overage from that ACL/sub-ACL and the amount of harvest is lower, fishery participants may experience negative economic impacts. Since the participants in the fishery from year to year vary, there could be a minor economic impact on the fishery participants operating in Area 1A in 2013 due to the overage deduction from 2011.

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

Dated: February 19, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–04261 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 110321210–3057–02]

RIN 0648–BA93

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Management Area; Groundfish Retention Standard

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

ACTION: Final rule.

SUMMARY: NMFS publishes a regulatory amendment to modify the groundfish retention standard (GRS) program in the Bering Sea and Aleutian Islands Management Area (BSAI). This final rule removes certain regulatory requirements that mandate minimum levels of groundfish retention by the owners and operators of trawl catcher/processor (C/P) vessels not listed in the American Fisheries Act (AFA), commonly referred to as either non-AFA trawl C/Ps or Amendment 80 vessels, and Amendment 80 cooperatives participating in the BSAI groundfish fisheries. The GRS program was implemented to increase the retention and utilization of groundfish; however, NMFS has discovered that the regulatory methodology used to calculate compliance with the GRS requires individual Amendment 80 vessels and Amendment 80 cooperatives to retain groundfish at rates well above the minimum retention rates recommended by the Council or implemented by NMFS. As a result, the GRS imposes significantly higher than predicted compliance costs on vessel owners and operators due to the increased level of retention needed to meet the minimum retention rates. Additionally, NMFS discovered that enforcement of the GRS has proven far more complex, challenging, and potentially costly than anticipated by NMFS. This action is necessary to relieve Amendment 80 vessels and Amendment 80 cooperatives from undue compliance costs stemming from the minimum retention rates while continuing to promote the GRS program goals of increased groundfish retention and utilization. This action maintains current monitoring requirements for the Amendment 80 fleet and establishes a new requirement for Amendment 80 cooperatives to annually report

groundfish retention performance as part of the report submitted to NMFS. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act, the fishery management plan, and other applicable law.

DATES: Effective March 27, 2013.

ADDRESSES: Electronic copies of the Environmental Assessment (EA), Regulatory Impact Review (RIR), and Final Regulatory Flexibility Analysis (FRFA) prepared for this action may be obtained from *http://www.regulations.gov* or from the Alaska Region Web site at *http://alaskafisheries.noaa.gov.*

Written comments regarding the burden-hour estimates or other aspects of the collection of information requirements contained in this final rule may be submitted by mail to NMFS, Alaska Region, P.O. Box 21668, Juneau, AK 99802–1668, Attn: Ellen Sebastian, Records Officer; in person at NMFS, Alaska Region, 709 West 9th Street, Room 420A, Juneau, AK; or by email to *OIRA_submission@omb.eop.gov* or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Seanbob Kelly, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the U.S. groundfish fisheries of the BSAI in the Exclusive Economic Zone (EEZ) under the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The North Pacific Fishery Management Council (Council) prepared the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and other applicable laws. Regulations implementing the FMP appear at 50 CFR part 679. General regulations that pertain to U.S. fisheries appear at subpart H of 50 CFR part 600.

This final rule implements a regulatory amendment to modify the GRS program by removing certain retention requirements. Under this final rule, Amendment 80 vessels and Amendment 80 cooperatives are relieved from undue compliance costs stemming from the mandatory GRS rates; however, NMFS is implementing new reporting requirements intended to maintain the increased retention rates achieved by the fleet under the GRS program. NMFS published a proposed rule for this regulatory amendment in the **Federal Register** on October 15, 2012 (77 FR 62482). The 30-day comment period on the proposed rule ended on November 14, 2012. NMFS received two comment letters during the comment period on the proposed rule. These letters contained two unique comments. A summary of these comments and NMFS' responses are provided in the ''Comments and Responses'' section of this preamble. There were no changes to the regulatory text between the proposed rule and this final rule.

Background

The following discussion provides a brief review of the rationale for this action and the regulatory changes to the management of Amendment 80 vessels and Amendment 80 cooperatives in the BSAI that are implemented with this final rule. A detailed review of the provisions of this regulatory amendment is provided in the preamble to the proposed rule (77 FR 62482, October 15, 2012). The proposed rule is available from the NMFS Alaska Region web site (see **ADDRESSES**).

In June 2003, the Council adopted Amendment 79 to the FMP and the GRS program. Amendment 79 revised section 2.2.1 of the FMP to include the management objective of improving the retention of groundfish where practicable, through establishment of minimum groundfish retention standards. The GRS program required certain non-AFA trawl C/Ps to annually retain a minimum percentage of groundfish catch. Table 1 shows the minimum GRS percentages established for the GRS program. The rationale for the GRS is described in the preamble to the final rule implementing the GRS program published on April 6, 2006 (71 FR 17362). The GRS program became effective in 2008.

TABLE 1—ANNUAL GROUNDFISH RETENTION STANDARD

GRS Schedule	Annual GRS (percent)
2008	65
2009	75
2010	80
2011 and each year after	85

Amendment 80 to the FMP and its implementing regulations modified the GRS program to encourage participants in the fishery to join an Amendment 80 cooperative (72 FR 52668, September 14, 2007). Vessels that are assigned Amendment 80 quota share (QS) and that are eligible to fish in the Amendment 80 sector are commonly called Amendment 80 vessels. Under Amendment 80, all Amendment 80 vessels, regardless of size, and Amendment 80 cooperatives were required to meet the GRS. Eligible vessels participating in an Amendment 80 cooperative were authorized to aggregate the total catch and total retained catch by all vessels in the cooperative for purposes of calculating the cooperative's compliance with the GRS. These changes created an incentive for vessels with lower groundfish retention rates to join a cooperative that included vessels with higher groundfish retention rates, which would offset the lower retention rates of those vessels.

Concerns With the GRS Program

In June 2010, NMFS reported to the Council two key concerns with the enforcement and prosecution of the GRS: (1) The regulatory method used to calculate compliance with the GRS required the fleet to retain groundfish at a higher rate than the rate initially considered by the Council; and (2) the agency was encountering difficulties in effectively enforcing and prosecuting the GRS for an individual vessel, and these difficulties would be exacerbated in the prosecution of a single cooperative comprised of several vessels, or multiple cooperatives. NMFS explained that compliance with and enforcement of the GRS had proven far more complex and challenging, as well as potentially more costly, than anticipated at the time it approved the GRS program. NMFS determined that the likelihood that additional vessels may be unable to meet the GRS, as calculated by NMFS, in future years would unnecessarily increase compliance and enforcement costs. NMFS also noted that since the GRS program was implemented, the retention rate of groundfish by the Amendment 80 fleet had increased substantially and available information indicated that the Council's objectives for groundfish retention had been met.

Representatives of the Amendment 80 sector also testified that vessel operators that met the GRS in 2009 would face significant additional challenges in meeting the increasing standard. Vessel operators reiterated NMFS' concerns that it may not be possible for vessels operating individually in the Amendment 80 limited access fishery, or collectively in a cooperative, to achieve the highest GRS required in regulation. Additional information on the concerns raised by NMFS and Amendment 80 participants can be found in the proposed rule for this action (77 FR 62482, October 15, 2012).

Emergency Action

After considering NMFS' report and public comment, the Council recommended that NMFS take

emergency action to relieve vessel owners and operators from mandatory compliance with the GRS. On December 15, 2010, NMFS published an emergency rule that exempted Amendment 80 vessels and cooperatives from GRS regulations during 2010 and 2011 (75 FR 78172). The preamble of the emergency rule describes NMFS' and the Council's justification for emergency action, and it is not repeated here. An extension of this emergency action was published on June 2, 2011, and was effective until December 17, 2011 (76 FR 31881).

Rationale for This Final Rule

This final rule is intended to provide a long-term solution to the problems identified by NMFS and the Council with the GRS program. NMFS and the Council determined that this action is necessary because the circumstances that justified the GRS have changed. NMFS and the Council determined that the regulatory constraints imposed by the GRS no longer achieve the goals that led to their establishment. This action is intended to mitigate higher than expected compliance costs of the GRS borne by the Amendment 80 sector. Furthermore, NMFS and the Council have determined that this action is needed to mitigate management and enforcement costs that were not foreseen when the regulation was promulgated. NMFS and the Council have determined that the additional and potentially significant compliance costs associated with the GRS are not warranted because the improvements in retention rates by Amendment 80 vessels through 2010 have met the Council's objectives of improved retention and utilization, and reduced bycatch.

Summary of the Regulations Implemented by This Final Rule

There were no changes between the proposed and final regulations in this final rule. This action establishes the following changes at 50 CFR part 679:

- Removes the definition of ''Groundfish Retention Standard (GRS)'' from § 679.2;
- Adds requirements for cooperative reporting and third party audits to § 679.5(s)(6)(iii)(D) and (E);
- Removes the prohibitions specific to the GRS at § 679.7(m);
- Removes the requirement that Amendment 80 cooperatives meet a minimum GRS at § 679.7(o)(4)(iv);
- Revises improved retention and improved utilization regulations at § 679.27(b)(4);
- Removes regulations implementing the GRS at § 679.27(j); and
- Revises regulations at § 679.93(c)(1).

The final rule removes regulations implementing the GRS at §§ 679.7 and 679.27. To meet Council intent for this action, NMFS revises regulatory text at § 679.27(b)(4) to remove references to the GRS program and removes § 679.27(j), which contained the bulk of the GRS program's regulations. This final rule does not change the use caps, sideboard limits, permitting, monitoring, or catch accounting requirements established for the Amendment 80 sector. This final rule retains regulations at § 679.27(b)(4) that require Amendment 80 vessels to meet a 15 percent utilization standard for all retained groundfish species listed in Table 2a to part 679 that are used in the calculation for percent of retained groundfish.

Current regulations at § 679.5(s)(6) require each Amendment 80 cooperative receiving allocations of Amendment 80 species to annually submit a report to NMFS detailing the use of the cooperative's quota. This final rule adds a requirement at § 679.5(s)(6) for an Amendment 80 cooperative to calculate and report its annual aggregate groundfish retention rate using the methodology initially established in regulation at § 679.27(j)(3). This additional reporting requirement is intended to provide NMFS with information as to whether the groundfish retention rates achieved under the GRS are being maintained by the Amendment 80 fleet.

The catch and production data needed to calculate annual groundfish retention are generally available to both NMFS and the Amendment 80 entity responsible for meeting current observer and production reporting requirements established for the Amendment 80 fleet. The authorized representative of an Amendment 80 cooperative could request that NMFS verify these data (see **ADDRESSES**). These data could then be used by an Amendment 80 cooperative to calculate its annual groundfish retention rate. In addition, this final rule requires each Amendment 80 cooperative to have a third party audit the cooperative's groundfish retention calculations and include these findings as part of the annual Amendment 80 cooperative report. Each third party audit will require the Amendment 80 cooperative to retain a third party to complete an audit of the cooperative's groundfish retention calculations. The third party audit will also require the cooperative to coordinate with NMFS and the appropriate Amendment 80 entities for a release of confidential observer and production data to the third party auditor.

This final rule does not require the owners of vessels participating in the Amendment 80 limited access fishery to report annual groundfish retention to NMFS. Instead, NMFS determined that it will prepare information on groundfish retention performance for Amendment 80 vessels participating in the Amendment 80 limited access fishery. NMFS currently produces these data as part of its inseason management report to the Council and will continue to report these retention rates to the Council during the October Council meeting.

This final rule also revises regulations at § 679.93(c)(1) to continue to require that the Amendment 80 sector weigh all catch, and to prohibit the pre-sorting of catch prior to weighing.

Comments and Responses

NMFS received two comment letters during the public comment period for the proposed rule to implement this regulatory amendment. One comment letter was received from a representative of the affected fishing industry and contained two unique comments; the other comment letter was received from a member of the public and did not contain any comments relevant to the proposed rule. A summary of the comments and NMFS' responses follow.

Comment 1: The commenter expressed general support for the proposed regulatory amendment.

Response: NMFS acknowledges this comment.

Comment 2: The proposed rule would require an Amendment 80 cooperative to report its groundfish retention rate in its annual cooperative report and would continue the requirement that Amendment 80 cooperative reports be submitted to NMFS. The information contained in the cooperative reports is confidential under NOAA Administrative Order (NAO) 216–100, 50 CRF 600.405, and section 402(b)(1) of the Magnuson-Stevens Act. Although NMFS states in the preamble of the proposed rule on page 62487 that it would provide Amendment 80 cooperative reports to the Council, NMFS is prevented from providing the cooperative reports to the Council given the confidential nature of information contained in the reports.

Response: In the preamble statement highlighted by the commenter, NMFS incorrectly stated that it would provide the annual cooperative report to the Council for purposes of this rule. Instead, NMFS anticipates providing to the Council and the public information on groundfish retention rates. NMFS will do so, consistent with section 402(b) of the Magnuson-Stevens Act and

applicable agency regulations and policies regarding any confidential information.

Classification

The Administrator, Alaska Region, NMFS, determined that this final rule is necessary for the conservation and management of the groundfish fisheries off Alaska and that it is consistent with the Magnuson-Stevens Act and other applicable laws.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. The preambles to the proposed rule and this final rule serve as the small entity compliance guide. This action does not require any additional compliance from small entities that is not described in the preambles. Copies of the proposed rule are available from NMFS at the following Web site: *http://alaskafisheries.noaa.gov.*

Executive Order 12866

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

Final Regulatory Flexibility Analysis

This FRFA incorporates the Initial Regulatory Flexibility Analysis (IRFA), a summary of the significant issues raised by the public comments, NMFS' responses to those comments, and a summary of the analyses completed to support the action. NMFS published the proposed rule on October 15, 2012 (77 FR 62482), with comments invited through November 14, 2012. An IRFA was prepared and summarized in the ''Classification'' section of the preamble to the proposed rule. NMFS received no comments to the IRFA. The description of this action, its purpose, and its legal basis are described in the preamble to the proposed rule and are not repeated here. The FRFA describes the impacts on small entities, which are defined in the IRFA for this action and not repeated here. Analytical requirements for the FRFA are described in the Regulatory Flexibility Act (RFA), sections 604(a)(1) through (5), and summarized below.

The FRFA must contain:

1. A succinct statement of the need for, and objectives of, the rule;
2. A summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. A description and an estimate of the number of small entities to which the rule will apply, or an explanation of why no such estimate is available;
4. A description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and
5. A 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, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

The ''universe'' of entities to be considered in a FRFA generally includes only those small entities that can reasonably be expected to be directly regulated by the final rule. If the effects of the rule fall primarily on a distinct segment of the industry, or portion thereof (e.g., user group, gear type, geographic area), that segment would be considered the universe for purposes of this analysis. In preparing a FRFA, an agency may provide either a quantifiable or numerical description of the effects of a rule (and alternatives to the rule), or more general descriptive statements, if quantification is not practicable or reliable.

Summary of Significant Issues Raised During Public Comment

No comments were received that raised significant issues in response to the IRFA specifically; therefore, no changes were made to the rule as a result of comments on the IRFA.

Number and Description of Small Entities Regulated by the Final Rule

The entities directly regulated by this action are those C/Ps that are members of the Amendment 80 sector that target flatfish, Atka mackerel, Pacific cod, and Pacific ocean perch in the EEZ of the BSAI. The Small Business Administration has established size criteria for all major industry sectors in the United States, including fish harvesting and fish processing businesses. Effective January 5, 2006, a business involved in fish harvesting is a small business if it is independently owned and operated, not dominant in its field of operation (including its affiliates), and if it has combined annual gross receipts not in excess of $4.0 million for all its affiliated operations worldwide. A seafood processor is a small business if it is independently owned and operated, not dominant in its field of operation, and employs 500 or fewer persons on a full-time, part-time, temporary, or other basis, at all its affiliated operations worldwide. A business involved in both the harvesting and processing of seafood products is a small business if it meets the $4.0 million criterion for fish harvesting operations.

NMFS estimated the number of small versus large entities by matching the gross earnings from all fisheries of record for 2009 with the vessels, the known ownership of those vessels, and the known affiliations of those vessels in the BSAI or Gulf of Alaska groundfish fisheries for that year. NMFS has specific information on the ownership of vessels and the affiliations that exist based on data provided by the Amendment 80 sector, as well as a review of ownership data independently available to NMFS from Federal fishing permit and license limitation program license applications. The vessels with a common ownership linkage in 2010, and therefore affiliation, are reported in Table 2 in Section 2.2.5 of the analysis for this action (see **ADDRESSES**). In addition, those vessels that are assigned to an Amendment 80 cooperative and receive an exclusive harvest privilege are categorized as large entities for the purpose of the RFA, under the principles of affiliation, due to their participation in a harvesting cooperative.

NMFS knows that as many as 28 Amendment 80 vessels could be active in the Amendment 80 fishery. Those persons who apply for and receive Amendment 80 quota share (QS) are eligible to fish in the Amendment 80 sector, and those QS holders will be directly regulated by the final rule. Vessels that are assigned Amendment 80 QS and that are eligible to fish in the Amendment 80 sector are commonly known as Amendment 80 vessels. Currently, there are 27 Amendment 80 vessels that will be directly regulated based on this action. One vessel owner, who could be eligible for the Amendment 80 program and could

apply for Amendment 80 QS, has not applied to NFMS to participate in this sector. Therefore, this vessel will not be directly regulated by the final rule unless and until the owner is approved to participate in the Amendment 80 sector and is assigned Amendment 80 QS. Based on the known affiliations and ownership of the Amendment 80 vessels, all but one of the Amendment 80 vessel owners are categorized as large entities for the purpose of the RFA. Thus, this analysis estimates that only one small entity will be directly regulated by the final rule. This one small entity could be linked by company affiliation to a large entity, which then could qualify the entity as large entity. Complete information, however, is not available to determine any such linkages.

Recordkeeping and Reporting

This action is projected to have a de minimis impact on the recordkeeping and reporting requirements of small entities participating in the BSAI groundfish fisheries. Some recordkeeping and reporting may be required of individual firms. Those firms that already record and report catch data will likely not be significantly impacted by this final action. It is not possible to determine which firms will be most impacted by the requirements, since the information each firm collects is based on what it needs to operate its business and the current reporting requirements. The regulations implemented by this final rule are not expected to impact the recordkeeping and reporting requirements for any other entities in the fishery.

Under this action, NMFS will not require the individual owners and operators of Amendment 80 vessels participating in the limited access fishery to annually report groundfish retention performance. Instead, NMFS will prepare retention estimates for each vessel in the limited access fishery and present these data to the Council annually as part of the inseason management report.

Description of Significant Alternatives to the Final Rule

The suite of potential actions included two alternatives. A detailed description of these alternatives is provided in Section 2 of the analysis for this action (see **ADDRESSES**). Alternative 1 is the ''no action'' alternative. Alternative 1 does not address the unintended and unforeseen burden of the GRS on directly regulated small entities and is not consistent with the purpose and need of this action.

The Council's preferred alternative, Alternative 2, has been selected as the action alternative. It removes the GRS from the GRS program for the Amendment 80 sector. Removal of the GRS will result in significant operational benefits and cost savings to all directly regulated entities. An Amendment 80 cooperative will monitor the cooperative's aggregate groundfish retention rate and will report its annual groundfish retention performance to NMFS, avoiding mandatory compliance standards and their associated costs.

The Council also considered an alternative to revise the GRS to require groundfish retention at rates similar to the estimates presented in the analysis prepared for the GRS program. The Council determined that, while revising the GRS could reduce economic hardship imposed on the Amendment 80 sector by more closely correlating groundfish retention rates with historical retention rates, it would not address the monitoring, enforcement, and prosecution issues that arise from the requirements for annual determination of vessel compliance with the GRS program. Because this alternative would not resolve the problems for the program, the Council decided not to forward this alternative in the analysis for the proposed action.

Based upon the best available scientific data and information, and consideration of the objectives of this action, there are no alternatives to the proposed action that have the potential to accomplish the stated objectives of the MSA and any other applicable statutes and that have the potential to minimize any significant adverse economic impact of the proposed rule on directly regulated small entities. The preferred alternative provides greater economic benefits for participants than Alternative 1 by allowing participants to maintain or improve the retention rates achieved under the GRS without the compliance costs associated with meeting a retention standard greater than that intended by the Council or NMFS. The lack of any quantitative data makes it impossible to rigorously assess the relative differences in expected economic impacts among the alternatives. The Council chose to recommend, and this final rule implements, the preferred alternative because it best meets the goals of this action and minimizes the potential negative impacts to directly regulated small entities by relieving regulatory requirements that no longer meet the intent of the GRS program.

Collection-of-Information Requirements

This rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) that has been approved by OMB under control number 0648–0565. Public reporting burden for the Amendment 80 cooperative report is estimated to average 26.5 hours per response, which includes a new requirement for an additional third-party audit, estimated to average 1.5 hours per response. These estimated reporting burdens include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate, or any other aspect of this data collection, including suggestions for reducing the burden, to NMFS (see **ADDRESSEES**) and by email to *OIRA_Submission@omb.eop.gov,* or fax to (202) 395–7285.

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.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: February 20, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 679 is amended as follows:

PART 679— FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447

§ 679.2 [Amended]

■ 2. In § 679.2, remove the definition of ''Groundfish Retention Standard (GRS).''

■ 3. In § 679.5, add paragraph (s)(6)(iii)(D) and paragraph (s)(6)(iii)(E) to read as follows:

§ 679.5 Recordkeeping and reporting (R&R).

* * * * *

(s) * * *

(6) * * *

(iii) * * *

(D) For each Amendment 80 cooperative, the percent of groundfish retained by that Amendment 80 cooperative of the aggregate groundfish retained by all Amendment 80 vessels assigned to that Amendment 80 cooperative using the following equations:

$$GFroundweight = \sum_{n}^{n} (PWspecies_n / PRRspecies_n)$$

Substituting the value for *GFroundweight* into the following equation:

GFR% = (*GFroundweight* /TotalGF)* 100

Where:

GFroundweight is the total annual round weight equivalent of all retained product weights retained by all Amendment 80 vessels assigned to that Amendment 80 cooperative for each IR/IU groundfish species.

$PWspecies_n$ is the total annual product weight for each groundfish species listed in Table 2a to this part by product type as reported in the vessel's production report for all Amendment 80 vessels assigned to that Amendment 80 cooperative required at § 679.5(e).

$PRRspecies_n$ is the standard product recovery rate for each groundfish species and product combination listed in Table 3 to this part.

GFR% is the groundfish retention percentage for an Amendment 80 cooperative calculated as GFroundweight divided by the total weight of groundfish catch.

TotalGF is the total groundfish round catch weight for all Amendment 80 vessels assigned to that Amendment 80 cooperative as measured by the flow scale measurement, less any non-groundfish, PSC species or groundfish species on prohibited species status under § 679.20.

(E) For each Amendment 80 cooperative, a third party must audit the Amendment 80 cooperative's annual groundfish retention calculations and the Amendment 80 cooperative must include the finding of the third party audit in its Amendment 80 annual cooperative report.

* * * * *

§ 679.7 [Amended]

■ 4. In § 679.7, remove and reserve paragraphs (m) and (o)(4)(iv).

■ 5. In § 679.27,

■ a. Remove and reserve paragraph (j); and

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

§ 679.27 Improved Retention/Improved Utilization Program.

* * * * *

(b) * * *

(4) For catcher/processors not listed in § 679.4(l)(2)(i) using trawl gear in the BSAI, all species listed in Table 2a to this part, except for groundfish in prohibited species status.

* * * * *

■ 6. In § 679.93, revise paragraph (c)(1) to read as follows:

§ 679.93 Amendment 80 Program recordkeeping, permits, monitoring, and catch accounting.

* * * * *

(c) * * *

(1) *Catch weighing.* All catch are weighed on a NMFS-approved scale in compliance with the scale requirements at § 679.28(b). Each haul must be weighed separately, all catch must be made available for sampling by a NMFS-certified observer, and no sorting of catch may take place prior to weighing.

* * * * *

[FR Doc. 2013–04262 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 78, No. 37
Monday, February 25, 2013

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.

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 120 and 121

RIN 3245–AG04

504 and 7(a) Loan Programs Updates

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (''SBA'') has determined that changing conditions in the American economy and persistent high levels of unemployment compel the agency to seek ways to improve access to its two flagship business lending programs: the 504 Loan Program and the 7(a) Loan Program. The purpose of this proposed rulemaking is to reinvigorate these programs as vital tools for creating and preserving American jobs. SBA proposes to strip away regulatory restrictions that detract from the 504 Loan Program's core job creation mission as well as the 7(a) Loan Program's positive job creation impact on the American economy. The 504 Loan Program and 7(a) Loan Program are SBA's two primary business loan programs authorized under the Small Business Investment Act of 1958 and the Small Business Act, respectively. This proposed rule will enhance job creation through increasing eligibility for loans under SBA's business loan programs, including its Microloan Program, and by modifying certain program participant requirements applicable to the 504 Loan Program. In addition, SBA proposes to revise Certified Development Company (CDC) operational requirements to clarify certain existing regulations.

DATES: SBA must receive comments to this proposed rule on or before April 26, 2013.

ADDRESSES: You may submit comments, identified by RIN: 3245–AG04 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: ocareg2013@sba.gov.* Include RIN 3245–AG04 in the subject line of the message.
- *Mail:* Patrick Kelley, Deputy Associate Administrator, Attention: Linda Reilly, Chief, 504 Program Branch, Office of Capital Access, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.
- *Hand Delivery/Courier:* Patrick Kelley, Deputy Associate Administrator, Attention: Linda Reilly, Chief, 504 Program Branch, Office of Capital Access, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416.

SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please submit the information to Patrick Kelley, Deputy Associate Administrator, Attention: Linda Reilly, Chief, 504 Program Branch, Office of Capital Access, U.S. Small Business Administration, 409 Third Street SW., Washington, DC 20416, or send an email to *ocareg2013@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: Linda Reilly, Chief, 504 Program Branch, Office of Financial Assistance, Small Business Administration, 409 3rd Street SW., Washington, DC 20416; telephone 202–205–9949.

SUPPLEMENTARY INFORMATION:

I. Background Information

Executive Order 13563 directs agencies to ensure that regulations are accessible, consistent, written in plain language, and easy to understand in order to foster economic growth and job creation. Executive Order 13563 provides that our regulatory system ''*must* identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends.'' (emphasis added). Executive Order 13563 further provides that ''[t]o facilitate the periodic review of existing significant regulations, agencies shall consider how best to promote *retrospective analysis* of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to *modify, streamline,* expand, or repeal them in accordance with what has been learned.'' (emphasis added). SBA has reviewed its regulations with regard to the loan programs and is proposing a number of amendments and revisions to accomplish this goal.

SBA's primary business loan programs are the 504 Loan Program (the ''504 Loan Program''), authorized pursuant to Title V of the Small Business Investment Act of 1958, 15 U.S.C. 695 *et seq.,* and the 7(a) Loan Program (the ''7(a) Loan Program'') authorized pursuant to Section 7(a) of the Small Business Act, 15 U.S.C. 631 *et seq.* (collectively referred to as the ''504 and 7(a) Loan Programs''). A description of each loan program is set forth below.

A. SBA's 504 Loan Program

The 504 Loan Program is an SBA financing program established to target companies in their growth cycle to create jobs, expand the tax base, and improve American communities. Specifically, the core mission of the 504 Loan Program is to provide long-term fixed asset financing to small businesses for the purchase or improvement of land, buildings, and major equipment purchases, in an effort to facilitate the creation of jobs and local economic development.

Under the 504 Loan Program, loans are made to small business applicants by Certified Development Companies (''CDCs''), which are SBA's community-based partners for providing 504 Loans. With the exception of several for-profit CDCs grandfathered into the 504 Loan Program, a CDC is a nonprofit corporation that promotes economic development within its community through 504 Loans. CDCs are certified and regulated by the SBA, and work with SBA and participating lenders (typically banks) to provide financing to small businesses, which in turn, accomplishes the goal of community economic development. There are over 260 CDCs nationwide each with a defined Area of Operations covering a specific geographic area. The Area of Operation for most CDCs is the state in which they are incorporated.

Transactions under the 504 Loan Program are typically structured with a CDC providing 40% of the total project costs (with SBA's guarantee assistance),

a participating lender covering up to 50% of the total project costs, and the borrower contributing 10% of the project costs. Under certain circumstances, a borrower may be required to contribute up to 20% of the total project costs.

In sum, the 504 Loan Program is an economic development tool and its success is measured, in large part, by the number of jobs it preserves and creates. In FY 2012, the agency made 7,047 loans through the 504 Loan Program, for a total volume of $4.4 billion, which led to the creation and/or retention of almost 80,000 jobs. SBA estimates that the proposed regulation revisions, set forth in detail below, will result in approximately 140,000 additional jobs created/retained over a five-year period. These additional jobs created/retained are based on an estimated 47,000 loans being made between FY 2013 and FY 2017, with an estimated total dollar volume of almost $30 billion and the creation/retention of over 500,000 jobs over the five-year period. The changes proposed primarily with regard to the Personal Resources Test and affiliation will increase the number of eligible borrowers.

B. SBA's 7(a) Loan Program

The 7(a) Loan Program's main purpose is to help eligible small businesses obtain credit when they cannot obtain ''credit elsewhere.'' In addition, the agency recognizes that the 7(a) Loan Program is also an important engine for job creation. The 7(a) Loan Program provides financing for general business purposes through the agency's guaranty of a loan made by an approved lender. Currently, there are approximately 4,500 lenders participating in the 7(a) Loan Program.

Below is a summary of the proposed changes to these business loan programs. The agency requests comments on all of the proposed regulatory revisions in this proposed rule, and on any related issues affecting the 7(a) Loan Program or the 504 Loan Program. SBA's intent is to revitalize the use of both loan programs as an engine of job retention and growth in an effort to use ''the best, most innovative, and least burdensome tools for achieving regulatory ends * * * and seek to improve, the actual results of regulatory requirements'' in accordance with Executive Order 13563.

II. Summary of Proposed Business Loan Program Changes

Though SBA's business loan programs differ in mission and focus, these loan programs share fundamental eligibility criteria and overlapping objectives. The goal of the proposed rule is to reinvigorate the business loan programs by eliminating unnecessary compliance burdens and loan eligibility restrictions in an effort to make necessary adjustments to increase lender accessibility without sacrificing program integrity. The major changes that SBA is proposing are described below, including changes relating to affiliation principles, the personal resources test, the 9-month rule for the 504 Loan Program, and CDC operational and organizational requirements. Additional changes are described in the section-by-section analysis.

A. Affiliation as Applied to the Business Loan Programs

Under SBA's regulations, applicants for an SBA loan must be small under SBA's size requirements (including affiliates) to be eligible for an SBA business loan. 13 CFR 120.100. When an entity is determined to be affiliated with an applicant, the entity's receipts and employees are added to those of the applicant for purposes of determining its size. Thus, certain businesses are deemed to be ineligible for assistance because they are not deemed to be ''small'' for program purposes by virtue of their combined size with affiliated entities.

SBA's regulations, at § 121.103, set forth the agency's principles of affiliation. Generally, affiliation exists when one business controls or has the power to control another or when a third party (or parties) controls or has the power to control both businesses. Control may arise through ownership, management, or other relationships or interactions between the parties. Affiliation is an important issue when determining size because SBA counts the receipts, employees, or other measure of the business, for all of a small business' domestic and foreign affiliates, regardless of whether the affiliates are organized for profit (13 CFR 121.103(a)(6)). SBA's affiliation rules generally apply to all Federal programs for which a business must qualify as ''small,'' including SBA's Government Contracting or Business Development programs, business loan programs and grant programs. Therefore, applicants for financing under the 504 Loan Program, 7(a) Loan Program or Microloan Program must qualify as ''small businesses'' taking into consideration the employees, receipts, and other measures of business of the applicant and all of the applicant's affiliates.

SBA believes that, in general, most of the principles of affiliation set forth in § 121.103 appropriately apply to the agency's business loan programs. However, SBA believes that certain affiliation principles—such as those concerning newly organized concerns—are not applicable to the 504 and 7(a) Loan Programs or the Microloan Program because assisting in the creation of new small businesses serves the purpose of the business loan programs. In addition, SBA is seeking to create a simple, bright-line test for business loan program applicants when determining eligibility with respect to size and affiliation. By eliminating or modifying certain affiliation principles, this proposed rule would also significantly reduce the burden on applicants of providing affiliation documentation. As described below, SBA is proposing to add a new § 121.302 to identify the principles of affiliation that should apply to the business loan programs in place of the affiliation principles set forth in § 121.103, and invites comments on these proposed changes.

With respect to determining affiliation based on ownership, the following principles *currently* apply to the business loan programs: (1) If the business concern's stock is widely held and no single block of stock is large as compared to others, the board of directors and Chief Executive Officer or President is deemed to have the power to control the business, absent evidence showing otherwise; (2) if two or more persons (including any individual, concern or other entity) each owns, controls or has the power to control less than 50% of the concern's voting stock, and the blocks of stock are equal or approximately equal in size and the blocks of stock are large in the aggregate as compared with any other stock holding, SBA presumes that each person controls or has the power to control the business concern whose size is at issue; or (3) if a person (including any individual, concern or other entity) owns, or has the power to control, 50 percent or more of a concern's voting stock, or a block of voting stock which is large compared to other outstanding blocks of voting stock, such person controls or has the power to control the business concern. It is also important to note that SBA's current affiliation rules (§ 121.103(a)(3)) may find affiliation based on ''affirmative control'' (e.g., owning more than 50% of the voting stock of a company) as well as ''negative control'' (e.g., owning less than 50% but still having the ability to block votes).

SBA is proposing to amend the principles described above for affiliation based on ownership in a manner similar to changes recently proposed by SBA for the Small Business Innovation Research

and Small Business Technology Transfer programs (77 FR 28520, May 15, 2012). Under these proposed changes, SBA would deem the Chief Executive Officer (CEO) or President of the concern (or other officers, managing members, partners, or directors who control the management of the concern) to control the concern when no one person owns or has the power to control more than 50% of the voting equity of the concern. SBA believes that for purposes of the agency's business loan programs, control in this situation would rest with the managing parties identified above since it is those parties that are truly running the concern. If one person does own or has the power to control more than 50% of the voting equity of the concern, that person is in control of the concern for purposes of determining affiliation. In addition, if two or more persons collectively own or have the power to control more than 50% of the voting equity of two or more concerns (the ''collective owners''), then there would be affiliation between such concerns and between each concern and each collective owner. In addition, in this proposed rule, SBA refers to 50% ownership or equity without designating that it is ''stock'' ownership because not all business loan applicants are corporations with ownership determined through stock issuance. SBA is also proposing to not consider ''negative control,'' by itself, as a factor in determining affiliation.

SBA requests comments on this proposed rule as it relates to business loan applicants where no person owns a majority of the applicant, and whether SBA should: (1) Retain the current affiliation rule with respect to minority holdings and, if so, whether it should set forth a specific threshold by which it will find control and therefore affiliation (e.g., if a person owns 33% or more of the company) in order to create a bright-line test for applicants; (2) find affiliation, as proposed, if two or more persons or concerns collectively own more than 50% of the applicant, and the same persons or concerns collectively own more than 50% of any other company or entity; or (3) implement a rule setting forth both options (1) and (2) above.

In addition to incorporating the above principles of affiliation based on ownership, SBA is proposing to incorporate in § 121.302(c) and (e), respectively, the existing affiliation principles currently contained in § 121.103(c) (Affiliation arising under stock options, convertible securities, and agreements to merge) and § 121.103(i) (Affiliation based on franchise and license agreements). SBA is also proposing to incorporate in § 121.302(d), with slight modifications, the existing affiliation principles currently contained in § 121.103(e) (Affiliation based on common management).

In addition to the above proposed change, SBA proposes changing current affiliation principles relating to the following three areas: identity of interest; newly organized concerns; and joint ventures. First, with respect to affiliation based on identity of interest, SBA proposes to not apply the current affiliation principle relating to identity of interest set forth in § 121.103(f) to the 504 Loan Program, the 7(a) Loan Program or the Microloan Program. Affiliation through identity of interest often is found between business partners, family members, and employers. SBA is aware that an applicant may have relationships with former employers, business partners, friends, or family members which can be important to the business success of the applicant. These relationships often strengthen the creditworthiness of the applicant by providing the applicant with more resources from which to draw, thus lowering taxpayer risk while increasing the job creation and small business growth missions of the business loan programs. It is the agency's view that these relationships are common and, in the context of the business loan programs, should not prevent an applicant from independently operating and growing a business and creating jobs. Moreover, small businesses would have less of a financial incentive to use family members or former employees as business ''fronts'' to obtain a business loan than to obtain a grant or bid on a contract under a government set-aside program. Businesses would appear to have little incentive to incur debt through the use of such tactics because, unlike a grant or contract, the debt must eventually be repaid. Weighing all of these factors, the agency proposes to end application of the identity of interest affiliation rule to the business loan programs; however, it strongly encourages comment on this proposal especially as it relates to potential threats to business loan program integrity.

Second, with respect to affiliation based on a newly organized concern, SBA proposes to not apply the current affiliation principle relating to newly organized concerns set forth in § 121.103(g) to the 504 Loan Program, the 7(a) Loan Program or the Microloan Program. The agency proposes this change for substantially the same reasons it is proposing the change related to identity of ownership discussed above. If employees of a former employer form a new business and the former employer does not have ownership control of the new business, SBA believes that for purposes of the business loan programs the former employees will generally have sufficient independence and control of the newly formed business to not be affiliated with the former employer. The newly organized concern principle is needed in the agency's grant and contracting programs to prevent large companies from misrepresenting themselves as small through a shell company in order to obtain a grant or lucrative government contract intended as a small business set aside. However, the principle is not necessary in the business loan programs because larger companies have greater access to private sector capital sources than small businesses and would have little need to form a new concern to obtain a government loan. Thus, the agency is proposing to exempt agency business loan program applicants from application of the affiliation based on newly organized concern rule.

Finally, with respect to affiliation based on joint ventures, SBA proposes to not apply the current affiliation principle relating to affiliation based on joint ventures set forth in § 121.103(h) to the 504 Loan Program, the 7(a) Loan Program or the Microloan Program. Agency records indicate that applicants for assistance under agency business loan programs are rarely, if ever, joint ventures and, therefore, this provision is unnecessary for the business loan programs. This proposed change is being made in the interest of streamlining and simplifying business loan program rules, and to provide bright line eligibility criteria regarding affiliation determinations for the business loan programs.

In conjunction with proposing the above revisions to 504 Loan Program regulations to expand program accessibility, streamline complicated processes, and minimize burdens to applicants and lenders, SBA seeks to ensure program integrity and maintain proper oversight through the following means. First, to assist in ensuring compliance with the affiliation principles, SBA proposes to require applicants to sign an affidavit certifying that all persons affiliated with the applicant have been identified in the affidavit. It is the agency's view that applicants are expected to know and disclose these persons and requiring this disclosure under sworn statement to the Federal government should deter applicants from omitting important

information necessary for determining compliance with the applicable size requirements. An affidavit on affiliate certifications would enable participant lenders to improve consistency and would also expedite SBA's review of the size eligibility of potential applicants. Completing the affidavit to document affiliated business owners of 50% or less would be less burdensome on applicants than having to submit tax documents or financial statements. In fact, SBA estimates that the proposed revision would reduce the burden on participants in both loan programs (both borrowers and lenders) by a total of 26,402 hours and result in savings totaling $700,777. Based on estimates using FY 2012 loan approvals as a base, the annual savings to borrowers for both programs combined is estimated at $700,000 and $750,000 annually. Similarly, SBA estimates that the proposed revision will reduce burden to the government by a total of 2,666 hours and result in savings totaling $78,085. Based on estimates using FY 2012 approvals as a base, this burden reduction in loan review time combined for both loan programs, is estimated at between $80,000 and $100,000 annually. Thus, not only would the affidavit on affiliates be a control mechanism to ensure against abuse of SBA's guaranty and simplify and reduce potential mistakes in size standard decisions, but it would also be a critical time and cost saving measure, as demonstrated by the above data.

Second, and notwithstanding the agency's goal to provide bright line eligibility criteria regarding affiliation determinations for the business loan programs, the agency realizes that egregious cases of large entities benefiting from a small business loan program can threaten program integrity and public support. Thus, the agency proposes to add a provision applicable only to the business loan programs which would give the agency the discretion to prevent business loan program participation of an applicant if, after consideration of the totality of the circumstances, it determines that affiliation exists rendering the applicant ineligible, even when no single factor is sufficient to constitute affiliation. For example, a finding of affiliation may be appropriate if an applicant lists a minor child as a majority owner and CEO of a concern, but a parent of the child actually owns or has the power to control the business. The Agency would look beyond the fiction of the child's ownership and position to determine who actually controls the business, and consider the affiliates of the party in control.

The agency does not expect to use this discretionary provision often and intends to apply it only in egregious cases, one being the example identified above, that might threaten business loan program integrity or viability. SBA encourages comments and suggestions regarding this proposal and, specifically, regarding additional standards to prevent loans to ineligible applicants, which could endanger the viability of the loan programs.

In sum, the elimination of unnecessary affiliation tests from the business loan programs would expand program eligibility to independently owned and controlled small businesses that would have previously been considered ineligible. This is illustrated by the fact that the SBA 504 loan program has not exhausted its program authority in the last 6 years. From 2006 through 2011, approximately 32% of authorized funds have gone unused. In 2012, SBA had left unused 41% of its 504 loan program authorized funds. Therefore, SBA recognizes the need to expand access to the program to more small businesses.

Moreover, as a result, this proposed change would also significantly reduce the excessive burden that is imposed on all eligible small businesses and participating lenders to provide documentation for numerous affiliates to make size evaluations. Under the current regulations for both loan programs, SBA estimates that borrowers and lenders expend $7,274,657 and spend 274,448 hours on providing the documentation for numerous affiliates for SBA to make size determinations. Under the proposed revisions, the SBA estimates that lenders and borrowers would expend $6,573,880 and spend 248,046 hours on providing the necessary documents to SBA. Along those same lines, under current regulations, SBA estimates that the Agency expends approximately $1,567,246 and 53,549 hours on reviewing all of the documents in making size eligibility determinations. Under the proposed revisions, the SBA estimates expending $1,489,161 and 50,883 hours on reviewing the necessary documents.

By mitigating the burdens imposed by the current regulations and streamlining processes, the proposed rule would expand eligibility for the 504 and 7(a) Loan Programs, as well as SBA's Microloan Program authorized under section 7(m) of the Small Business Act (the ''Microloan Program''), by redefining the permitted affiliations for borrowers for purposes of determining the applicant's size, but balancing that expansion by requiring an affidavit as to ownership and including a discretionary provision allowing the SBA to analyze the ''totality of the circumstances'' in egregious cases.

B. The Personal Resources Test

An applicant is ineligible for financing under the agency's business loan programs if it can obtain credit elsewhere. A brief history surrounding the current regulation is instructive here. The initial version of Section 7(a) of the Small Business Act authorized SBA to make loans to small businesses with the restriction that ''no financial assistance shall be extended * * * unless the financial assistance applied for is not otherwise available on reasonable terms.'' (Pub. L. 85–536, 72 Stat 388 (1958)). During the initial implementation of the 7(a) Loan Program in 1958, the agency interpreted the financial resources test to include the requirement that the funds applied for by the applicant ''not appear to be obtainable without undue hardship through utilization of the personal credit or resources of the owner, partners, management, or principal shareholders of the applicant.'' (23 FR 10513, December 31, 1958). Thus, the agency required documentation that obtaining the needed financing through use of personal credit or personal resources would create undue hardship before the applicant would be eligible for agency assisted financing.

As early as 1971, the agency received feedback from the U.S. General Accounting Office that loans or guarantees were being made on behalf of applicants in greater amounts than were necessary considering the personal credit and personal resources of those applicants. The recommendation at that time was that the agency create criteria that would specify to agency loan specialists when a loan should be disapproved or agency participation reduced because the personal resources or credit of principals were substantial enough to be used without undue hardship of the principals.

In response, SBA began to provide strict criteria including procedures for ''careful review'' of any person with 20% ownership in the company or engaged in active management of the company (and in tandem excusing from review persons with less than 5% ownership interest in the applicant with no active management role with the applicant). Still, there was no bright-line established for what would presumptively constitute an ''undue hardship'' or what contribution of personal resources was appropriate. For

example, in the agency's standard operating procedures effective in 1985, guidance to loan specialists for the 7(a) Loan Program stated that ''reasonable utilization of personal assets'' of applicant principals applied to each principal's family as well, with exemptions for cash surrender of life insurance and IRAs, reasonable education expenses, and an additional exemption for each family equal to $50,000 or 25% of the loan amount, whichever was greater. (SBA SOP 50 10 2A (page 38, effective September 16, 1985) (available upon request.)) There was also guidance regarding the requirement that certain family real estate could be counted as personal resources to be used in lieu of program assistance (e.g., ''refinancing or sale of real estate may be considered when a principal owner has funds readily available through sale or refinancing that would provide a *majority* of the loan request'' though owner occupied residences were generally exempted and there was an exemption when ''these general rules appear to work as a hardship due to the circumstances of the individual case.'') (SBA SOP 50 10 2A (page 39, effective September 16, 1985) (available upon request.)) This history demonstrates the difficulty the agency had in establishing clear standards for determining when the use of personal resources would create undue hardship to the principals of a business. In 1996, the agency revised its regulations in an effort to create a more objective standard by quantifying the amount of personal resources that must be injected into the business. (61 FR 3226, January 31, 1996)

While there have been numerous amendments to Section 7(a), the credit elsewhere restriction has remained, with slight modifications. For instance, the phrase ''credit elsewhere'' was introduced in 1981 when the provision was changed to read that ''[n]o financial assistance shall be extended pursuant to this subsection if the applicant can obtain credit elsewhere.'' (The Small Business Budget Reconciliation and Loan Consolidation/Improvement Act of 1981, Pub. L. 97–35, title XIX, section 1902, 95 Stat. 767 (1981)). A definition for ''credit elsewhere'' was added at the same time. Section 3(h) of the Small Business Act defines ''credit elsewhere'' as the ''availability of credit from non-Federal sources on reasonable terms and conditions taking into consideration the prevailing rates and terms in the community in or near where the concern transacts business, or the homeowner resides, for similar purposes and periods of time.'' 15 U.S.C. 632(h).

Similarly, for the 504 Loan Program, section 503(b)(2) of the Small Business Investment Act of 1958 authorizes financing of applicants only when ''necessary funds for making such loans are not available to such companies from private sources on reasonable terms.'' Historically, to meet this requirement, the agency verified that private financing on reasonable terms was not available to the 504 applicant, but did not require a review of the personal resources of the applicant's principals and owners. As late as 1993, the agency issued standard operating procedures that instructed loan specialists that the availability of personal resources would not usually disqualify an applicant from receiving assistance under the 504 Loan Program because the primary focus of that program was economic development (job creation). (SBA SOP 50 22 3A (page 58, effective December 30, 1993) (available upon request)). In 1995, however, SBA published proposed regulations explaining that the agency had come to the conclusion that ''there is no difference between the business loan programs regarding evidence of need [and that] SBA will consider the personal wealth and resources of the principals and owners in determining an applicant's need for SBA financial assistance in all business loan programs, and SBA may require the principals and owners of the applicant to use their personal resources before SBA will grant financial assistance'' (60 FR 64362, December 15, 1995). This change was adopted as final in 1996, and the 504 Loan Program was made subject to the same personal resources test as the 7(a) Loan Program. (61 FR 3226, January 31, 1996).

Under the current personal resources test for the 7(a) and 504 Loan Programs, an assessment is required of the liquid assets of each owner of 20 percent or more of the equity of the applicant company to determine the overall dollar value of personal resources that do not have to be injected into the business (referred to as the ''exemption''). The current allowable exemption is determined on the basis of the ''total financing package.'' The total financing package includes any SBA loans, together with any other loans, equity injection, or business funds used or arranged for at the same general time for the same project as the SBA loan. If the total financing package:

- Is $250,000 or less, the exemption is two times the total financing package or $100,000, whichever is greater;
- Is between $250,001 and $500,000, the exemption is one and one-half times the total financing package or $500,000, whichever is greater; or
- Exceeds $500,000, the exemption equals the total financing package or $750,000, whichever is greater.

Once the exemption is determined, it is subtracted from the liquid assets. If the result is positive, that amount must be injected into the project.

The agency is proposing to eliminate this personal resources test from the regulations. SBA has become concerned, that even borrowers whose principals have significant personal resources may be unable to obtain long-term fixed asset financing from private sources at reasonable rates. The agency is now questioning whether the existence of personal resources directly correlates to the ability to obtain commercial credit on reasonable terms and is, therefore, rethinking the appropriateness of using personal resources as an indirect means of determining whether credit is available from private sources. The agency believes it is part of the agency's core mission regarding the assistance of small businesses to increase access to capital and that a personal resource test does not promote access to capital as it unnecessarily restricts the pool of potential investors for small businesses that participate in both loan programs. The agency notes that if the personal resources test is eliminated, more robust borrowers will be eligible to participate in the 504 and 7(a) Loan Programs, The agency is proposing to eliminate this personal resources test from the regulations thereby mitigating risk to the agency's portfolio of loans while facilitating job growth. Based on the agency's records, the number of loan approvals dropped by 42% in 1997, the year after the personal resource test was first instituted for the 504 Loan Program. As the recession has limited access to capital, eliminating the personal resource test would assist small businesses in attracting more types of investors.

For reasons set forth above, the agency believes that the core business loan program missions, including the core job creation mission of the 504 Loan Program (15 U.S.C. 695) and the small business credit support mission of the 7(a) Loan Program (15 U.S.C. 636), would best be served by focusing on the statutory requirement regarding the availability of credit on reasonable terms without attempting to document and enforce precise determinations regarding the appropriateness of personal resource contributions. The agency is therefore proposing to

eliminate the personal resources test from the regulations for both loan programs.

The agency continues to believe, however, that the personal resources of the applicant should be taken into consideration in determining what equity injection, if any, should be required of the applicant's principals and owners. Prudent lending includes a determination that the business is adequately capitalized and, if not, that available personal resources be injected into the business. In addition, it is important to note that agency regulations require that persons with a 20% or more ownership interest in an applicant guarantee a business loan program financing (and other persons may also be required to provide personal guarantees). This means that if such guarantors have substantial personal resources, those resources will conditionally support the financing.

SBA invites comments on this specific issue and on the general issue of whether a personal resources test should be retained and, if so, in what form.

C. The ''9-Month Rule'' (applies to 504 Loan Program Only)

Under current 504 Loan Program regulations, § 120.882(a) permits financing of expenses toward a project only if they were incurred ''within nine months prior to receipt by SBA of a complete loan application, unless the time limit is extended or waived by SBA for good cause.'' SBA proposes to eliminate this nine month limitation and permit financings of expenses toward a project regardless of when they were incurred. Some general context related to this proposed revision follows.

Refinancing of debt unrelated to the 504 project is currently allowed in the 504 Loan Program only pursuant to statutorily limited circumstances as set forth in § 120.882(e) and (g). There are, however, circumstances when an applicant might incur short term debt to cover expenses directly attributable to a larger project that is eligible for financing under the 504 Loan Program. This is particularly true when building construction is part of the project. Acquisition of a building, and particularly the decision to construct from the ground-up, is the result of planning over months, if not years. Diligent small business owners approach the process in a series of steps based upon what is affordable and how the business is performing. Financing for these initial expenditures also is determined by what is cost-effective for the business. In such cases, the agency has under certain conditions allowed those expenses/debts to be included as part of a 504 Loan Program project. What follows is a short summary of the relevant history of how those conditions evolved under the program to its current criteria.

On July 5, 1985 (50 FR 27754), SBA proposed § 108.503–5(d), which allowed financing of expenditures made in anticipation of a financing under the 504 Loan Program if, among other conditions, the applicant filed a written notice to SBA within 60 days after the expenditure.

On June 6, 1986 (51 FR 20764), SBA finalized the above rule and, in response to comments, added that previously acquired land should be eligible to be included in project costs without regard to the timing of the acquisition. It was added as § 108.503–5(d)(2) and the rule above became (d)(1).

On January 31, 1996 (61 FR 3226), SBA published final regulations which essentially re-wrote the loan program regulations and in the process added what is now referred to as the ''9-month rule'' providing the following explanation in the preamble:

> ''§ 120.882. In the current regulations, costs incurred by a Borrower in anticipation of receiving a 504 loan are not eligible to be included in Project costs unless the applicant has filed a written notice with the CDC and SBA within 60 days of incurring the expense and SBA gives written approval. As a result, CDCs and SBA receive notices from many potential borrowers considering 504 financing who desire to maximize potential financing. Many of these businesses never actually apply or their applications are denied. In those cases, the written notices are a useless paperwork burden on SBA, the CDC and the applicant. Therefore, SBA proposed in § 120.882(a)(2) to eliminate the requirement for written notice and allow as an eligible Project cost any expense incurred toward a Project within six months of receipt by SBA of a complete loan application.
>
> SBA received 16 comments opposing the 6 month limit. Commenters pointed out that in actual practice the time it takes to reach the point of application is often far greater than 6 months. In many metropolitan areas, the zoning use permits, building permits, and other clearances can take 9 to 12 months. Often engineering plans and architectural drawings may need to be completed or redone, and lengthy environmental studies may be required. In states like Minnesota with long winters, the delay between site preparations and construction may span more than 6 months.
>
> The intent of the proposed rule was to alleviate unnecessary paperwork. It was not intended to limit eligible costs. Therefore, SBA increases the limit in this final rule to 9 months and adopts a comment suggesting a waiver of the limit by the SBA District Office for good cause, which waiver should not be unreasonably withheld.'' (61 FR 3226 at 3233, (January 31, 1996)).

In practice, exceptions to the 9-month rule have been granted regularly because, generally speaking, the date the expense was incurred is a poor indicator as to whether the expense was directly attributable to the applicant's 504 project. For example, because of the weak economy, many businesses' expansion plans have been delayed or placed on hold. Now, in the post-recession recovery period, many small business owners are preparing to resume their plans only to discover that expenditures already made, or the method of financing those expenditures, results in those costs not being eligible for 504 financing. As a result, SBA receives about 6–8 rule exceptions requests on a weekly basis, for an approximate total of 312–416 such requests yearly. Out of those requests, SBA declines only 1–2 per week, for an approximate total of 52–100 denials yearly. Based on these estimates, in the last five years, SBA has declined about 19% of rule exception requests, while approving approximately 81% of such requests. This data confirms the agency's belief that determining whether an expense has been incurred by an applicant for a 504 project requires a fact specific analysis which appropriate agency personnel need to make regardless of when the expense was incurred. As it relates to loan processing, the agency will continue to review any expense that was incurred prior to the date of application to ensure that it is ''directly attributable'' to the project. Based on SBA's experience in the application of the 9-month rule and having, for the most part, approved requests from applicants that SBA make an exception to this policy, the agency believes that the 9-month restriction can and should be eliminated from the regulations.

D. CDC Operational and Organizational Requirements

SBA also proposes to revise regulations dealing with corporate governance including eliminating the requirement for CDC membership and emphasizing the responsibility of the board of directors. A detailed discussion of these proposed changes can be found in the section-by-section analysis below.

E. Other Changes

The proposed rule would make other technical corrections and changes resulting in simplification of some regulations for both the 504 Loan Program and the 7(a) Loan Program, and a discussion of these proposed changes can be found in the section-by-section analysis.

II. Section-by-Section Analysis

Section 120.102 Funds not available from alternative sources, including personal resources of principals. SBA proposes to remove this regulation regarding the availability of personal assets of the principals of the Borrower. For the reasons described above under Background Information, SBA has determined that in order to better serve the small business community and economic development, the regulation should be removed for both the 504 Loan Program and the 7(a) Loan Program.

Section 120.816 CDC nonprofit status and good standing. SBA proposes to redesignate the current § 120.820 as a new § 120.816. The content would remain unchanged.

Section 120.818 Applicability to existing For-Profit CDCs. SBA proposes to add this new section to clarify that, unless expressly provided otherwise in the regulations, any Loan Program Requirement that applies to non-profit CDCs also applies to for-profit CDCs. This proposed change reflects current SBA practice.

Section 120.820 CDC Affiliation. SBA proposes to substitute the current § 120.820 with a new § 120.820 that sets forth requirements regarding CDC affiliations. In paragraph (a), SBA proposes to require that a CDC be independent and not be affiliated with any Person (as defined in § 120.10) except as permitted under this section. In paragraph (b), SBA proposes to permit CDCs to be affiliated with non-profit economic development entities or State and local government political subdivisions (e.g., councils of government). In paragraph (c), SBA proposes to permit a CDC to continue to be affiliated with a 7(a) Lender if: (1) the affiliation was in effect as of the effective date of this regulation; and (2) the 7(a) Lender is either a state development company approved by SBA as of November 6, 2003, or a credit union. This proposed change will permit the continuation of existing relationships between CDCs and 7(a) Lenders that are credit unions or state development companies, but does not permit the creation of such relationships going forward. In paragraph (d), consistent with current policy, SBA proposes adding a provision prohibiting one CDC from affiliating with or investing in or financing, directly or indirectly, another CDC.

Section 120.822 Membership. Currently, this section requires CDCs to have at least 25 members or stockholders, and also sets forth membership group requirements. SBA proposes to eliminate the requirement that a CDC have membership. Now that CDCs currently have authority to loan in a statewide (or multistate) area, the local membership board does not have the same impact as when CDCs represented a smaller service area. Maintaining both membership and a Board of Directors places an unnecessary burden on CDCs. Lessening this burden may encourage more entities to become CDCs, resulting in an expansion of the program and loans to small businesses. A CDC may continue to have membership but it is no longer an SBA requirement. Instead, SBA is emphasizing the responsibilities and duties of the CDC Board of Directors in the following section. Accordingly, SBA is proposing to remove § 120.822 from the regulations.

Section 120.823 CDC Board of Directors. In paragraph (a), SBA proposes to revise the regulations to emphasize the authority and the responsibilities of the CDC Board of Directors. The proposed regulation provides that the initial board may be created as permitted by state law. It also outlines proposed requirements for the directors' backgrounds and areas of expertise. SBA proposes adding a requirement that the Board size shall be not less than 11 voting directors and not more than 25. SBA recommends that CDCs have an odd number of Directors to avoid tie votes, which is consistent with best practices of Boards generally. SBA has based this revision upon an extensive review of the average size of non-profit boards, not limited to CDCs, which typically ranges from 7–15 Board members. Based upon the mission and responsibilities of CDCs and the average size for both for-profit and non-profit CDCs in the 504 Loan Program, however, SBA is proposing a range of 11–25 Board members. While SBA supports limiting the number of directors on the Board for efficiency of operations, the agency also understands that an important function of the Board is to provide representation for the communities served by the CDC. Having an upper limit of 25 directors for the CDC Board would provide CDCs with the opportunity to convert existing membership (currently set at a minimum of 25) to directors if they choose to do so. To increase community representation, the CDC would still have the option to have a membership to which the CDC may admit as many members as it deems appropriate.

The Agency lists several proposed areas of expertise that it believes are essential to the successful operation of the CDC Board. SBA proposes to require that a CDC have, at a minimum, one director that is a representative from the economic, community or workforce development field and two directors that are representatives from the commercial lending field. This proposed change is intended to expand the pool of potential directors and to encourage more diversity and expertise on the Board. Retired individuals may represent the fields from which they retired, as the Agency recognizes the value of their knowledge and experience.

Paragraph (b) regarding commercial lending experience is language from the existing regulation except that SBA proposes to increase the minimum number of voting directors on the Board with commercial lending experience from one to two. Further, at least two directors with commercial lending experience must be present and vote when the Board is acting on SBA approvals or servicing actions. SBA believes that this requirement is prudent now that the maximum loan amount has been increased to $5,000,000 and, in some cases, $5,500,000.

Paragraph (c) outlines the proposed minimum requirements for Board meetings and explicitly establishes the Board's responsibilities for the actions of the CDC, its staff, and any committees established by the Board of Directors. The requirement in subparagraph (c)(1) does not reflect any changes to the current regulations. To ensure effective operation and oversight of the CDC by the Board, and to encourage maximum involvement by each Director, the Agency proposes requiring that a quorum of not less than 50% of the Board be present to conduct all business. Non-voting directors will not be included for the purposes of establishing a quorum. SBA is aware that some CDCs were requiring that a quorum be present only to begin a meeting; this practice would not comply with the proposed rule. In subparagraph (c)(3), SBA proposes that meetings may be held in any manner permitted by state law, recognizing that there are methods for meeting other than being physically present. Paragraph (c)(4) proposes to maximize diversity on the Board by limiting representation by commercial lenders to less than 50% of the Board of Directors. Paragraph (c)(5) proposes to limit the ability of an outside entity (including affiliates of that entity) to control the Board by restricting the entity's representation on the CDC Board to one member.

In paragraph (d), SBA proposes to require that the Board be responsible for ensuring that the structure and operation of the CDC, as set forth in the Bylaws, comply with SBA's Loan Program Requirements. In

subparagraphs (d)(1) and (2), SBA proposes to require that the Board be responsible for setting the mission and hiring, firing, supervising and evaluating the CDC manager. To emphasize the fiscal responsibility of the Board as it relates to salaries, subparagraph (d)(3) explicitly outlines the duties of the Board to set salaries for the CDC manager and to review all other salaries to provide greater transparency and accountability. SBA requires that a Report on Compensation be included in the Annual Report (see proposed § 120.830). SBA also proposes in subparagraph (d)(4) to provide the CDC with flexibility in determining whether to have committees, but addresses the requirements for Executive and Loan Committees, if established. Emphasis has been placed on the Board of Directors in this proposed rule. If a Board chooses to have an Executive Committee, then its members must be chosen from the Board as the Agency does not want this authority to be delegated to individuals who are not members of the Board. The Executive Committee must be chosen by and from the Board and meet the same requirements as the Board with the exception that the Executive Committee would be required to have no fewer than 5 voting members, and there must be a quorum of at least 5 voting members to conduct business. The proposed regulations also permit the Board to establish a Loan Committee and outline the requirements as to committee membership selection and background. As is provided in the current rule regarding the Loan Committee, no CDC staff may serve on the Loan Committee. Further, the regulation as proposed defines a quorum as five voting Loan Committee members. Subparagraph (d)(4)(ii)(D) additionally proposes that there be no actual or appearance of a conflict of interest. For example, a member of the Loan Committee must not participate in deliberations on a loan for which the Third Party Lender is the Committee member's employer.

Subparagraph (d)(5), as proposed, requires the Board to ensure that the CDC's expenses are reasonable and customary, and proposed subparagraph (d)(6) requires the Board to hire an independent auditor to ensure compliance with Loan Program Requirements.

The proposed provisions in subparagraphs (d)(7) and (8) emphasize the requirement that the Board monitor the portfolio and review the semiannual status report from the CDC to ensure that the Board provides appropriate oversight of the CDC's portfolio. SBA proposes to add requirements in subparagraph (d)(9) that the Board ensure that the CDC establishes and maintains adequate reserves to enable the CDC to operate.

As provided in current § 120.825, a CDC must invest in its Area of Operations. Subparagraph (d)(10) of § 120.823 proposes to require that the Board approve all investments of over $2,500 and that the CDC manager approve investments of $2,500 or less in order to ensure that the investments constitute appropriate economic development activity and that such investments do not compromise the adequacy of the reserves. Examples of economic development activities could include non-profit activities such as workforce development programs, lending programs or other like activities in the CDC's Area of Operations.

The Agency proposes to require in subparagraph (d)(11) that the Board establish a policy in the Bylaws of the CDC prohibiting an actual or apparent conflict of interest, and enforce such policy. The agency would expect that the policy would provide, among other things, that no director may participate in deliberations on a loan if the director is employed by or is otherwise associated with the Third Party Lender. Subparagraphs (d)(12) and (d)(13), as proposed, express the Board's retention of accountability for all actions of the CDC, and establishes the responsibility for establishing written internal control polices as set forth in § 120.826. SBA proposes to add subparagraph (d)(14) requiring the CDC's Board of Directors to establish commercially reasonable loan approval policies, procedures, and standards. The CDC's credit approval process and delegations of authority, if any, must be set forth in the Bylaws. In addition, the loan must be credit-approved before the application is submitted to SBA. The proposed rule would require that the Board of Directors, or the Executive Committee, if authorized by the Board, provide credit approval for loans greater than $2,000,000 prior to submission to the agency, as SBA believes that it is important that the Board, or Executive Committee, approve these larger loans. However, SBA recognizes that Boards may not meet frequently enough to provide the needed credit approval in a timely manner prior to submission of an application to SBA and that allowing approval of smaller loans by the Loan Committee would present minimal additional risk to the Agency. Therefore, SBA is proposing to allow Boards to delegate authority to the Loan Committee to provide credit approval of: (1) loans of less than $1 million, and (2) loans of $1 million to $2 million subject to ratification by the Board or the Executive Committee prior to debenture closing. SBA invites comment on this proposal. To further emphasize the responsibilities of the Board, in subparagraph (d)(15), SBA proposes an annual certification by all Board members acknowledging their responsibilities.

In paragraph (e), SBA proposes to add the requirement that the Board must maintain directors' and officers' liability and errors and omissions insurance to protect the CDC. The Agency requires at least $5,500,000 for each occurrence and $5,500,000 in the aggregate per year, as well as a deductible of not more than $50,000 for both directors' and officers' liability insurance and errors and omissions insurance. These coverage amounts correspond to the maximum loan amount. SBA invites comment on the amounts of both the insurance and the deductible.

Section 120.830 Reports a CDC must submit. SBA proposes to revise the requirements for reporting by CDCs in order to improve transparency and accountability and for other purposes discussed in this paragraph. In paragraph (a), SBA proposes adding a requirement that copies of Federal tax returns be submitted in the Annual Report to assist the Agency in reducing risk by reviewing the financial condition of the CDC and compensation of CDC employees. The requirements for the audited or reviewed financial statements are set forth in subparagraph (a)(1) and remain unchanged. In addition, as a matter of practice, SBA does not require a CDC to submit an Annual Report for the year in which it was certified if the CDC is certified by SBA within 6 months of its fiscal year-end, and SBA proposes to reflect this practice in the regulations. In subparagraph (a)(2), SBA proposes to add a requirement for an annual compensation report covering all current and former officers and directors receiving compensation during the covered period, and any current and former employees and independent contractors with total compensation of more than $100,000 during the covered period. For this purpose, total compensation includes all compensation, including salary, bonuses and expenses. Additionally, in subparagraph (a)(3), the Agency proposes to require that the annual report include an annual certification by each of the directors that he or she has read and understands the requirements set forth in the proposed § 120.823. In subparagraph (a)(4), SBA is proposing to require that the CDC report on investments in economic development

activities in each State in which the CDC has an outstanding 504 loan. With the exception of the revisions noted above, the reporting requirements for CDCs remain the same.

Section 120.835 Application to expand an Area of Operations. SBA proposes to incorporate subparagraph (c)(1) into paragraph (c) and remove subparagraph (c)(2), which currently requires the CDC to meet the requirements as to membership for each state in a Multi-state expansion, since the proposed revisions to § 120.822 make membership optional.

Section 120.882 Eligible Project costs for 504 loans. SBA proposes to eliminate paragraph (a)(2) of § 120.882, which limits Project expenses eligible for 504 Loan Program financing to those incurred within 9 months prior to receipt by SBA of a complete loan application. (The cost of acquiring land to be used in the Project is not subject to the 9-month restriction.)

For the reasons described above under Background Information, SBA's proposal would permit prior expenses that are directly attributable to the 504 project to be considered eligible project costs regardless of when those expenditures were made. If financing was required for the costs incurred, SBA would determine whether the 504 loan should be made under § 120.882(e) as a 504 project that includes a refinancing component or under § 120.882(a) because the costs are directly attributable to the project.

Section 120.920 Required participation by the Third Party Lender. SBA proposes revising this section to provide that if a Third Party Lender requires collateral in addition to that which the CDC takes, the Third Party Lender, in the event of liquidation, must first apply the proceeds from the sale of the additional collateral to the balance of the Third Party Lender's loan. This marshaling of assets would protect the CDC's position in the Common Collateral (as defined in the proposed revision to this section) and could lead to greater recovery for SBA

Section 120.925 504 Preferences. SBA proposes removing this section, and addressing the concern with respect to the application of the proceeds from additional collateral held by the Third Party Lender in § 120.920 as described above.

Section 121.103 How does SBA determine affiliation? SBA proposes to amend this section to provide that affiliation for 7(a), 504 and microloan loan applicants would be determined under a new § 121.302, as described below, and not under § 121.103.

Section 121.302 What are the standards for determining affiliation for loan applicants?

SBA proposes to redefine ''affiliation'' for the purpose of the business loan programs. Proposed paragraph (a) of § 121.302 contains a statement of general principles of affiliation for business loan applicants and incorporates the exceptions to affiliation set forth in § 121.103(b). Proposed paragraph (b) sets forth the affiliation principles based on ownership. Proposed paragraph (c) describes the effect on affiliation of stock options, convertible securities, and agreements to merge. Proposed paragraph (d) outlines affiliation based upon common management. Proposed paragraph (e) incorporates § 121.103(i) regarding affiliation based on franchise and license agreements. Proposed paragraph (f) requires that each applicant for a 7(a) loan or a 504 loan submit with its application an Affidavit in which discloses all owners of the applicant and the percentage of ownership of each, and any affiliates as determined under this section.

The existing §§ 120.302 through 120.305 are proposed to be redesignated as §§ 120.303 through 120.306, respectively, without any further changes.

Compliance With Executive Orders 13563, 12866, 12988, and 13132, the Paperwork Reduction Act (44 U.S.C., Ch. 35,), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Order 13563 and Executive Order 12866

The Office of Management and Budget (OMB) has determined that this proposed rule is a ''significant'' regulatory action for the purposes of Executive Order 12866. Accordingly, the next section contains SBA's Regulatory Impact Analysis. However, this is not a major rule under the Congressional Review Act, 5 U.S.C. 800.

Regulatory Impact Analysis

1. Is there a need for this regulatory action?

The agency believes it needs to reduce regulatory burdens and expand business loan program access to reinvigorate the programs and facilitate job creation.

2. What are the potential benefits and costs of this regulatory action?

As stated above, the potential benefits of this proposed rule are based on its elimination of unnecessary participation burdens and eligibility criteria. Specifically, the proposed rule would eliminate certain eligibility criteria related to the personal resources of certain people or companies associated with the applicant. It would also exempt the business loan program from certain rules that determine whether an entity is deemed affiliated with an applicant. When an entity is determined to be affiliated with an applicant, then that entity's receipts and employees are added to those of the applicant when determining its size. Thus, certain businesses are deemed to be ineligible for assistance because they are not deemed to be ''small'' for program purposes by virtue of their combined size with affiliated entities. By eliminating unnecessary affiliation tests from the business loan programs, independently owned and controlled small businesses that would otherwise be ineligible for business loan program assistance will become eligible. In addition, the excessive burden related to providing documentation for size evaluation for numerous affiliates now faced by lenders and borrowers would be significantly reduced by the proposed rule.

In the 504 Loan Program, SBA is proposing to eliminate what is commonly referred to as the ''9-month rule''. The 9-month rule essentially states that costs incurred by an applicant that otherwise would be eligible for financing under the 504 Loan Program are presumptively deemed to be ineligible project costs if incurred more than 9 months prior to a complete loan application submitted by an applicant. Also pertaining only to the 504 Loan Program, the proposed rule would revise regulations dealing with corporate governance including eliminating the requirement for CDC membership and emphasizing the responsibility of the board of directors. CDCs participating in the 504 Loan Program would no longer need to maintain a membership, thus eliminating that program participation burden. Requirements for the CDC Board of Directors are clarified and detailed to compensate for the potential loss of oversight that might result from the lack of CDC membership participation. SBA could have allowed CDC Directors to operate without clearly articulated basic standards that are commonly accepted best practices that most CDCs already follow. SBA welcomes comments and suggestions on the benefit of allowing CDC Boards to operate without the basic governance standards and oversight proposed in this rule.

With respect to CDC Board requirements, the agency proposes to establish a minimum quorum of 50% of the Board and to require that the Board set the CDC manager's salary and review

all CDC staff salaries. There are additional operational requirements which are discussed more fully in the section-by-section analysis of this proposed rule. It is the agency's view that these rules basically would codify best practices for CDC Board operation and would not significantly add to the burden of being a responsible CDC director. The agency encourages public comment on the Board requirements, especially with respect to any possible significant economic impact, as well as suggestions regarding how to ensure proper Board operations in a less burdensome way.

Finally, there are miscellaneous proposed revisions which clarify or slightly revise exiting regulations with very minor regulatory impact. For example, consistent with current policy, § 120.818 clarifies that CDC requirements apply to for-profit CDCs. Another example is § 120.830, which the agency believes would allow several CDCs to maintain existing affiliations and still qualify for expanded CDC status without impacting the operational requirements of other CDCs. With respect to any of the proposed revisions relating to CDC operational and organizational requirements, the agency welcomes any comments regarding potentially significant impact on CDC operations and views regarding how the agency can responsibly reduce CDC operational and organizational compliance burdens.

3. What alternatives have been considered?

One ''alternative'' would be to eliminate even more regulatory burdens and the agency enthusiastically encourages public comment and suggestions on how that can be done responsibly without substantially increasing the risk of waste, fraud, or abuse of the programs or otherwise threatening the integrity of the business loan program or taxpayer dollars. With respect to the proposed changes to CDC Board of Director requirements, the agency considered allowing CDC directors to operate with virtually no agency oversight or standards, relying on state non-profit corporation laws and state oversight to ensure proper Board performance. This idea was quickly rejected because SBA's review of actual state oversight of non-profit directors and the applicable state law requirements indicated that state oversight and laws would not provide the parameters and oversight necessary for a Federal loan program that potentially puts billions of taxpayer dollars at risk each year.

Executive Order 13563

A description of the need for this regulatory action and benefits and costs associated with this action, including possible distributional impacts that relate to Executive Order 13563, are included above in the Regulatory Impact Analysis under Executive Order 12866.

The business loan programs operate through the agency's lending partners, which are 7(a) Lenders and CDCs. The agency has held public forums and meetings which allowed it to reach hundreds of its lending partners and gain valuable insight, guidance, and suggestions from many of them and the trade associations which represent many of them. The agency's outreach efforts to engage stakeholders before proposing this rule was extensive.

Executive Order 12988

This action meets applicable standards set forth in Sections 3(a) and 3(b) (2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminates ambiguity, and reduce burden. The action does not have retroactive or preemptive effect.

Executive Order 13132

SBA has determined that this proposed rule will not have substantial, direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, for the purposes of Executive Order 13132, SBA has determined that this proposed rule has no federalism implications warranting preparation of a federalism assessment.

Paperwork Reduction Act, 44 U.S.C., Ch. 35

The SBA has determined that this proposed rule would impose additional reporting and recordkeeping requirements under the Paperwork Reduction Act (PRA), 44 U.S.C. Chapter 35. First, SBA proposes to amend the currently approved CDC Annual Report to require CDCs to report on executive compensation and economic development projects, and to submit a copy of the CDC's tax return. Under the proposed rule, each CDC director must certify that he or she has read and understands the requirements set forth in 13 CFR 120.823.

Second, SBA proposes to require each loan applicant to certify in an Affidavit (the ''Applicant Affidavit on Affiliation'') as to the applicant's affiliation with any other entities. Requiring submission of this Affidavit would significantly reduce the burden on the small businesses and the CDCs as the small businesses applying for a 504 or 7(a) loan would be required to submit certain documentary evidence (e.g., credit reports, financial statements and tax returns) only with respect to their affiliates as defined in the proposed rule. In addition, applicants would be required to identify all owners of the applicant as opposed to each owner of 20% or more interest as is now required only on Form 4, Application for Business Loan.

As a result of these new requirements, SBA proposes to revise the information collections identified below:

1. *Title and Description of Information Collection:* The Certified Development Company (CDC) Annual Report (SBA Form 1253) is the method through which the CDC provides information to SBA on economic development, its financial condition, operations and employment impact. The additional information that would be required to be submitted with the Annual Report is a certification by each CDC director, a report on compensation, and a copy of the CDC's federal tax return. This information collection will also be revised to reflect changes in governance of CDC membership; composition of CDC board of directors and increases to insurance coverage.

OMB Control Number: 3245–0074.

Description of and Estimated Number of Respondents: All CDCs must provide an annual report. Currently there are approximately 260 CDCs. There is 1 form per respondent. SBA has prepared an estimate based on the fact that respondents keep the information requested in the ordinary course of business (all the loan information including jobs created and retained.).

Estimated Number of Responses: 260 (260 CDCs × 1 form per respondent = 260).

Estimated Time per Response: SBA estimates the time needed to complete this collection will average 28 hours.

Total Estimated Hour Burden: 260 × 28 hours = 7,280 total annual burden hours. This is 168 hours less than the current OMB inventory (7,488).

2. *Title and Description of Information Collection:* Applicant Affidavit on Affiliation as to applicant's affiliation with any other entities. This new information collection, as described above, will be submitted with the following applications:

(i) Application for Section 504 Loan (SBA Form 1244).

OMB Control Number: 3245–0071

Description of and Estimated Number of Respondents: The Applicant would execute this Affidavit which would be part of exhibit 12 to SBA Form 1244.

Based upon FY 2011 loan totals, SBA estimates that 6,800 respondents will complete the Affidavit annually (4,625 ASM submission + 2,75 standard submissions = 6,800).

Estimated Number of Responses: 6,800 based upon the FY 2011 loan totals.

Estimated Time per Response: SBA estimates that each applicant would require 15 minutes to complete the new proposed form, thereby decreasing the total estimated burden for this collection, which depending on the Lenders status, is currently 2.25 hours or 2.45 hours per application.

Total Estimated Burden: 15,736 hours, which is identical to current OMB inventory.

(ii) Application for Business Loan (SBA Form 4–I and 4 Schedule A).

OMB Control Number: 3245–0016.

Description of and Estimated Number of Respondents: 17,300 Applicants for 7(a) loans based upon FY 2011 totals.

Estimated Number of Responses: 32,130 based upon the FY 2011 totals.

Estimated Time per Response: SBA estimates that each applicant would require 15 minutes to complete the new proposed form, which would result in a corresponding reduction in the current burden for this collection.

Total Estimated Burden: 206,340 hours (8.625 hours less than current OMB inventory).

(iii) SBA Express, Export, Express, Small Loan Advantage, PLP-CapLines, and Pilot Loan Programs (Patriot Express and Dealer Floor Plan) Borrower Information Form (SBA Form 1919, 1920SX (A, B & C) and 2237).

OMB Control Number: 3245–0348.

Description of and Estimated Number of Respondents: 4,450 Applicants for SBA Express, Export Express, Small Loan Advantage, PLP-Caplines and Pilot Loan Programs based upon FY 2011 totals.

Estimated Number of Responses: 117.900.

Estimated Time per Response: 12 minutes.

Total Estimated Burden: 22,620 hours (36,236 hours less than current OMB inventory).

(iv) Lender Advantage (SBA Form 2301–A, B & C).

OMB Control Number: 3245–0361.

Description of and Estimated Number of Respondents: 15,900 Applicants for SBA's Lender Advantage Loan Initiative Program based upon a projection of program activity during FY 2013.

Estimated Number of Responses: 15,900 respondents based upon a projection of program activity during FY 2013.

Estimated Time per Response: SBA estimates that each applicant would require 30 minutes to complete the new proposed form, which would result in a reduction in the current burden hours for this collection.

Total Estimated Burden: 46,095 hours (2,895 hours less than current OMB inventory).

(v) PCLP Quarterly Loan Reserve Report and PCLP Guarantee Request (SBA Forms 2233 and 2234–A, B & C).

OMB Control Number: 3245–0346.

Description of and Estimated Number of Respondents: 19 PCLP Lenders.

Estimated Number of Responses: 1,700 respondents based on an estimate of the loan volume.

Estimated Time per Response: SBA estimates that each applicant would require 50 minutes to complete the new proposed form, which would result in a reduction in the current burden hours for this collection.

Total Estimated Burden: 1,402 hours less than current OMB inventory.

SBA has submitted these amended collections to the Office of Management and Budget (OMB) for review, and invites the public to comment on the proposed changes, particularly on: (1) Whether the proposed collection of information is necessary for the proper performance of the program, including whether the information will have a practical utility; (2) the accuracy of SBA's estimate of the burden of the proposed collections of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Please send comments by the closing date for comment for this interim final rule to SBA Desk Officer, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20503, and to Linda Reilly, Chief, 504 Program Branch, Office of Financial Assistance, Small Business Administration, 409 Third Street SW., Washington, DC 20416.

Regulatory Flexibility Act, 5 U.S.C. 601–612

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires the agency to ''prepare and make available for public comment an initial regulatory analysis'' which will ''describe the impact of the proposed rule on small entities.'' Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the proposed rulemaking is not expected to have a significant economic impact on a substantial number of small entities. Although the rulemaking will impact all of the approximately 4,500 7(a) Lenders (some of which are small) and all of the approximately 260 CDCs (all of which are small), SBA does not believe the impact will be significant. As stated above, the proposed rule will expand access to the business loan program but this will not increase the burden of the agency's lending partners because they choose their own level of program participation (i.e., 7(a) Lenders and CDCs are not required to process more loan applications simply because more small businesses are eligible to apply for a business loan). For those CDCs and lenders that process more businesses loans, the benefit of the increase in revenue will far exceed any increased burden. In addition, the proposed elimination of certain program participation requirements would not have a substantial economic impact or cost on the small business borrower, lender or CDC.

SBA believes that this rule is SBA's best available means for facilitating American job preservation and creation by removing unnecessary regulatory requirements. Since the main purpose of this proposed rule is to reduce unnecessary regulatory burdens and program eligibility criteria, a review of the preamble sections above will provide more detailed explanations regarding how and why this proposed rule will reduce regulatory burdens and responsibly increase program participation flexibility. For these reasons, SBA has determined that there is no significant impact on a substantial number of small entities. SBA invites comment from members of the public who believe there will be a significant impact either on CDCs, or their borrowers.

List of Subjects

13 CFR Part 120

Community development, Equal employment opportunity, Loan programs—business, Reporting and recordkeeping requirements, Small business.

13 CFR Part 121

Grant programs-business, Individuals with disabilities, Loan-programs-business, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, SBA proposes to amend 13 CFR parts 120 and 121 as follows:

PART 120—BUSINESS LOANS

■ 1. The authority for 13 CFR part 120 continues to read as follows:

Authority: 15 U.S.C. 634(b)(6), (b)(7), (b)(14), (h) and note, 636(a), (h) and (m), 650, 687(f), 696(3) and 697(a) and (e); Pub. L. 111–240, 124 Stat. 2504.

§ 120.102 [Removed]

■ 2. Remove § 120.102.

§ 120.820 [Redesignated as § 120.816]

■ 3. Redesignate § 120.820 as § 120.816.
■ 4. Add § 120.818 to read as follows:

§ 120.818 Applicability to existing for-profit CDCs.

Unless expressly provided otherwise in the regulations, any Loan Program Requirement that applies to non-profit CDCs also applies to for-profit CDCs.
■ 5. Revise newly redesignated § 120.820 to read as follows:

§ 120.820 CDC Affiliation.

(a) A CDC must be independent and may not be affiliated (as determined in accordance with § 121.103) with any Person (as defined in § 120.10) except as permitted under this section.

(b) A CDC may be affiliated with an entity whose function is economic development in the same Area of Operations and that is either a non-profit entity or a State or local government or political subdivision (e.g., council of governments).

(c) A CDC that is affiliated with a 7(a) Lender may continue such affiliation if:

(1) The affiliation was in effect as of [EFFECTIVE DATE OF FINAL RULE], and

(2) The 7(a) Lender is either a state development company approved by SBA as of November 6, 2003, or a credit union.

(d) A CDC must not be affiliated with, or directly or indirectly invest in or finance, another CDC.

§ 120.822 [Removed]

■ 6. Remove § 120.822.
■ 7. Revise § 120.823 to read as follows:

§ 120.823 CDC Board of Directors.

(a) The CDC, whether for-profit or nonprofit, must have a Board of Directors with at least eleven (11), and no more than twenty-five (25), voting directors. The Board must be actively involved in encouraging economic development in the Area of Operations. The initial Board may be created by any method permitted by applicable State law. At a minimum, the Board must have directors with background and expertise in internal controls, financial risk management, commercial lending, legal issues relating to commercial lending, and corporate governance. Directors may be either currently employed or retired. A CDC must have at least one voting director that represents the economic, community or workforce development fields, and at least two voting directors that represent the commercial lending field.

(b) At least two voting members of the Board of Directors, other than the CDC manager, must possess commercial lending experience satisfactory to SBA. When the Board votes on SBA loan approval or servicing actions, at least two voting Board members, with such commercial lending experience, other than the CDC manager, must be present and vote.

(c) The Board of Directors must meet at least quarterly and shall be responsible for the actions of the CDC and any committees established by the Board of Directors. In addition, the Board of Directors is subject to the following requirements:

(1) Except for the CDC manager, no person on the CDC's staff may be a voting director of the Board;

(2) A quorum must be present to transact business. The quorum shall be set by the CDC but shall be no less than 50% of the voting members of the Board of Directors;

(3) Attendance at meetings may be through any format permitted by State law;

(4) Directors from the commercial lending fields must comprise less than 50% of the representation on the Board; and

(5) A CDC shall not permit more than one individual who is employed by or serves on the Board of Directors of a single entity (including the entity's affiliates) to serve on the CDC's Board of Directors.

(d) The Board shall have and exercise all corporate powers and authority and be responsible for all corporate actions and business. There must be no actual or appearance of a conflict of interest with respect to any actions of the Board. The Board is responsible for ensuring that the structure and operation of the CDC, as set forth in the Bylaws, comply with SBA's Loan Program Requirements. The responsibilities of the Board include, but are not limited, to the following:

(1) Approving the mission and the policies for the CDC;

(2) Hiring, firing, supervising and annually evaluating the CDC manager;

(3) Setting the salary for the CDC manager and reviewing all salaries;

(4) Establishing committees, at its discretion, including the following:

(i) *Executive Committee.* To the extent authorized in the bylaws, the Board of Directors may establish an Executive Committee. The Executive Committee may exercise the authority of the Board; however, the delegation of its authority does not relieve the Board of its responsibility imposed by law or Loan Program Requirements. No further delegation or redelegation of this authority is permitted. If the Board establishes an Executive Committee and delegates any of its authority to the Executive Committee as set forth in the bylaws of the CDC, the Executive Committee must:

(A) Be chosen by and from the Board of Directors from the Board; and

(B) Meet the same organizational and representational requirements as the Board of Directors, except that the Executive Committee must have a minimum of five voting members who must be present to conduct business.

(ii) *Loan Committee.* The Board of Directors may establish a Loan Committee. The Loan Committee may exercise the authority of the Board only as set forth in paragraphs (d)(4)(ii)(A) through (D) of this section; however, the delegation of its authority does not relieve the Board of its responsibility imposed by law or Loan Program Requirements. If the Board of Directors chooses to establish a Loan Committee, no CDC staff or manager may serve on the Loan Committee. The Loan Committee must:

(A) Be chosen by the Board of Directors from the membership (if any), shareholders or the Board;

(B) Have a quorum of at least five (5) committee members authorized to vote;

(C) Have at least two members with commercial lending experience satisfactory to SBA; and

(D) Have no actual or appearance of a conflict of interest, including for example, a Loan Committee member participating in deliberations on a loan for which the Third Party Lender is the member's employer or the member is otherwise associated with the Third Party Lender.

(5) Ensuring that the CDC's expenses are reasonable and customary;

(6) Hiring directly an independent auditor to provide the financial statements in accordance with Loan Program Requirements;

(7) Monitoring the CDC's portfolio performance on a regular basis;

(8) Reviewing a semiannual report on portfolio performance from the CDC manager, which would include, but not be limited to, asset quality and industry concentration;

(9) Ensuring that the CDC establishes and maintains adequate reserves for operations;

(10) Ensuring that the CDC invests in economic development in each of the States in its Area of Operations in which it has a portfolio; and:

(i) For investments of $2,500 or less: The CDC manager may approve such investments; and

(ii) For investments over $2,500: The Board must approve each such investment.

(11) Establishing a policy in the Bylaws of the CDC prohibiting an actual conflict of interest or the appearance of same, and enforcing such policy;

(12) Retaining accountability for all of the actions of the CDC;

(13) Establishing written internal control polices, in accordance with § 120.826;

(14) Establishing commercially reasonable loan approval policies, procedures, and standards. The Bylaws must include a credit approval process and set forth any delegations of authority to the Loan Committee and Executive Committee, if either Committee has been established. All 504 loan applications must have credit approval prior to submission to the Agency. The Loan Committee, if established, may be delegated the authority to provide credit approval for loans up to $2,000,000 but, for loans of $1,000,000 to $2,000,000, the Loan Committee's action must be ratified by the Board or Executive Committee prior to Debenture closing. Only the Board or Executive Committee, if authorized by the Board, may provide credit approval for loans greater than $2,000,000.

(15) All members of the Board of Directors must annually certify in writing that they have read and understood this section, and copies of the certification must be included in the Annual Report to SBA.

(e) The Board of Directors shall maintain Directors' and Officers' Liability and Errors and Omissions insurance in an amount of at least $5,500,000 per occurrence and in the aggregate per year with a deductible of not more than $50,000.

■ 8. Amend § 120.830 by revising paragraph (a) to read as follows:

§ 120.830 Reports a CDC must submit.

* * * * *

(a) An Annual Report within one hundred-eighty days after the end of the CDC's fiscal year (to include Federal tax returns for that year). A CDC that is certified by SBA within 6 months of the CDC's fiscal year-end is not required to submit an Annual Report for that year. The Annual Report must include, but is not limited to, the following:

(1) *Audited or Reviewed Financial Statements* as required in § 120.826(c) and (d) for the CDC and any affiliates or subsidiaries of the CDC.

(i) Audited financial statements must, at a minimum, include the following:

(A) Audited balance sheet;

(B) Audited statement of income (or receipts) and expenses;

(C) Audited statement of source and application of funds;

(D) Such footnotes as are necessary to understand the financial statements;

(E) Auditor's letter to management on internal control weaknesses; and

(F) The auditor's report.

(ii) Reviewed financial statements must, at a minimum, include the following:

(A) Balance sheet;

(B) Statement of income (or receipts) and expenses;

(C) Statement of source and application of funds;

(D) Such footnotes as are necessary to an understanding of the financial statements; and

(E) The accountant's review report.

(2) *Report on compensation.* CDCs are required to provide detailed information on total compensation (including salary, bonuses and expenses) paid within the CDC's most recent tax year for current and former officers and directors, and for current and former employees and independent contractors with total compensation of more than $100,000 during that period.

(3) *Certification of members of the Board of Directors.* Written annual certification by each Board member that he or she has read and understands the requirements set forth in § 120.823.

(4) *Report on investment in economic development.* Written report on investments in economic development in each State in which the CDC has an outstanding 504 loan.

* * * * *

■ 8. Amend § 120.835 by revising paragraph (c) to read as follows:

§ 120.835 Application to expand an Area of Operations.

* * * * *

(c) *Multi-State CDC Expansion.* A CDC may apply to be a Multi-State CDC only if the state the CDC seeks to expand into is contiguous to the State of the CDC's incorporation and the CDC has a loan committee meeting the requirement of § 120.823.

■ 9. Amend § 120.882 by revising paragraph (a) to read as follows:

§ 120.882 Eligible Project costs for 504 loans.

* * * * *

(a) Costs directly attributable to the Project including expenditures incurred by the Borrower (with its own funds or from a loan) to acquire land used in the Project, or for any other expense directly attributable to the Project, prior to applying to SBA for the 504 loan;

* * * * *

■ 10. Amend § 120.920 by adding two sentences at the end of paragraph (b) to read as follows:

§ 120.920 Required participation by the Third Party Lender.

* * * * *

(b) * * * The 504 loan is usually collateralized by a second lien on Project Property (''Common Collateral''). If the Third Party Lender requires a lien on collateral in addition to the Common Collateral, in the event of liquidation, the Third Party Lender must apply the proceeds from the sale of such additional collateral to the balance outstanding on the Third Party Loan prior to the application of proceeds from the sale of the common collateral to the Third Party Loan.

§ 120.925 [Removed]

■ 11. Remove § 120.925.

PART 121—SMALL BUSINESS SIZE REGULATIONS

■ 12. The authority citation for part 121 continues to read as follows:

Authority: 15 U.S.C. 632, 634(b)(6), 636(b), 662, and 694a(9).

■ 13. Amend § 121.103 by removing and reserving paragraph (a)(7) and adding paragraph (a)(8) to read as follows:

§ 121.103 How does SBA determine affiliation?

(a) * * *

(8) For applicants for 7(a) loans, 504 loans and microloans, affiliation is determined under § 121.302 instead of this § 121.103.

* * * * *

§§ 121.302 through 121.305 [Redesignated as §§ 121.303 through 121.306]

■ 14. Redesignate §§ 121.302 through 121.305 as §§ 121.303 through 121.306 and add a new § 121.302 to read as follows:

§ 121.302. Principles of affiliation to determine size of applicants for 7(a) loans, 504 loans, and microloans.

(a) *General principles of affiliation.* Generally, affiliation exists when one concern controls or has the power to control another, or when a third party (or parties) controls or has the power to control both concerns. Control may arise through ownership, management, or other relationships or interactions between the parties. In determining an applicant's size, SBA counts the receipts, employees, or other measure of size of the applicant whose size is at issue and all of its domestic and foreign affiliates, regardless of whether the affiliates are organized for profit. The exceptions to affiliation coverage set

forth in § 121.103(b) are incorporated into this section by reference. SBA will not consider negative control, by itself, as set forth in § 121.103(a)(3) of this part to create affiliation under this section. In determining affiliation under this section, SBA will consider the totality of the circumstances to determine whether affiliation exists, even though no single factor may be sufficient to constitute affiliation.

(b) *Affiliation based on ownership.* For determining affiliation based on ownership:

(1) A concern is an affiliate of a person (including any individual, concern or other entity) that owns or has the power to control more than 50 percent of the voting equity of the concern. If no person owns or has the power to control more than 50 percent of a concern's voting equity, SBA will deem the Chief Executive Officer (CEO) or President of the concern (or other officers, managing members, partners, or directors who control the management of the concern) to be in control of the concern.

(2) If any two or more persons (including any individual, concern or other entity) collectively own or have the power to control more than 50 percent of the voting equity of two or more concerns (the ''collective owners''), then there is affiliation between such concerns and between each concern and each collective owner.

(c) *Affiliation arising under options, convertible securities, and agreements to merge.* In determining size, SBA considers options, convertible securities, and agreements to merge (including agreements in principle) to have a present effect on the power to control a concern. SBA treats such options, convertible securities, and agreements as though the rights granted have been exercised.

(1) Agreements to open or continue negotiations towards the possibility of a merger or a sale of stock or other equity at some later date are not considered ''agreements in principle'' and are thus not given present effect.

(2) Options, convertible securities, and agreements that are subject to conditions precedent which are incapable of fulfillment, speculative, conjectural, or unenforceable under state or Federal law, or where the probability of the transaction (or exercise of the rights) occurring is shown to be extremely remote, are not given present effect.

(3) An individual, concern or other entity that controls one or more other concerns cannot use options, convertible securities, or agreements to appear to terminate such control before actually doing so. SBA will not give present effect to individuals', concerns' or other entities' ability to divest all or part of their ownership interest in order to avoid a finding of affiliation.

(d) *Affiliation based on common management.* Affiliation exists where the CEO or President of a concern (or other officers, managing members, partners or directors who control the management of the concern) also controls the management of one or more other concerns. Affiliation also arises where a single person or entity that controls the board of directors of one concern also controls the board of directors or management of one or more other concerns.

(e) *Affiliation based on franchise, license and similar agreements.* If the applicant is a franchisee, licensee or other similar entity, the provisions of § 121.103(i) apply.

(f) *Affidavit of applicant.* Each applicant for a 7(a) loan or a 504 loan must include as part of its application for financial assistance an Affidavit in which it discloses all owners of the applicant and their percentage of ownership and discloses any affiliates as determined under this section. The Affidavit must be executed by the applicant's CEO or equivalent.

Dated: February 19, 2013.

Karen G. Mills,

Administrator.

[FR Doc. 2013–04221 Filed 2–22–13; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0145; Directorate Identifier 2012–SW–059–AD]

RIN 2120–AA64

Airworthiness Directives; Agusta S.p.A. and Bell Helicopter Textron Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Agusta S.p.A. (Agusta) Model AB412 and AB412 EP, and Bell Helicopter Textron (Bell) Model 412, 412CF, and 412EP helicopters with certain DART Aerospace Ltd. (Dart) high gear aft crosstubes (crosstube) installed. This proposed AD would require adding a life limit of 10,000 landings to the crosstube and removing from service any crosstubes with more than 10,000 accumulated landings. This proposed AD is prompted by five separate reports of crosstube failures. The actions in this proposed AD are intended to prevent failure of the crosstube and subsequent collapse of the landing gear.

DATES: We must receive comments on this proposed AD by April 26, 2013.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Dart Aerospace LTD., 1270 Aberdeen St, Hawkesbury, ON, K6A 1K7, Canada; telephone: 1 613 632 5200; Fax: 1 613 632 5246; or at *www.dartaero.com.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Jeffrey Zimmer, Airframe Engineer, New York Aircraft Certification Office, Engine and Propeller Directorate, FAA, 1600 Stewart Ave., Suite 410, Westbury, New York 11590; telephone (516) 228–7306; email *jeffrey.zimmer@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the

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

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

Discussion

Transport Canada (TC), which is the aviation authority for Canada, has issued TC AD No. CF–2012–14R1, dated May 9, 2012 (CF–2012–14R1), to correct an unsafe condition for the Dart high gear aft crosstube assembly, part number (P/N) D412–664–203, approved under TC Supplemental Type Certificate (STC) SH01–9, FAA STC SR01298NY, and European Aviation Safety Agency (EASA) STC IM.R.S.01304, and installed on Agusta Model AB412 and AB412 EP and Bell Model 412, 412EP, and 412CF helicopters. TC advises that they have received five reports of these crosstubes failing. According to TC, based on these reports, the affected crosstube requires a life limitation of 10,000 landings. As a result, TC issued CF–2012–14R1, which requires amending the instructions for continued airworthiness (ICA) to establish the new life limitation, and removing from service all crosstubes with more than 10,000 landings.

FAA's Determination

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

Related Service Information

We reviewed Dart ICA No. ICA–D212–664, Revision 8, dated October 20, 2011, which contains the airworthiness limitations, inspection requirements, proper placards and markings, and maintenance procedures for crosstube P/N D212–664 and D412–664. Revision 8 establishes a life limit of 10,000 landings for crosstube P/N D412–664–203.

Proposed AD Requirements

This proposed AD would require establishing a component history card for each crosstube, P/N D412–664–203; revising the airworthiness limitations of the maintenance manual to establish a life limit of 10,000 landings for each crosstube; and removing from service any crosstube with more than 10,000 landings.

Costs of Compliance

We estimate that this proposed AD would affect 76 helicopters of U.S. Registry. Based on an average labor cost of $85 per hour, we estimate that operators may incur the following costs in order to comply with this AD. Creating a component history card and amending the ICA would require about 1 work-hour, for a cost per helicopter of $85 and a total cost to U.S. operators of $6,460. Replacing a crosstube that has exceeded its life-limit would require about 6 work-hours and required parts would cost about $10,351, for a total cost per helicopter of $10,861.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Agusta S.P.A. and Bell Helicopter Textron Helicopters: Docket No. FAA–2012–*****; Directorate Identifier 2012–SW–059–AD.

(a) Applicability

This AD applies to Agusta S.p.A. Model AB412 and AB412 EP helicopters and Bell Helicopter Textron Model 412, 412CF, and 412EP helicopters with a DART Aerospace Ltd. high gear aft crosstube (crosstube), part-number (P/N) D412–664–203 installed under Supplemental Type Certificate SR01298NY, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a crosstube, which could result in collapse of the landing gear.

(c) Reserved

(d) Compliance

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

(e) Required Actions

Within 30 days:

(1) Create a component history card or equivalent record for each crosstube. Determine the number of landings on each crosstube and enter it on the component history card or equivalent record. If the number of landings is unknown, calculate 10 landings per flight hour.

(2) Revise the Airworthiness Limitations section of the maintenance manual to reflect that crosstube, P/N D412–664–203, has a retirement life of 10,000 landings.

(3) Remove from service any crosstube with a number of landings equal to or greater than 10,000.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, New York Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Ave., suite 410, Westbury, New York 11590; telephone (516) 228–7300; fax (516) 794–5531.

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

(g) Additional Information

(1) The subject of this AD is addressed in Transport Canada AD No. CF–2012–14R1, dated May 9, 2012.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 3213: Main Landing Gear Strut/Axle/Truck.

Issued in Fort Worth, Texas, on February 18, 2013.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–04223 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0159; Directorate Identifier 2012–SW–010–AD]

RIN 2120–AA64

Airworthiness Directives; Robinson Helicopter Company

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) for Robinson Helicopter Company (Robinson) Model R22, R22 Alpha, R22 Beta, R22 Mariner, R44, and R44 II helicopters with certain main rotor blades (blade) installed. The existing AD currently requires inspecting each blade at the skin-to-spar line for debonding, corrosion, a separation, a gap, or a dent and replacing any damaged blade with an airworthy blade. Since we issued that AD, a terminating action for the inspection requirements of that AD has been developed. The proposed actions are intended to detect debonding of the blade skin, which could result in blade failure and subsequent loss of control of the helicopter, and to correct the unsafe condition by replacing the main rotor blades with new blades that do not require the AD inspection.

DATES: We must receive comments on this proposed AD by April 26, 2013.

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

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

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505; telephone (310) 539–0508; fax (310) 539–5198; or at *http://www.robinsonheli.com/servelib.htm.* You may review a copy of service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Fred Guerin, Aviation Safety Engineer, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5232; email *fred.guerin@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

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

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

Discussion

On June 2, 2011, we issued AD 2011–12–10, amendment 39–16717 (76 FR 35330, June 17, 2011) (AD 2011–12–10) for Robinson Model R22, R22A, R22 Beta, and R22 Mariner helicopters, with a blade, part number (P/N) A016–4; and Model R44 and R44 II helicopters, with a blade, P/N C016–2 or C016–5. We

corrected a typographical error in AD 2011–12–10 on March 5, 2012 (77 FR 12991). AD 2011–12–10 requires a pilot check of the blade skin-to-spar joint area for any bare metal before the first flight of each day. That AD also requires, within 10 hours time-in-service (TIS), and thereafter at 100-hour TIS intervals or at each annual inspection, or if any bare metal is found during the pilot check, inspecting each blade for corrosion, separation, a gap, or a dent by following certain procedures in Robinson R22 Service Bulletin SB–103, dated April 30, 2010, for Model R22 series helicopters or Robinson R44 Service Bulletin SB–72, dated April 30, 2010, for Model R44 series helicopters. That AD also requires refinishing any bare metal before further flight and replacing any damaged blade with an airworthy blade.

AD 2011–12–10 superseded AD 2007–26–12, Amendment 39–15314 (73 FR 397, January 3, 2008) (AD 2007–26–12) which requires a one-time visual inspection for skin separation along the leading edge of the blade skin aft of the skin-to-spar bond line on the lower surface of each blade and in the tip cap area. AD 2007–26–12 also requires a ''tap test'' for detecting a separation or void in both bonded areas, repainting any exposed area of the blades, and replacing any blade if separation or a void occurs. That AD was prompted by 11 reports of blade debond, some occurring in flight and some found during routine maintenance.

Actions Since Existing AD Was Issued

Since we issued AD 2011–12–10, Robinson has developed replacement blades on both the R22 and R44 helicopters, and we have determined that replacing P/N A016–2 and –4 blades with P/N A016–6 blades for the Model R22 helicopter and P/N C016–2 and –5 blades with P/N C016–7 blades for the Model R44 helicopter will constitute terminating action for all requirements of that AD. We have also determined that it is in the interest of safety that all blades are replaced within 5 years. The actions of this AD are intended to detect debonding or a void in the blade, which could lead to failure of the blade and subsequent loss of control of the helicopter. These actions will also correct the unsafe condition by replacing the main rotor blades with new blades that do not require the AD inspection.

Also, since issuing AD 2011–12–10, we have received comments from 13 commenters and have given due consideration to each one. We have identified seven unique issues and addressed those issues as follows:

Three commenters stated that making a logbook entry each day showing the AD check for paint is unnecessary and burdensome. The commenters also stated it is the same importance as other pre-flight checks that are not documented. One commenter suggested replacing the daily check and logbook entry with a pre-flight check and no logbook entry. One commenter stated that ''we need to trust the pilots and maintenance people to do their jobs and not add to this burden of it looks good on paper world.'' We do not agree. FAA policy requires a logbook entry for checks performed pursuant to the directions of an AD.

Four commenters stated it is not necessary to shorten the retirement life of main rotor blades by AD. They stated the cost is high compared to the safety benefit, it could put small operators out of business, and the problem is caused by poor inspection practices. One commenter added that routine inspections are performed before flight and if any defects were discovered that operator would be aware of it and not attempt flight until repairs were made. If operated in an environment where none of the causal factors exist, reliance on continued inspections is an adequate and appropriate long term solution to blade replacement. We do not agree. AD 2011–12–10 does not decrease the retirement life of the affected blades. While this proposed AD supersedure would require blade life reduction and replacement, we are providing for public comment prior to adoption of the proposed AD.

Three commenters expressed concern that the cost estimates for older R44 Astro model helicopters is inaccurate, as these models must be refitted with hydraulic assisted controls before the new aluminum blades can be operated. They further stated that this modification can only be performed at the Robinson factory and the cost for shipping and overhaul is high. They question who will pay for the loss of income and state that mandating replacement of the –5 blade would have the unintended consequence of immediately grounding and placing an entire class of safe machines beyond economical repair. One of these commenters stated that replacing the blades on his R44 has been ''financially devastating'' due to both replacement costs and his loss of revenue, and believes Robinson should be responsible for these costs, not owners.

We do not agree. We are aware that the replacement blades for the R44 Astro are not compatible with a helicopter without hydraulic assisted controls, but we disagree that the R44 Astro will be beyond economical repair as many R44 Astros have been refitted with hydraulics, and conversions occur often. AD 2011–12–10 estimated costs for replacing one blade if debonding was present, and did not address any costs to modify the helicopter to accept the new part-numbered blades manufactured by Robinson. The FAA does not concur with the commenter's request that the FAA require the manufacturer to cover the cost of replacing the blades. The FAA recognizes that the general obligation of the operator to maintain aircraft in an airworthy condition is vital, but sometimes expensive. The FAA considers that, in the interest of maintaining safe aircraft, prudent operators would accomplish the required actions even if they were not required to do so by the AD. However, the manufacturer, not the FAA, determines if the manufacturer will cover the cost of implementing a particular action. Therefore, no change in this regard is necessary.

One commenter requested the immediate adoption of an airworthiness directive requiring replacement of the main rotor blades, and expressed concern that the FAA was giving more consideration to any financial impact on Robinson than to the risk to the flying public. We do not agree that immediately requiring replacement of the blades is necessary, as we have determined that proper inspection is adequate to protect the safety of the fleet for the short term. This proposed AD to terminate the inspections by mandating blade replacement after five years is intended to allow time for blade manufacture, distribution, and installation without causing undue hardship to operations, and to protect the long term safety of the fleet.

One commenter stated that the current method of detecting the debonding issue is acceptable provided the inspection is performed properly and repainted when necessary to prevent the bonding from being exposed to the elements. This commenter disagreed that the problem is not a manufacturing problem and expressed concern that the variance in design of the blades is contributing to the situation. The commenter questioned whether other manufacturers are having similar issues and whether the new –7 replacement blades are produced under a different manufacturing process to ensure the current problem will be eliminated. The FAA disagrees that the cause of the debond is a failure of the manufacturing process. The debonding is being caused by the basic blade design, which allows erosion of the

bond line if left unprotected in an erosive environment. The replacement blades were redesigned using best practices, engineering integrity, and heightened oversight. While we believe the redesigned blades will correct the unsafe condition, the FAA cannot guarantee any design change will not, in the future, develop a problem that requires correction.

One commenter noted that a previous Civil Aviation Safety Authority (CASA) AD required a detailed inspection to determine blade airworthiness should any exposed blade skin aft of the skin-to-spar bond line be found, and that AD 2011–12–10 only requires refinishing the blade should the bond line be found to be exposed, without further inspection. The FAA agrees. Due to a typographical error in the AD, the requirement to skip further inspection prior to refinishing was caused by an incorrect reference to the refinishing paragraph instead of the inspection paragraph. A revision to AD 2011–12–10, Amendment 39–16717 (77 FR 12991, March 5, 2012) was issued on January 3, 2012, so that the AD language now refers to the correct paragraph.

FAA's Determination

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

Related Service Information

We have reviewed the following Robinson service information:

- Letter titled ''Additional Information Regarding Main Rotor Blade Skin Debonding,'' dated May 25, 2007, discussing blade skin debonding;
- Rotorcraft Flight Manual (RFM) changes to the Normal Procedures Section 4 and Systems Description Section 7, revised April 20, 2007, for each applicable model helicopter containing a ''caution'' about skin-to-spar bond line erosion;
- One Service Letter with two different Nos.: R22 SL–56B and R44 SL–32B, both revised April 30, 2010, specifying proper inspection and protection (refinishing) of bonded areas; and
- Service Bulletins SB–103 for the Model R22 and SB–72 for the Model R44, both dated April 30, 2010, specifying proper inspection and protection (refinishing) of bonded areas for certain affected blades.
- R44 Service Letter SL–37, dated June 18, 2010, specifying the required modifications for a carbureted R–44 to install P/N C016–7 blades.

Proposed AD Requirements

This proposed AD would retain the pilot check, recurring inspection, and blade refinishing requirements of AD 2011–12–10. The pilot check may be performed by an owner/operator (pilot) holding at least a private pilot certificate and must enter compliance into the aircraft maintenance records in accordance with 14 CFR 43.11 and 91.417(a)(2)(v). This authorization is an exception to our standard maintenance regulations.

This proposed AD would add a requirement, within five years of the effective date, to replace both main rotor blades with the new part-numbered aluminum blades. Replacing the blades with the new part-numbered blades would constitute terminating action of the recurring inspection requirements.

Costs of Compliance

We estimate that this proposed AD would affect 1,290 Model R22 helicopters and 1,353 Model R44 helicopters, for a total of 2,643 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD:

- Time to perform the before flight check each day is negligible.
- Inspecting both blades will require about three work hours at an average labor rate of $85 per hour, for a total cost per helicopter of $255 and a total cost to the U.S. operator fleet of $673,965.
- Replacing both blades on a Model R22 helicopter will require about 20 work hours at an average labor rate of $85 per hour and required parts will cost $29,808, for a total cost per helicopter of $31,508 and a total cost to the U.S. R22 operator fleet of $40,645,320 over a 5-year period.
- Replacing both blades on a Model R44 helicopter with hydraulically boosted flight controls installed (approximately 1053 helicopters) will require about 20 work hours at an average labor rate of $85 per hour and required parts will cost $43,783, for a total cost per helicopter of $45,483 and a total cost to the U.S. R44 operator fleet of $47,893,599 over a 5-year period.
- Replacing both blades on a Model R44 helicopter without hydraulically boosted flight controls installed (approximately 300 helicopters) will require modifying the aircraft with hydraulic flight controls, which will cost a flat rate (parts and labor) of $40,000, which includes the P/N C016–7 blades, and installing the required airframe provisions will require about 13 work-hours, at an average labor rate of $85 per hour, and required parts will cost $28,199, for a total cost per helicopter of $112,247, and a cost to U.S. operators of $33,674,100 over a 5-year period.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–16717 (76 FR 35330, June 17, 2011), and adding the following new AD:

Robinson Helicopter Company: Docket No. FAA–2013–0159; Directorate Identifier 2012–SW–010–AD.

(a) Applicability

This AD applies to Model R22, R22 Alpha, R22 Beta, and R22 Mariner helicopters with main rotor blade (blade), part number (P/N) A016–2 or A016–4; and Model R44 and R44 II helicopters with blade, P/N C016–2 or C–016–5, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as blade skin debonding, which could result in blade failure and subsequent loss of control of the helicopter.

(c) Affected ADs

This AD supersedes AD 2011–12–10, Amendment 39–16717 (76 FR 35330, June 17, 2011).

(d) Compliance

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

(e) Required Actions

(1) Before the first flight of each day, visually check for any exposed (bare metal) skin-to-spar joint area on the lower surface of each blade. The actions required by this paragraph may be performed by the owner/operator (pilot) holding at least a private pilot certificate and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9(a)(1)–(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.417, 121.380, or 135.439.

(2) If there is any bare metal in the area of the skin-to-spar bond line, before further flight, inspect the blade by following the requirements of paragraph (e)(3) of this AD.

(3) Within 10 hours time-in-service (TIS), and at intervals not to exceed 100 hours TIS or at each annual inspection, whichever occurs first, inspect each blade for corrosion, separation, a gap, or a dent by following the Compliance Procedure, paragraphs 1 through 6 and 8, of Robinson R22 Service Bulletin SB–103, dated April 30, 2010 (SB103), or Robinson Service Bulletin SB–72, dated April 30, 2010 (SB72), as appropriate for your model helicopter. Although the Robinson service information limits the magnification to 10 x, a higher magnification is acceptable for this inspection. Also, an appropriate tap test tool which provides similar performance, weight, and consistency of tone may be substituted for the ''1965 or later United States Quarter-dollar coin,'' which is specified in the Compliance Procedure, paragraph 2, of SB72 and SB103.

(4) Before further flight, refinish any exposed area of a blade by following the Compliance Procedure, paragraphs 2 through 6, of Robinson R22 Service Letter SL–56B or R44 Service Letter SL–32B, both dated April 30, 2010, as appropriate for your model helicopter.

(5) Before further flight, replace any unairworthy blade with an airworthy blade.

(6) Within 5 years of the effective date of this AD:

(i) For Model R22 series helicopters, replace blade P/N A016–2 or A016–4 with a blade, P/N A016–6.

(ii) For Model R44 series helicopters fitted with hydraulically boosted main rotor flight controls, replace blade P/N C016–2 or C016–5 with a blade, P/N C016–7.

(iii) For Model R44 series helicopters without hydraulically boosted main rotor flight controls, replace blade P/N C016–2 or C016–5 with a blade, P/N C016–7. Prior to installing a blade P/N C016–7, verify the helicopter has been modified as required by Robinson R44 Service Letter SL–37, dated June 18, 2010, Compliance Procedures, paragraphs 1. through 10.

(iv) Installing blades, P/N A016–6 or P/N C016–7, is terminating action for the inspection requirements of paragraphs (e)(1) through (e)(4) of this AD.

(f) Special Flight Permit

Special flight permits will not be issued.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles Aircraft Certification Office, FAA, may approve AMOCs for this AD. Send your proposal to: Fred Guerin, Aviation Safety Engineer, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, FAA, 3960 Paramount Blvd., Lakewood, CA 90712; telephone (562) 627–5232; email *fred.guerin@faa.gov.*

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

(h) Additional Information

The Robinson letter titled ''Additional Information Regarding Main Rotor Blade Skin Debonding,'' dated May 25, 2007, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Robinson Helicopter Company, 2901 Airport Drive, Torrance, CA 90505; telephone (310) 539–0508; fax (310) 539–5198; or at *http://www.robinsonheli.com/servelib.htm.* You may review a copy of this information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

(i) Subject.

Joint Aircraft Service Component (JASC) Code: 6210: Main Rotor Blades.

Issued in Fort Worth, Texas, on February 12, 2013.

Bruce Cain,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–04217 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0146; Directorate Identifier 2012–SW–060–AD]

RIN 2120–AA64

Airworthiness Directives; Agusta S.p.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede an existing airworthiness directive (AD) for Agusta S.p.A. (Agusta) Model A109E helicopters that requires reducing the tail rotor (T/R) blade life limit, modifying a T/R hub and grip assembly, re-identifying two T/R assemblies, clarifying the never-exceed speed (Vne) limitation and reducing the inspection interval. Since we issued that AD, the manufacturer has redesigned a T/R grip bushing (bushing) that reduces the loads, which caused the T/R cracking, on the T/R blades. This action would require installing the new bushing and re-identifying the T/R hub-and-grip and hub-and-blade assemblies and require a recurring inspection of each bushing. The proposed actions are intended to prevent fatigue failure of a T/R blade and subsequent loss of control of the helicopter.

DATES: We must receive comments on this proposed AD by April 26, 2013.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

• *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the economic evaluation, any comments received and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed AD, contact Agusta Westland, Customer Support & Services, Via Per Tornavento 15, 21019 Somma Lombardo (VA) Italy, ATTN: Giovanni Cecchelli; telephone 39–0331–711133; fax 39–0331–711180; or at *http://www.agustawestland.com/technical-bullettins.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

FOR FURTHER INFORMATION CONTACT: Sharon Miles, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 222–5110; email *sharon.y.miles@faa.gov.*

SUPPLEMENTARY INFORMATION

Comments Invited

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

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

Discussion

On June 12, 2002, a T/R blade on an Agusta Model 119 helicopter failed and resulted in an autorotative landing. As a result of this failure, based on the commonality of the T/R blades on the model 109E helicopter, Agusta issued Alert Bollettino Tecnico (ABT) No. 109EP–30, dated June 21, 2002, for the Model 109E helicopter. The aviation authority for Italy, Ente Nazionale per L'Aviazione Civile (ENAC), issued Emergency AD No. 2002–340, dated June 28, 2002, for the Model 109E helicopters. On July 9, 2002, we issued Emergency AD 2002–14–51 to require a pilot-check before each flight, and initial and repetitive inspections of the T/R blades for a crack.

''As a precautionary measure,'' Agusta issued Revision A, dated July 25, 2002, to ABT 109EP–30. On July 29, 2002, ENAC issued AD No. 2002–384, adopting the requirements of Revision A of this Agusta ABT. On October 17, 2002, we issued immediately adopted AD 2002–17–51 (67 FR 67510, November 6, 2002) to require a reduction in V_{NE}, a pilot-check of each T/R blade before each start of the helicopter engines, and initial and recurring inspections of each T/R blade for a crack.

Following increased ground vibrations in a Model A 109E helicopter, another crack was discovered in a T/R blade, which prompted Agusta to issue Revision B, dated November 17, 2002, to ABT 109EP–30. Analysis and tests had shown that the fatigue failure of the T/R blade was caused by unanticipated loads on the T/R blade. Revision B to that ABT specified maintaining the V_{NE} reduction until a new bushing was installed in the T/R grip assembly. Further, that ABT established, for T/R blade P/N 109–8132–01–111 on grip assembly P/N 109–8131–02–127, a retirement life of 200 hours TIS. ENAC adopted the provisions of Revision B of the Agusta ABT in ENAC AD No. 2002–592, dated November 28, 2002.

On February 14, 2003, we issued AD 2002–25–51, Amendment 39–13060 (68 FR 9504, February 28, 2003), to require:

For helicopters with T/R hub and blade assembly, part number (P/N) 109–8131–02–151 (the T/R hub and blade assembly consists of two T/R blades, P/N 109–8132–01–111, and one T/R hub and grip assembly, P/N 109–8131–02–127):

• Before further flight, installing a placard and marking the airspeed indicator to reduce the helicopter V_{NE} by 28 knots-indicated air speed (KIAS) in addition to any additional reduction in V_{NE} caused by optional equipment.

• Before each start of the helicopter engines, allowing an owner/operator (pilot) to check the T/R blade for a crack so long as the pilot records that AD compliance in the maintenance records in accordance with 14 CFR 43.9(a)(1)-(4) and 91.417(a)(2)(v).

• Within 5 hours time-in-service (TIS), and thereafter at intervals not to exceed 5 hours TIS, and before further flight any time there is an increase in vibration levels, inspecting each T/R blade for a crack using a 5x or higher magnifying glass.

• Establishing a new life limit for T/R blade, P/N 109–8132–01–111, of 200 hours TIS and requiring T/R blades with 190 hours or more TIS to be replaced within 10 hours TIS.

• On or before May 31, 2003, modifying and re-identifying the T/R hub and grip assembly and the T/R hub and blade assembly, which removes the V_{NE} restriction and restores the T/R blade life limit to 1,000 hours TIS.

For helicopters with T/R hub and blade assembly, P/N 109–8131–02–157 (the T/R hub and blade assembly consists of two T/R blades, P/N 109–8132–01–111, and one T/R hub and grip assembly, P/N 109–8131–02–159):

• Before each start of the helicopter engines, allowing an owner/operator (pilot) to check the T/R blade for a crack so long as the pilot records that AD compliance in the maintenance records in accordance with 14 CFR 43.9(a)(1)-(4) and 91.417(a)(2)(v).

• Within 25 hours TIS, and thereafter at intervals not to exceed 25 hours TIS, and before further flight any time there is an increase in vibration levels, inspecting each T/R blade for a crack using a 5x or higher magnifying glass.

• On or before accumulating 150 hours TIS on the T/R hub assembly, P/N 109–8131–02–159, and thereafter at intervals not to exceed 150 hours TIS, inspecting the bushings, P/N 109–8131–30–109, linings for wear, and replacing any unairworthy bushing.

Also, the existing AD states that T/R blades, P/N 109–8132–01–111, which have been operated as part of the T/R hub and blade assembly, P/N 109–8131–02–151, are considered unairworthy components of the T/R hub and blade assembly, P/N 109–8131–02–157, regardless of TIS.

Finally, AD 2002–25–51 requires replacing any unairworthy T/R blade before further flight.

Actions Since Existing AD Was Issued

Since we issued AD 2002–25–51, Agusta has issued Revision C, dated September 29, 2006, to ABT No. 109EP–30, and states that the service experience of T/R hub and blade assemblies with the newly-designed bushings that reduce T/R blade loading has shown improvement and has determined that increasing the amount of time between inspections is appropriate, based upon the service history and the results of the maintenance performed.

In response to Revision C of the ABT, the European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2006–0353, dated December 4, 2006, which supersedes ENAC AD 2002–597 to extend the inspection interval ''from 150 to 200 FH.'' Subsequently, EASA AD No. 2007–0010, dated January 31, 2007, was issued to supersede AD No. 2006–0353 to restore the initial requirements of ABT 109EP–30, Revision C, which were unintentionally omitted from AD No. 2006–0353.

FAA's Determination

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

Related Service Information

We reviewed ABT No. 109EP–30, Revision C, dated September 29, 2006, which describes procedures for checking/inspecting for cracks on both the upper and lower surfaces of T/R blades, P/N 109–8132–01–111; replacing each bushing, P/N 109–0132–55 and spacer P/N 109–0132–13, with bushing, P/N 109–8131–30–109, and instituting a recurring inspection of each bushing; and cancelling the V_{NE} limitations when the newly-designed bushing is installed on each T/R grip assembly, P/N 109–8131–29–101, a ''new'' pair of T/R blades, P/N 109–8132–01–111, is installed, and the T/R hub-and-grip and hub-and-blade assemblies are re-identified.

Proposed AD Requirements

This proposed AD would require:

• Before each start of the helicopter engines, visually checking both sides of each T/R blade for a crack. An owner/operator (pilot) may perform this check and must enter compliance into the aircraft records in accordance with 14 CFR 43.9 (a)(1)-(4) and 14 CFR 91.417(a)(2)(v). A pilot may perform this check because it involves only a visual check for a crack and can be performed equally well by a pilot or a mechanic. This procedure is an exception to our standard maintenance regulations.

• For helicopters with T/R hub and blade assembly, P/N 109–8131–02–151, before further flight, modifying each T/R hub and blade assembly by installing a new bushing in each grip assembly and two zero-TIS T/R blades; and re-identifying the hub and grip assembly and the T/R hub and blade assembly with different P/Ns.

• For helicopters with T/R hub and blade assembly, P/N 109–8131–02–157, within 25 hours TIS and thereafter at intervals not to exceed 25 hours TIS, and before further flight any time there is an increase in vibration levels, using a 5x or higher power magnifying glass, visually inspecting each T/R blade for a crack.

• On or before accumulating 200 hours TIS on the T/R hub and grip assembly, and thereafter at intervals not to exceed 200 hours TIS, inspecting the linings and measuring the internal diameter of the bushings. If the internal diameter of the bushing exceeds 41.35 millimeters, replacing the bushing.

• If there is a crack, before further flight, replacing the T/R blade.

• Revising the Airworthiness Limitations section of the maintenance manual to reflect that a T/R blade, P/N 109–8132–01–111, which has not been operated as part of T/R hub and blade assembly, P/N 109–8131–02–151, has a retirement life of 1,000 hours TIS.

Costs of Compliance

We estimate that this proposed AD would affect 75 helicopters of U.S. Registry. Based on an average labor rate of $85 per hour, we estimate that operators may incur the following costs in order to comply with this AD:

• Visually inspecting the T/R blades would require about 0.5 work hours for a cost per helicopter of $43 and a total cost to U.S. operators of $3,225 per inspection cycle.

• Replacing a cracked T/R blade would require about 2 work hours, and required parts would cost about $25,320, for a total cost per helicopter of $25,490.

• Modifying the hub assembly with new T/R blades and bushings would require about 16 work hours, and required parts would cost about $58,690, for a total cost per helicopter of $60,050.

• Inspecting the T/R bushings would require about 7 work hours, for a cost per helicopter of $595 and a total cost to U.S. operators of $44,625 per inspection cycle.

• Revising the Airworthiness Limitations section of the maintenance manual would require about .25 work hour, for a cost per helicopter of $22 and a total cost to U.S. operators of $1,650.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed, I certify this proposed regulation:

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–13060 (68 FR 9504, February 28, 2003), and adding the following new Airworthiness Directive (AD):

AGUSTA S.p.A. (Agusta): Docket No. FAA–2013–0146; Directorate Identifier 2012–SW–060–AD.

(a) Applicability

This AD applies to Agusta Model 109E helicopters with tail rotor (T/R) hub and blade assembly, part number (P/N) 109–8131–02–151 and P/N 109–8131–02–157, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a fatigue crack in a T/R blade. This condition could result in failure of the T/R blade and subsequent loss of control of the helicopter.

(c) Affected ADs

This AD supersedes AD 2002–25–51, Docket No. 2002–SW–55–AD, Amendment 39–13060 (68 FR 9504, February 28, 2003).

(d) Reserved

(e) Compliance

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

(f) Required Actions

(1) Before each start of the helicopter engines, visually check both sides of each T/R blade for a crack in the inspection area depicted in Figure 1 to paragraph (f) of this AD. This action may be performed by the owner/operator (pilot) holding at least a private pilot certificate, and must be entered into the aircraft records showing compliance with this AD in accordance with 14 CFR 43.9 (a)(1)–(4) and 14 CFR 91.417(a)(2)(v). The record must be maintained as required by 14 CFR 91.173, 121.380, or 135.439.

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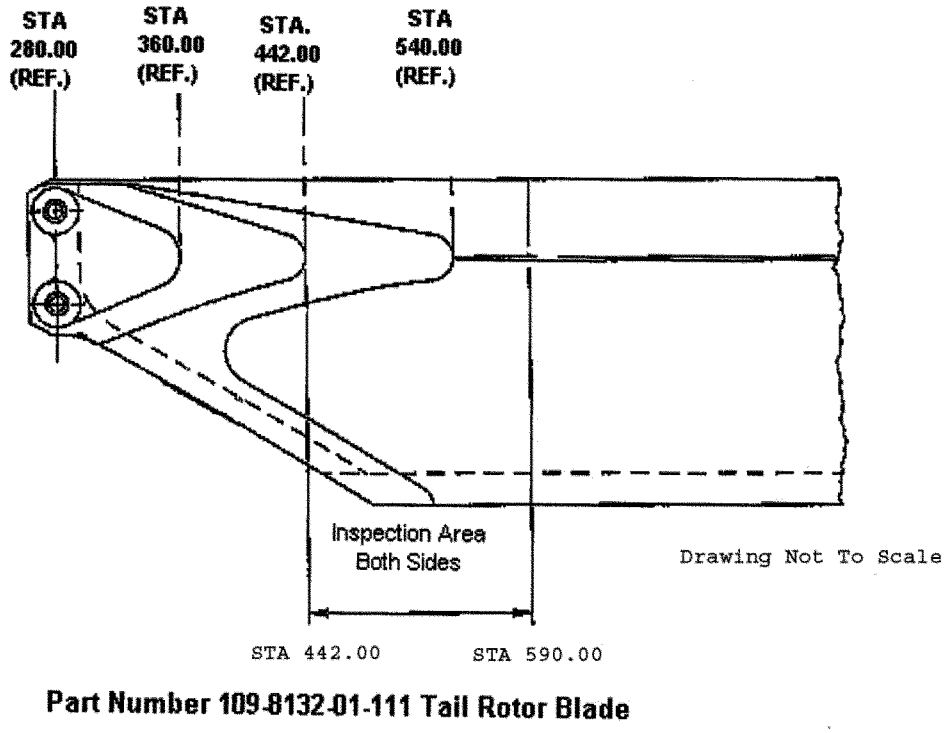

Figure 1 to paragraph (f)

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(2) For helicopters with T/R hub and blade assembly, P/N 109–8131–02–151 (consisting of two T/R blades, P/N 109–8132–01–111, and one T/R hub and grip assembly, P/N 109–8131–02–127), before further flight, modify each T/R hub and blade assembly by installing a new bushing, P/N 109–8131–30–109, in each grip assembly and two zero-hour time-in-service (TIS) T/R blades, P/N 109–8132–01–111; re-identifying the hub and grip assembly as P/N 109–8131–02–159; and re-identifying the T/R hub and blade assembly as P/N 109–8131–02–157 in accordance with the Compliance Instructions, Part V, paragraphs 2. through 13., of Agusta Bollettino Tecnico No. 109EP–30, Revision C, dated September 29, 2006 (BT). A T/R blade, P/N 109–8132–01–111, which has been operated as part of T/R hub and blade assembly, P/N 109–8131–02–151, must be retired regardless of TIS and may not be used as part of the T/R hub and blade assembly, P/N 109–8131–02–157. Returning the removed T/R blades, grips, or bushings to Agusta is not required.

(3) For helicopters with T/R hub and blade assembly, P/N 109–8131–02–157 (consisting of two T/R blades, P/N 109–8132–01–111, and one T/R hub and grip assembly, P/N 109–8131–02–159), within 25 hours TIS, and thereafter at intervals not to exceed 25 hours TIS, and before further flight any time there is an increase in vibration levels, using a 5x or higher power magnifying glass, visually inspect each T/R blade for a crack in accordance with the Compliance Instructions, Part III, paragraphs 1. through 5. of the BT. Reporting to Agusta is not required.

(4) On or before accumulating 200 hours TIS on the T/R hub and grip assembly, P/N

109–8131–02–159, and thereafter at intervals not to exceed 200 hours TIS, inspect the linings and measure the internal diameter of the bushings, P/N 109–8131–30–109, by referring to Figure 2 of the BT. If the internal diameter of the bushing exceeds 41.35 millimeters, replace the bushing.

(5) If there is a crack in a T/R blade, before further flight, replace the cracked T/R blade.

(6) Revise the Airworthiness Limitations section of the maintenance manual to reflect that a T/R blade, P/N 109–8132–01–111, which has not been operated as part of T/R hub and blade assembly, P/N 109–8131–02–151, has retirement life of 1,000 hours TIS.

(g) Special Flight Permit

Special flight permits will not be issued.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Sharon Miles, Aviation Safety Engineer, Regulations and Policy Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas, 76137; telephone (817) 222–5110; email *sharon.y.miles@faa.gov.*

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

(i) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency AD No. 2007–0010, dated January 31, 2007.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6410, Tail Rotor Blades.

Issued in Fort Worth, Texas, on February 11, 2013.

Kim Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–04220 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 619

RIN 1205–AB64

Federal-State Unemployment Insurance (UI) Program; Data Exchange Standardization as Required by Section 2104 of the Middle Class Tax Relief and Job Creation Act of 2012

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Labor's (Department's) Employment and Training Administration proposes to designate in regulation data exchange standards, developed in consultation with an interagency work group established by the Office of Management and Budget (OMB), for Unemployment Insurance (UI) administration as required by amendments to Title IX of the Social Security Act (SSA) made by the Middle Class Tax Relief and Job Creation Act of 2012 (the Act). This proposed regulation would establish data exchange standards for three categories of information: real-time applications on the Interstate Connection Network (ICON); the State Information Data Exchange System (SIDES); and implementation of the standards identified for ICON and SIDES in major Information Technology (IT) modernization projects to upgrade UI Benefits and Tax systems by State Workforce Agencies (SWAs) using Federal funds.

DATES: Submit comments on or before April 26, 2013.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 1205–AB64, by one of the following methods:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the Web site instructions for submitting comments.

Mail and hand delivery/courier: Written comments, disk, and CD–ROM submissions may be mailed to Michael S. Jones, Acting Administrator, Office of Policy Development and Research, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5641, and Washington, DC 20210.

Instructions: Label all submissions with ''RIN 1205–AB64.''

Please submit your comments by only one method. Please be advised that the Department will post all comments received that relate to the proposed data exchange standardization on *http://www.regulations.gov* without making any change to the comments or redacting any information. The *http://www.regulations.gov* Web site is the Federal e-rulemaking portal and all comments posted there are available and accessible to the public. Therefore, the Department recommends that commenters remove personal information such as Social Security Numbers, personal addresses, telephone numbers, and email addresses included in their comments as such information may become easily available to the public via the *http://www.regulations.gov* Web site. It is the responsibility of the commenter to safeguard personal information.

Also, please note that due to security concerns, postal mail delivery in Washington, DC may be delayed. Therefore, the Department encourages the public to submit comments on *http://www.regulations.gov.*

Docket: All comments on this proposed rule will be available on the *http://www.regulations.gov* Web site and can be found using RIN 1205–AB64. The Department also will make all the comments it receives available for public inspection by appointment during normal business hours at the above address. If you need assistance to review the comments, the Department will provide appropriate aids such as readers or print magnifiers. The Department will make copies of this proposed rule available, upon request, in large print and electronic file on computer disk. To schedule an appointment to review the comments and/or obtain the proposed rule in an alternative format, contact the Office of Policy Development and Research at (202) 693–3700 (this is not a toll-free number). You may also contact this office at the address listed below.

Instructions for Submitting Comments on Paperwork Burden: Submit any comments that concern the information collection request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.* OMB recommends that comments on the information collection requirements be submitted within 30 days of publication of this NPRM. Comments on the information collections may also be submitted to the ETA in the same manner as any other issue addressed in this NPRM.

FOR FURTHER INFORMATION CONTACT: Michael S. Jones, Acting Administrator, Office of Policy Development and Research, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5641, Washington, DC 20210; telephone (202) 693–3700 (this is not a toll-free number).

Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The preamble to this proposed rule is organized as follows:

I. Background—provides a brief description of the development of the proposed rule.

II. Section-by-Section Review—summarizes and discusses the proposed regulations.
III. Administrative Information—sets forth the applicable regulatory requirements.

I. Background

On February 22, 2012, the President signed the Act. Section 2104 of the Act amends Title IX, SSA (42 U.S.C. 1101 *et seq.*) by adding a new section 911, which requires the Department to issue rules, developed in consultation with an interagency workgroup established by the Office of Management and Budget (OMB), that establish data exchange standards for certain functions related to administration of the Unemployment Insurance (UI) [1] program. Before enactment of this requirement for data exchange standardization, the Department had been a proponent of and strong advocate for the use of open source technologies and data exchange standards in the development of IT systems supporting critical UI functions (such as ICON and SIDES), and of SWAs' overall UI information technology modernization efforts. Section 911, SSA, contains two major subsections (a) and (b), each of which requires data exchange standards; these requirements are discussed in detail below.

Section 911(a)(1), SSA, requires that DOL ''shall, by *rule,* designate a data exchange standard for *any* category of information required under title III [42 U.S.C. 501 *et seq.*], title XII [42 U.S.C. 1401 *et seq.*], or this title [IX].'' (Emphasis added.) This allows the Department to identify ''any'' category of information under the specified titles to require, by rule, for which to establish a data exchange standard. Section 911(b)(1), SSA, requires that DOL ''shall, by rule, designate data exchange standards to govern the reporting required under [the same specified titles].'' The Department has chosen to establish data exchange standards for information required under section 303(a)(1), SSA, that meet the requirements of both sections 911(a)(1) and 911(b)(1), SSA.

Section 303(a)(1), SSA, commonly known as the ''methods of administration'' requirement, provides that State law, as a condition of the State receiving UC administrative grants, must include ''such methods of administration…as are found by the Secretary of Labor to be reasonably calculated to insure full payment of unemployment compensation when due.'' Section 303(a)(1), SSA, was chosen because it is the foundational statutory authority for the Department's guidance to States on the administration of the UI program, including guidance on program operations and reporting requirements.

The Department chose to establish data exchange standards for categories of information under Title III, SSA, because Titles IX and XII, SSA, provide fewer opportunities for establishment of data exchange standards that would benefit the UI system broadly, given that their focus is primarily on Unemployment Trust Fund (UTF) management issues. Title IX establishes the account structure for the UTF, and Title XII establishes the processes for States to obtain advances if their States' accounts in the UTF are depleted. While Titles IX and XII, SSA, relate to how money flows between accounts, there are no data exchange activities associated with these two titles.

While developing this proposed rule for data exchange standards, the Department considered and determined that it is neither feasible nor practicable to set standards for all reports under the three titles listed in Section 911(b), SSA. Imposing data exchange standards for certain reporting for the UI program is, in fact, counter-productive and would interfere with the Department's ability to use and analyze the data. For example, State UI agencies currently send data, such as weekly UI claims data, to the Department in a format that enables the Department to store the data in a relational database for purposes of analysis and performance management. If data were instead required to be received in eXtensible Markup Language (XML) [2] format, pre-processing of the data would be required to store this information within a relational database, thus adding a layer of complexity for the analytical software. That approach would result in unnecessary inefficiency and there would be no benefit to any user of the data.

The Department did identify an area of reporting in which data exchange standardization is appropriate—SIDES. SIDES involves the type of data transactions that would benefit from a designated searchable, computer-readable and interoperable XML format standard. Therefore, the XML format is the designated data exchange standard for SIDES in this proposed rule. Nevertheless, we request comment on how the Department might apply the data exchange standards of Section 911(b), SSA, more broadly to the three listed titles.

Sections 911(a)(1) and 911(b)(1), SSA, both require consultation with an interagency work group established by OMB. The Department has participated in a work group convened by OMB for this purpose. The consultation included discussion of the standards proposed in this rulemaking as well as other possible standards that might be established in the future that impact multiple Federal programs. The work group provided the opportunity for multiple agencies to share their approaches to data exchange standardization, but to date, no cross-agency data exchange functions have been identified as being feasible, efficient and cost effective to implement data exchange standards as required by section 911, SSA. The Department will continue to work with OMB and other Federal agencies to identify additional data exchange standards that support interagency data exchange activities. Additional standards identified will be the subject of future regulations promulgated through advance notice and opportunity for public comment as required by section 553 of the Administrative Procedure Act (APA).

Sections 911(a)(1) and 911(b)(1), SSA, also both provide that the Department should consider State and employer perspectives. The Department consulted with States on the content of the rules required by section 911, SSA, through the National Association of State Workforce Agencies (NASWA), including NASWA's UI Committee and its Information Technology Support Center Steering Committee. The feedback provided from this consultation was that States continue to struggle with antiquated IT infrastructure and vary widely in their capacity to implement new technologies that support data exchange standardization. In addition, the limits of State IT capacity have been severely tested since the onset of the last recession through the present, as the economy slowly recovers. During this period, States experienced extraordinarily high claims loads and implemented a very complex Emergency Unemployment Compensation (EUC) program and extensions. EUC had multiple iterations over the course of the recession and during the recovery, requiring States to reprogram computers frequently to accommodate the changes to the program. In addition, the Act required implementation of a number of new

[1] The Department's Office of Unemployment Insurance uses the term Unemployment Compensation (UC) when referring to UC benefits paid or UC laws and to use the term Unemployment Insurance (UI) to refer to the UI program, administration and operations.

[2] XML is a nonproprietary, searchable, computer-readable format, and has the capacity to be upgraded continually, as necessary. Interoperability helps information technology systems more readily interface to carry out shared functions and manage communications.

reforms to the EUC program, also requiring computer programming and rapid implementation. States also identified lack of sufficient funding as a challenge to modernizing their IT systems. States recommended leveraging work to implement data exchange standards as a desirable approach to meeting the data exchange requirements of section 911, SSA.

The Department also considered employers' perspectives in the development of this regulation. The data exchange standards proposed in this rule to address the requirements of sections 911(a)(1) and 911(b)(1), SSA, support processes that will reduce the burden employers have in providing required information to the SWAs. The first data exchange standard will apply to ICON, which facilitates the sharing of employer reported wage information among the States. Efficiently sharing routinely reported wage data among the States prevents SWAs from having to contact employers through manual processes to provide the wage information again. The second standard mandated by this rule relates to SIDES. The Department is currently working with States to automate and standardize the flow of data between SWAs and employers and/or employer third-party administrators (TPAs). TPAs are organizations that contract with employers to act on their behalf with SWAs for processing the employers' UC claims-related activities, such as filing quarterly wage and tax reports, responding to requests for separation information, and managing UC accounts and costs. The goal of SIDES is to effectively automate and streamline the data exchange that occurs between SWAs and employers or their TPA so as to enable efficiencies. Both employers and TPAs have been involved in the development of all SIDES data exchange modules, including the choice of XML as the data exchange standard for SIDES. Employers and TPAs are represented on the SIDES operations committee. SIDES provides a method for SWAs, employers, and TPAs to improve timeliness and accuracy of UC claims processing, and reduce costs by creating an electronic exchange of information using a standardized, secure format with data validations that are strictly enforced to prevent the transfer of incomplete or incorrectly formatted data. Both ICON and SIDES are discussed in more detail below.

To meet the requirements of section 911, SSA, the Department is designating XML as the data exchange standard for two systems that support the reporting of data and information for two core UI administrative functions: (1) Employer reporting of information requested by SWAs to support eligibility determinations (SIDES); and (2) the reporting and exchange of wage information among the States that also supports determination of eligibility for benefits (ICON). XML is a markup language that defines a set of rules for encoding documents in a format designed to structure, store and transport data. XML data are stored in plain text format that is both human-readable and machine-readable. Use of XML also provides for a software- and hardware-independent method of exchanging data over incompatible applications or systems over the Internet.

Section 911(a)(2), SSA, requires that the data exchange standard implemented in this rulemaking ''to the extent practicable, be nonproprietary and interoperable.'' Section 911(b)(2), SSA, also requires that the data exchange standards implemented in this rulemaking ''to the extent practicable incorporate a widely accepted, nonproprietary, searchable, computer-readable format,'' and ''be capable of being continually upgraded as necessary.'' Section 911(b)(3), SSA, specifically requires that this rule, ''to the extent practicable, incorporate existing nonproprietary standards, such as the eXtensible Markup Language.'' The data exchange standards established in this proposed rule mandate the use of XML to meet the aforementioned requirements of sections 911(a) and (b), SSA.

XML[3] provides an interoperable standard framework using common computer languages and standard formats and protocols to manage certain functions or communications. Gaining interoperability among the Department and 53 States and territories with different IT infrastructure and different program parameters (State UI programs have differing eligibility requirements and processes for supporting those requirements) is challenging. Therefore, the Department is focusing on core functions and reporting requirements that are truly common among the States to codify data exchange standards.

Finally, section 911(a)(3)(A), SSA, requires that for data exchange reporting standards, the rule, to the extent practicable, incorporate interoperable standards developed and maintained by an international voluntary consensus standards body. The XML standard herein designated meets this requirement as it is recognized by the World Wide Web Consortium, an international voluntary consensus standards body. The rule also meets the requirement of incorporating standards developed and maintained by intergovernmental partnerships like the National Informational Exchange Model (NIEM) referenced in section 911(a)(3)(B), SSA. XML is a data exchange standard recognized by NIEM. The standard to be considered under Section 911(a)(3)(C), SSA, requires incorporation, to the extent practicable, of ''interoperable standards developed and maintained by Federal entities with authority over contracting and financial assistance, such as the Federal Acquisition Regulations Council.'' This applies to contracting and procurement processes and is not applicable to UI processes.

In accordance with these provisions, the Department proposes the following in this rulemaking:

- Under section 911(a), SSA, designating XML as the data exchange standard for the real-time applications[4] of ICON;
- Under section 911(a), SSA, designating XML as the standard for the SIDES data exchange modules;
- Under section 911(b), SSA, designating XML as the data exchange standard to govern reporting of information shared through SIDES; and
- Under section 911(a), SSA, designating XML as the data exchange standard for real-time applications of ICON and SIDES data exchange modules in association with major IT modernization project using Federal funds.

The Department is not ruling out the establishment of additional data exchange standards by regulation, promulgated through advance notice and opportunity for public comment, in the future. The Department intends to continue to explore other functions where data exchange standards would be valuable to the UI program and as it relates to shared data exchange with other Federal agencies.

ICON

ICON is used to implement sections 3304(a)(9)(A) and (B) of the Federal Unemployment Tax Act (FUTA), providing for interstate and combined-

[3] The use of the term ''XML'' means XML and any XML-based markup language(s) that defines a set of rules for encoding documents and/or data in a format that is both human-readable and machine-readable. The term ''XML'' encapsulates the provisions specified in newly added section 911, SSA.

[4] ICON applications are available in real-time and batch mode. States vary in the use of real-time applications versus the batch mode. The batch mode allows for processing of multiple requests at a scheduled time instead of immediate ''real-time'' processing.

wage claims.[5] ICON enables States to request, submit, and receive much of the information necessary to establish claims and determine eligibility. The requirement to pay UC ''when due'' under section 303(a)(1), SSA, includes timeliness of these payments. Interstate and combined wage claims are more complex to administer since they require communication and transmission of information between States or between a State and a Federal agency. To ensure that these claims are paid ''when due,'' the Department supports development and maintenance of ICON. ICON is a secure multi-purpose telecommunications network that supports the transfer of data among the SWAs needed for critical program functions, including:

- Interstate Benefits/Combined-Wage Claims;
- Unemployment Compensation for Federal Civilian Employees and Unemployment Compensation for Ex-Servicemembers programs;
- The Wage Record Interchange System, which allows SWAs to obtain wage data for program performance purposes of individuals who have participated in workforce investment programs in SWAs;
- The UI Inquiry data exchange with the Social Security Administration (Social Security) that enables SWAs to validate Social Security Numbers (SSNs) with Social Security; and
- The Health Coverage Tax Credit that enables a SWA to transmit information to the Internal Revenue Service about individuals eligible for help paying for their health insurance coverage.

The Department proposes XML as the data exchange standard under section 911(a), SSA, for a subset of these functions due to both State and ICON capacity to adopt standards for some of these functions at this time. In relation to these chosen functions, ICON currently supports the following applications in real-time allowing for States to use XML standards for these functions. These are applications currently used by some SWAs to support the processing of all UC claims:

- Interstate Wages and Benefits Inquiries/Responses, which supports online transmission of interstate wages and benefits inquiries and responses between SWAs;
- Withdrawn/Invalid Claims, which allows for the posting and viewing of withdrawn or invalid claim information for SWAs; and
- State Identification Inquiry, which allows SWAs to inquire about wages reported to other SWAs by SSN.

Currently, seven SWAs are involved in modernizing some of their ICON applications and it is not practical to require all States to comply with this standard immediately. The Department contemplates providing SWAs lead time to adopt and implement the new data exchange standard for these applications. Since States need time to implement the real-time ICON applications, it is not feasible to designate a data exchange standard to govern the reporting of this information under section 911(b), SSA, at this time. Accordingly, as explained below, the Department proposes that all SWA's using real-time ICON applications comply with the XML data exchange standard no later than September 30, 2018. A SWA may request an extension of the September 2018 deadline if it demonstrates that resources are not available to meet this requirement. These requests must be submitted in writing to the Administrator of the Office of Unemployment Insurance no later than 6 months before the deadline; requests will be reviewed and decided within 30 days.

SIDES

SIDES is necessary to effectuate the Standard for Claim Determinations—Separation Information, codified in regulation at 20 CFR part 625 Appendix B. This standard is based significantly on the ''methods of administration'' requirement in section 303(a)(1), SSA, and includes a requirement that a State promptly obtain information from the worker, employer, or other source that is sufficient to reasonably insure payment of UC when due. For this reason, the Department supports development and maintenance of SIDES, which enables States to exchange information with employers electronically, thereby markedly improving the timeliness and accuracy of the employer-provided information about the reasons individuals separated from employment.

SIDES is an automated information exchange and reporting system to standardize SWAs' delivery of information to employers and collection of information by SWAs from employers and TPAs. In FY 2010, the first format of SIDES for exchange of employee separation information was implemented. This exchange of information with employers or their TPAs on the circumstances underlying individual UC claimants' job separations will reduce UC payments to ineligible claimants, yield administrative cost savings to both employers and taxpayers, and promote more timely benefit determinations. Currently, 29 SWAs and 3 large TPAs are participating in the SIDES effort. In FY 2011, the SIDES exchange of data to verify claimant wages was implemented. The addition of the earnings verification exchange allows SWAs and employers to more quickly and accurately verify when UC claimants return to work, thus reducing the leading cause of UC overpayments: claimants' receipt of UC while employed.

SIDES is managed by NASWA which contracts with a vendor for its maintenance, support, and operations. The Department has provided specific funding to State consortia and SWAs for development, maintenance, and operations of SIDES. State consortia are groups of States collaborating to jointly establish a project team to oversee the design, development and implementation of an IT solution that will be shared across the States. The Department recently funded a consortium of States to oversee the development of new SIDES data exchanges modules to allow SWAs to notify employers and TPAs of benefits charges to their accounts and of non-monetary determinations. SWAs, participating in the SIDES consortia, identify and help prioritize new SIDES modules to be developed and direct these funds to NASWA for the development of these modules. All SWAs using SIDES modules provide administrative funding to NASWA for the continued operations of SIDES.

The Department continues to facilitate the expansion and enhancement of the functionality and use of SIDES as a vital tool for SWAs with respect to prevention and detection of improper payments, and has provided supplemental funding to a State consortium for the development of additional data exchange modules. These modules include:

- *UC Benefit Charge Notices.* This enhancement will make it possible for SWAs to provide employers notice of benefit charges to their accounts electronically rather than by paper and mail. This permits a quicker delivery and review by the employer and the ability to reply electronically if the

[5] Section 3304(a)(9)(A), (FUTA) requires, as a condition of the Secretary's certification of a State law under FUTA, that ''compensation shall not be denied or reduced to an individual solely because he files a claim in another State * * * or because he resides in another State * * * at the time he files a claim for unemployment compensation.'' Section 3304(a)(9)(B), FUTA, also requires as a condition of the Secretary's certification that ''the State shall participate in any arrangements for the payment of compensation on the basis of combining an individual's wages and employment covered under the State law with his wages and employment covered under the State unemployment compensation law of other States* * *''

charges are questionable. This expedited information exchange can detect potential improper payments earlier, particularly those related to identity theft and employees that return to work and continue to collect benefits.

• *Non-Monetary Determinations Exchange.* This enhancement will notify employers electronically, rather than on paper, of SWA decisions on the eligibility of their former workers who quit or were let go for cause. This will improve the timeliness of employer appeals and allow for quicker appeal decisions, halting improper payments faster if the employer prevails in the appeal.

Additionally, several other data exchange modules are under consideration for the expansion of SIDES including Monetary and Potential Charges, and Appeals Decisions. The XML standard will apply to the development of these additional data exchange modules as well.

The proposed rule designates a data exchange standard under section 911(a), SSA, to apply to the SIDES data exchange modules and designates a standard under section 911(b), SSA, to govern reporting of information through SIDES data exchange modules.

Major IT Modernization of UI Benefits and Tax Systems

For the purpose of this regulation, a major IT Modernization of UI Benefits and Tax systems includes conversion, re-engineering, rewriting, or transferring of an existing system to a modernized framework such as transferring a process from mainframe operations to web-based operations, converting to modern computer programming languages, or upgrading software libraries, protocols, or hardware platform and infrastructure. As the Department provides funding to States to modernize their information technology systems, the opportunity exists to use new data exchange standards that improve operations of the UI system as a whole and may further enable improved data exchanges with other States and Federal agencies.

The Department facilitates SWAs' efforts to modernize IT systems supporting their UI programs by providing funding for administration and operations, and appropriate technical assistance. While the Federal-State structure of the UI program places primary responsibility for its administration on the States, the Department provides periodic supplemental funding opportunities for IT modernization activities. In addition, Congress periodically provides special distributions of administrative UI funding to States.

Federal funds for UI modernization efforts come primarily from three sources: (1) Supplemental budget funds that are designated by the Department for State IT modernization efforts, (2) State UI administration funding, and (3) special distributions. State administration funding primarily consists of State UI operations funds (an administrative grant issued by the Department at the beginning of each fiscal year). Recent special distributions to States, pursuant to section 903, SSA, include those provided under the Job Creation and Worker Assistance Act of 2002 funds (distributed under the Reed Act, a mechanism by which the Federal government transfers surplus UI funds to States) and American Recovery and Reinvestment Act funds (an economic stimulus package enacted in February 2009). Also, since 2009, the Department has provided supplemental funding to State consortia to develop jointly functional requirements and development of modernized UI IT Benefits and/or Tax systems. One of the requirements was that the technology tools developed use open source components to the extent feasible, be transferable, and be capable of being shared by multiple SWAs. The goal is for multiple SWAs to share common systems/tools that accommodate each SWA's specific needs. Each of the consortia has its State leadership engaged in the process and soliciting vendors to assist with the system design and development efforts.

This proposed rule will require SWAs, when using Federal funds to modernize their UI systems, to use XML as a data exchange standard when developing the functionality to interface with ICON, to implement SIDES and the reporting of information through SIDES. This requirement will potentially further accelerate State adoption of this standard for both functions. The Department strongly encourages SWAs, to the extent feasible, to begin conforming to the XML standard for any major UI IT modernization projects already underway.

Effective Date

Section 2104(b)(1) of the Act requires that a proposed rule under section 911(a), SSA, be issued ''within 12 months after the date of the enactment of this section,'' and a final rule to be issued ''after public comment, within 24 months after such date of enactment.'' Section 2104(b)(2) of the Act requires that a proposed rule under section 911(b), SSA, will ''become effective with respect to reports required in the first reporting period, after the effective date of the final rule referred to in paragraph (1) of this subsection.''

Accordingly, we propose that the data exchange standard for SIDES, under both sections 911(a) and (b), SSA, become effective 30 days after publication of the final rule, consistent with the APA as codified at 5 U.S.C. 553(d). States implementing new data exchange modules after that date will utilize XML as the data exchange standard.

Additionally, we propose that the date by which SWAs will be required to comply with the data exchange standard for ICON, proposed under section 911(a), SSA, to be September 30, 2018. This will allow States to begin implementing the standard as soon as practicable, while still providing enough advance time to account for the current technology capacity of States and the fact that many States will need to make substantial changes to their technology systems to implement XML for their ICON exchanges.

Finally, the effective date of designation of XML as the data exchange standard for SIDES data exchange modules and for the real-time ICON applications, proposed under section 911(a), SSA, is 30 days after publication of the final rule, consistent with the APA as codified at 5 U.S.C. 553(d).

II. Section-by-Section

Definitions (§ 619.1)

This section proposes definitions of terms used in this rule. Most are self-explanatory; however, of particular note is paragraph (c), which defines XML, the standard we propose to use for data exchange. XML data are stored in plain text format that is both human-readable and machine-readable and provides for a software- and hardware-independent method of exchanging data over incompatible applications or systems over the internet. This definition includes any future upgrades, iterations, or releases of XML-based language.

Data Exchange Standardization for ICON (§ 619.2)

Proposed paragraph (a) designates XML as the data exchange standard for the real-time ICON applications. These applications are: Interstate Wages and Benefits Inquiries/Responses; Withdrawn/Invalid Claims; and State Identification Inquiry. These applications, used by States, are currently supported by ICON in real-time using two data exchange formats—Extended Binary Coded Decimal Interchange Code (EBCDIC) and Web

Services Description Language (WSDL), which is a XML-based language. As stated previously, the Department has selected this sub-set of the applications supported on ICON for applying a data exchange standards because they represent the applications which both ICON and States currently have capacity to implement. The Department will continue to consider ways to apply data exchange standards to the other ICON functions, but the technology solutions are currently not available. It may be over five years before these new technology solutions can be effectively applied in the ICON environment.

Proposed paragraph (b) requires that all SWAs using real-time ICON applications conform to the XML data exchange standard no later than September 30, 2018. The rule provides that a SWA may request an extension of this deadline if it demonstrates that resources are not available to meet the requirements. The request must be submitted to the Administrator of the Office of Unemployment Insurance no later than 6 months before the deadline and the request will be approved or denied within 30 days.

ICON is funded by a cooperative agreement between the Department and State of Maryland. The Maryland Department of Labor, Licensing and Regulation acts as the Department's agent to contract with a vendor for the maintenance, support, and operations of ICON. Beginning in FY 2007, the Department facilitated and later provided funding for the conversion of data exchange formats from EBCDIC to WSDL. EBCDIC is a format specifically used for mainframes and is not an interoperable standard. However, the migration of SWAs from EBCDIC to WSDL is still in its infancy requiring ICON to support a dual environment (Web Services and Mainframe).

A few SWAs currently are in the process of implementing some of the modernized, XML-based real-time applications in conjunction with their efforts to modernize their IT systems or replace outdated systems. The goal of this proposed section is to accelerate State adoption of XML-based real time applications in order to eventually eliminate the need for ICON to manage mainframe applications in addition to the XML-based applications.

The Department will continue to support SWAs' transition to modernized XML-based real-time ICON applications and expects that the proposed data exchange standard will accelerate SWAs' adoption of the XML exchange standard. The development of a single environment will result in improved efficiencies and cost savings and allow the Department to more effectively manage the development of future data exchanges and maintenance of resources.

Data Exchange Standardization for SIDES (§ 619.3)

Proposed paragraph (a) designates XML as the data exchange standard for SIDES. Proposed paragraph (b) requires that this standard apply to any Federally-funded SIDES consortium, and any future agents of the Department providing vendor services for the development, maintenance, support and operations of the SIDES. Paragraph (c) designates XML as the data exchange standard to govern the reporting of information through the SIDES data exchange modules. Paragraph (d) denotes when the standard set in paragraph (c) becomes effective.

SIDES uses Web services and the XML data format for the information exchange between the SWAs and employers. The Department is requiring that all SIDES exchanges (current and future), which are developed in whole or part with Department funds, continue to conform to the XML data exchange standard. Additionally, as States, employers, and TPAs chose to implement SIDES or new data exchange modules of SIDES, they must conform to this data exchange standard by application design.

SIDES offers two options for implementation for SWAs and employers: SIDES web services, and SIDES E-Response. Both systems are designed to meet the unique needs of businesses, large and small. For employers with a limited number of UC claims, the SIDES E-Response Web site provides an easy and efficient way to respond to information requests from SWAs. For employers and TPAs that handle a large volume of UC claims information requests, SIDES web services provides an automated, computer-to-computer interface between employers' and TPAs' IT systems and SWA networks.

Data Exchange Standardization for the UI Benefits and Tax Systems (§ 619.4)

Proposed paragraph (a) designates XML as the data exchange standard for the real-time ICON applications and SIDES data exchange modules associated with major IT modernization projects to upgrade UI Benefits and Tax Systems by SWAs using Federal funds. This proposed standard would improve the interoperability of State, Federal, and employer systems that collect and exchange information for UI administrative purposes. Linking data between these systems at the State level will allow for better service delivery and faster eligibility determinations, and should facilitate program integrity efforts.

Proposed paragraph (b) requires that, beginning on the effective date of this regulation, major IT modernization efforts funded by the Department must conform to the proposed XML data exchange standard for the implementation of the real-time ICON applications and the SIDES exchange modules.

III. Administrative Information

Executive Orders 12866 and 13563: Regulatory Planning and Review

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. This rule has been designated a ''significant regulatory action'' because, although not economically significant under section 3(f) of Executive Order 12866, it raises novel issues of law and policy. Therefore, the Department had the rule reviewed by OMB.

The Department anticipates that the changes in this NPRM would have limited, if any, direct impact on employers above and beyond any impact that would occur in the absence of the proposed rule. There will be an impact on SWAs in adopting the real-time ICON applications, but this impact may be mitigated because many States are likely to modernize their IT operations in any event, which will require implementing these interoperable real-time applications. This proposed rule also would result in several benefits that are discussed below. The Department is requesting comment on the benefits and costs of these policies.

1. Need for Regulation

Section 2104(b) of the Middle Class Tax Relief and Job Creation Act of 2012; (Pub. L. 112–96) requires the Department to issue a rule establishing data exchange standards for certain information-sharing and reporting processes. The Department is issuing this NPRM to fulfill its responsibility under the Act. As discussed earlier in this notice, these standards will

improve the interoperability of certain State, Federal, and employer-operated systems that collect and exchange information for UI administrative purposes.

2. Economic Analysis

a. Baseline and Overview

The baseline for the analysis reflects the conditions that exist (or that would exist) in the absence of a standard.

Twenty-nine States already have implemented the SIDES Separation Information data exchange, and some have begun implementation of the SIDES Earning Verification exchanges with employers. Another 16 have agreed to implement SIDES. The Department has also provided funding for the development of other SIDES formats, including Benefit Charge Notices and Nonmonetary Determinations Exchange. Subject to the availability of funds, the Department intends to provide additional funding opportunities for States that have not yet committed to implementing SIDES. Existing SIDES formats were developed using an XML-based interface, and thus, there will be no incremental cost or benefit to current users. Furthermore, while additional States may adopt SIDES in the future, this proposed rule would not require them to do so. With respect to ICON, seven SWAs are in the process of implementing modernized, XML-based real-time applications. These SWAs are adopting the XML-based real-time ICON applications due to the need for modernizing their IT systems to replace outdated systems. The Department estimates that all SWAs would transition to the XML-based real-time in about 10 years. However, this proposed rule will require the SWAs to accelerate the transition to the XML-based real-time applications by September 30, 2018. A 6-year acceleration could increase the present value cost of the project by approximately 15-to-40 percent (depending on the assumed discount rate and on how far in the future the acceleration occurs, *e.g.,* from 2024 to 2018). The Department also expects the conversion to the XML-based real-time applications by all SWAs will be a significant step to consolidating ICON applications to a single environment and realizing cost savings in ICON operations. To facilitate this transition, subject to the availability of funds, the Department plans to provide funding opportunities for SWAs to modernize to using the real-time ICON applications.

For the IT modernization of UI Benefits and Tax systems, the Department expects many SWAs to begin re-engineering their IT systems with modern technologies to replace existing systems that have ceased to function cost effectively, subject to the availability of resources and expected availability of Federal funding to support their migration to newer systems.

b. Benefits

As a result of the proposed rule, SWAs will adopt the XML standard as they implement the current and future data exchange modules of SIDES and adapt to XML-based real-time ICON applications, and will integrate these standards as they pursue overall modernization of their UI benefits and tax systems with Federal funds. The standardization of these systems is expected to result in a reduction in erroneous or fraudulent unemployment insurance payments. Economically, this reduction is properly classified as an economic ''transfer'' and consequently is discussed later (in Section d).

The proposed rule will improve the interoperability of State, Federal, and employer systems that collect and enhance information for UI administrative purposes by:

- Improving the efficiency and quality of the communications between SWAs and employers and/or their TPAs that are required to determine UC eligibility through the elimination of the need to create and mail hard copy documents;
- Increasing accuracy and reducing errors (in both directions), thereby enhancing program integrity (*i.e.,* transparency, consistency) and customer satisfaction (accuracy, flexibility);
- Improving the timeliness of information transferred between States, employers, TPAs and Federal agencies; and
- Helping large TPAs that serve employers in multiple States to train their employers in using uniform system interfaces, thereby improving efficiency, timeliness, and accuracy.

As discussed above, there are tangible program administration efficiencies for SWAs and employers in the implementation of this standard. However, implementation of these systems is still in its infancy and currently the Department does not have adequate data to support a formal cost-benefit analysis.

c. Costs

Costs to the Department

SIDES and real-time ICON applications using XML and XML-based languages have already been developed and implemented (though not by all SWAs). Consequently, the Department does not anticipate incurring any significant incremental costs as a result of the proposed rule when it is finalized. Any future data exchanges planned for SIDES or for ICON will conform to the standard proposed. However, there is no dedicated funding stream associated with assisting States with their IT modernization efforts. On occasion, when the economy is expanding and workloads fall below levels funded by the budget, remaining funds have been made available to States to support automation projects. (The Department expects to provide some funding, if available, to SWAs to help implement this proposed rule when it is finalized, as discussed in Section d.)

Costs to States

SIDES uses an XML-based interface. SWAs, employers and TPAs will incur one-time costs for the implementation of SIDES. Once a SWA, employer or TPA has implemented SIDES, they automatically conform to the XML data exchange standard. Therefore, there is no incremental cost to users for the implementation of the XML standard. SIDES is designed to offer two options for employers and TPAs, depending on their size. Large employers and TPAs can implement a version of SIDES that requires them to program their own systems to enable the communication with the SIDES applications. Large employers have an incentive to do this because it creates efficiencies in their processing of requests for information from SWAs creating a cost savings. Smaller employers who do not have sufficient numbers of claims to warrant reprogramming their computers have access to a web-based SIDES option that is also more efficient that paper processing, which also creates efficiencies and cost savings. SWAs are the users of ICON. Employers do not use ICON and so do not incur any incremental costs related to ICON.

d. Transfers

As noted above, the Department estimates that the proposed rule when finalized will lead States to adopt the modernized XML-based real-time applications of ICON approximately 6 years sooner than they would in the absence of the proposed rule. This accelerated use of the modernized ICON applications results in up to 6 years' worth of improved performance with respect to erroneous or fraudulent unemployment insurance payments. This is properly referred to as an economic ''transfer'' from individual

recipients of payments to the States. The Department has estimated the total UC overpayments in 2011 alone to be $13 billion (Annual Report Rate [6]) and overpayments that SWAs should be expected to detect and establish for recovery to be $7 billion (Operational Rate [7]) (*http://oui.doleta.gov/unemploy/improp_payrate.asp#*). Therefore, any actions that reasonably can be expected to reduce the rate of erroneous or fraudulent payments, such as the expanded use of SIDES, which is expected to result from this proposed rule, could lead to a significant dollar-value reduction in UC payments.

In addition, subject to availability, the Department expects to provide supplemental funding opportunities to States to support implementation of the data exchange standards required by the rule when it is finalized.

Paperwork Reduction Act

The purposes of the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* include minimizing the paperwork burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information, including publishing a summary of the collection of information and a brief description of the need for and proposed use of the information.

A Federal agency may not conduct or sponsor a collection of information unless it is approved by OMB under the PRA, and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number. Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

While this NPRM is not imposing new information collections, §§ 619.2–619.4 would impose formatting requirements for the data exchanges of various UI applications that may impose a burden under the PRA.

The Department is filing an Information Collection Request with OMB to support the format changes. SIDES and ICON were developed by and for the use of the States through collaboration with States and NASWA, and with funding from the Department. SIDES interfaces have been designed using XML and the States and employers participating in SIDES automatically comply with the data exchange standard proposed. Therefore, there is no additional cost burden for SIDES due to this proposed regulation. However, for States currently using the EBCDIC format for ICON, there may be costs incurred to comply with this proposed regulation. The explanation of substantive provisions regarding these data exchange standards for information sharing can be found in the preamble discussion of §§ 619.2–619.4 of this proposed rule.

The Department estimates that the one-time added burden for States to conform to the new data exchange standards for ICON will be minimal. States differ considerably in terms of hardware platforms and software used to develop their ICON applications. Additionally, the Department estimates that some States may use in-house IT staff while others may contract with IT vendors to implement the proposed data exchange standard. The estimated costs associated with this burden, includes assessing current system status, planning and implementation of changes, and any necessary hardware and software needed to implement the proposed data exchange standard for the real-time ICON applications.

The burden for the information collection exchange can be summarized as follows:

Agency: DOL–ETA.

Title of Collection: Federal-State Unemployment Insurance Program Data Exchange Standardization.

OMB ICR Reference Number Control Number: 201302–1205–003.

Affected Public: State Governments.

Total Estimated Number of Respondents: 53.

Total Estimated Number of Responses: 53.

Total Estimated Annual Burden Hours: 6,360.

Total Estimated Annual Other Costs Burden: $1,057,329.

Executive Order 13132: Federalism

Section 6 of Executive Order 13132 requires Federal agencies to consult with State entities when a regulation or policy may have a substantial direct effect on the States or the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government, within the meaning of the Executive Order.

Section 3(b) of the Executive Order further provides that Federal agencies must implement regulations that have a substantial direct effect only if statutory authority permits the regulation and it is of national significance. This proposed regulation is specifically required by the Middle Class Tax Relief and Job Creation Act of 2012.

The proposed rule does not have a substantial direct effect on the current nature of the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of Government, within the meaning of the Executive Order. The Department is exercising its existing authority to interpret Federal statutes with regard to States' administration of UI programs. In the Federal-State UI system, States have a great deal of flexibility to design their UC laws and operations as long as they comply with the broad Federal requirements in FUTA and the SSA. This regulation implements a new statutory requirement for a uniform data exchange and reporting standard and thus is no different from other UC regulations that interpret Federal law with regard to State requirements. It simply sets a new standard for data exchanges of information used in the administration of the UI program under Title III of the SSA. The Department consulted with the National Association of State Workforce Agencies' (NASWA) Information Technology Support Center (ITSC) and NASWA's UI Committee to discuss the impacts of this enactment and identify State application interfaces which will benefit by the implementation of the XML data exchange standard. NASWA agreed with the Department's approach to implement uniform data exchange standards in areas already identified as valuable to the UI system and for applications developed collaboratively with the States.

Unfunded Mandates Reform Act of 1995

This regulatory action has been reviewed in accordance with the Unfunded Mandates Reform Act of 1995. Under the Act, a Federal agency must determine whether a regulation proposes a Federal mandate that would result in the increased expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any single year. The Department has determined this rule does not include any Federal mandate that may result in increased

[6] The Annual Report rate includes fraud, nonfraud recoverable overpayments, and nonfraud non-recoverable overpayments. All causes and responsible parties are included in this rate.

[7] The Operational rate includes those overpayments that the States are reasonably expected to detect and establish for recovery—fraud and nonfraud recoverable overpayments, excluding work search, employment service registration, base period wage issues and miscellaneous causes, such as benefits paid during a period of disqualification, redeterminations, and back pay awards.

expenditure by State, local, and Tribal governments in the aggregate of more than $100 million, or increased expenditures by the private sector of more than $100 million. Most if not all of the costs of implementing this regulation will be covered by Federal funding.

Plain Language

The Department drafted this proposed rule in plain language.

Effect on Family Life

The Department certifies that this proposed rule has been assessed under section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681) for its effect on family well-being. This provision will not adversely affect the well-being of the nation's families. Therefore, the Department certifies that this rule does not adversely impact family well-being as discussed under section 654 of the Treasury and General Government Appropriations Act of 1999.

Regulatory Flexibility Act/Small Business Regulatory Enforcement Fairness Act

We have notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification according to the Regulatory Flexibility Act (RFA) at 5 U.S.C. 605(b), that this NPRM will not have a significant economic impact on a substantial number of small entities. Under the RFA, no regulatory flexibility analysis is required where the rule ''will not * * * have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). A small entity is defined as a small business, small not-for-profit organization, or small governmental jurisdiction. 5 U.S.C. 601(3)–(5).

This proposed rule establishes a data exchange standard that would be used in SIDES and ICON. ICON is used only by States and Federal entities, neither of which qualifies as small entities under the RFA. SIDES, however, is used by States and by employers, including TPAs, in the private sector. However, because SIDES already uses an XML-based interface, there is no incremental cost to current users. Furthermore, while additional employers and TPAs may adopt SIDES in the future, the rule would not require them to do so, nor would the rule affect their costs if they did. Consequently, the rule will not have a significant economic impact on a substantial number of small entities, and a Regulatory Flexibility Analysis is not required under the RFA.

In addition, this rule does not require review by the Congress under the Small Business Regulatory Enforcement Fairness Act of 1996 because it will not result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

As discussed above, the most significant effect of the rule will be to accelerate action (e.g., the adoption of the real-time XML-based ICON applications) that the Department expects to occur even in the absence of the proposed rule. The noteworthy cost of the proposed rule is the cost of this acceleration. That is, the rule would change the timing—and therefore the present value—of nominal costs that would have been incurred even in the absence of the rule. These costs will be borne by the State and Federal governments, not by small entities.

List of Subjects in 20 CFR Part 619

Employment and Training Administration, Labor, and Unemployment Compensation.

For the reasons stated in the preamble, the Department proposes to amend 20 CFR chapter V by adding part 619 as set forth below:

PART 619—UNEMPLOYMENT COMPENSATION DATA EXCHANGE STANDARDIZATION FOR IMPROVED INTEROPERABILITY

Sec.

619.1 Definitions.
619.2 Data exchange standardization for ICON.
619.3 Data exchange standardization for SIDES.
619.4 Data exchange standardization for the UI Benefits and Tax Systems.

Authority: 42 U.S.C. 1111; Section 2104(b) of Pub. L. 112–96; 42 U.S.C. 1302(a).

§ 619.1 Definitions.

As used in this part—

Administrator of the Office of Unemployment Insurance means the Department's Employment and Training Administration's chief administrative officer directly responsible for the operation of the Unemployment Insurance (UI) program and oversight of the Unemployment Compensation (UC) program and UC laws.

Department means the United States Department of Labor.

Extensible Markup Language or *XML* means a markup language that defines a set of rules for encoding documents in a format designed to structure, store and transport data between applications or systems over the Internet. This term includes any future upgrades, iterations, or releases of XML-based language.

Federal funds or *Federally-funded* means funds that include, but are not limited to:

(1) Supplemental budget funds that are designated by the Department for State IT modernization efforts;

(2) General State UI administration funding for State program operations (an administrative grant issued by the Department at the beginning of each fiscal year); and

(3) Special UI funding distributions.

Interstate Connection Network or *ICON* means a secure multi-purpose telecommunications network that supports the transfer of data among the SWAs.

Interstate Wages and Benefits Inquiries/Responses means the ICON application which supports online transmission of interstate wages and benefits inquiries and responses between SWAs.

Major IT Modernization Project means conversion, re-engineering, rewriting, or transferring of an existing system to a modernized framework such as transferring a process from mainframe operations to web-based operations, converting to modern computer programming languages, or upgrading software libraries, protocols, or hardware platform and infrastructure. These are projects to upgrade UI Benefits and Tax Systems by SWAs using Federal funds.

National Association of State Workforce Agencies or *NASWA* means the organization of State administrators of unemployment insurance laws (SWAs), employment services, training programs, employment statistics and labor market information and other programs and services provided through the publicly-funded State workforce system, or its successor organization.

State or *States* refers to, individually or collectively, the 50 States of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and the United States Virgin Islands.

State Identification Inquiry means the ICON application which allows SWAs to inquire about wages reported to other SWAs by Social Security Number.

State Information Data Exchange System or *SIDES* means an automated response system used by SWAs to collect claim-related information from employers and third-party administrators.

State unemployment compensation law or *UC law* means the law of a State approved under Section 3304(a) of the Internal Revenue Code of 1986 (26 U.S.C. 3304(a)).

State Workforce Agency or *SWA* means the agency of the State charged with the administration of the State's Unemployment Compensation (UC) law.

Unemployment compensation or *UC* means cash benefits payable to individuals with respect to their unemployment, as defined in 26 U.S.C. 3306(h).

Unemployment Insurance or *UI* means the Federal-State system and operations administering and implementing UC law.

Withdrawn/Invalid Claims means the ICON application which allows for the posting and viewing of withdrawn or invalid claim information for SWAs.

§ 619.2 Data exchange standardization for ICON.

(a) XML is the data exchange standard for the real-time ICON applications. These applications are: Interstate Wages and Benefits Inquiries/Responses; Withdrawn/Invalid Claims; and State Identification Inquiry.

(b) All SWAs using real-time ICON applications must comply with this XML data exchange standard no later than September 30, 2018. A SWA may request an extension of this deadline if it demonstrates that resources are not available to meet this requirement. These requests must be submitted in writing to the Administrator of the Office of Unemployment Insurance no later than 6 months before the deadline; requests will be approved or denied within 30 days.

§ 619.3 Data exchange standardization for SIDES.

(a) XML is the data exchange standard for SIDES.

(b) This standard applies to any Federally-funded SIDES consortium, and any future agents of the Department providing vendor services for the development, maintenance, support, and operations of the SIDES, and for any State that adopts SIDES. A SIDES consortium involves a group of two or more States jointly establishing a project team to oversee the design, development, and implementation of a new SIDES data exchange module. As States implement SIDES or new data exchange modules of SIDES, they must conform to this data exchange standard by application design.

(c) XML is designated as the data exchange standard to govern the reporting of information through SIDES data exchange modules. The regulation applies to current SIDES data exchange modules and any future SIDES data exchange modules developed with Federal funds.

(d) The standard designated in paragraphs (a), (b), and (c) of this section is effective [date 30 days after publication of the Final Rule in the **Federal Register**].

§ 619.4 Data exchange standardization for the UI Benefits and Tax Systems.

(a) XML is the data exchange standard for the real time ICON applications set out in § 619.2 and for the SIDES exchanges set out in § 619.3 associated with major IT modernization projects, to upgrade UI Benefits and Tax Systems by SWAs using Federal funds.

(b) The standard designated in paragraph (a) of this section is effective [date 30 days after publication of the Final Rule in the **Federal Register**].

Signed at Washington, DC, this 20th day of February, 2013.

Jane Oates,

Assistant Secretary, Employment and Training Administration, Labor.

[FR Doc. 2013–04332 Filed 2–22–13; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 812, and 814

[Docket No. FDA–2013–N–0080]

RIN 0910–AG48

Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on acceptance of data from clinical studies for medical devices. We are proposing to require that clinical studies conducted outside the United States as support for an investigational device exemption (IDE) application, a premarket notification (510(k)) submission, a premarket approval (PMA) application, a product development protocol (PDP) application, or a humanitarian device exemption (HDE) application be conducted in accordance with good clinical practice (GCP), which includes obtaining and documenting the review and approval of the study by an independent ethics committee (IEC) and obtaining and documenting freely given informed consent of study subjects. The proposed rule is intended to update the standards for FDA acceptance of data from clinical studies conducted outside the United States and to help ensure the protection of human subjects and the quality and integrity of data obtained from these studies. As part of this proposed rule, we are also proposing to amend the IDE and 510(k) regulations to address the requirements for FDA acceptance of data from clinical studies conducted inside the United States. The proposed amendments are intended to provide consistency in FDA requirements for acceptance of clinical data, whatever the application or submission type.

DATES: Submit either electronic or written comments on the proposed rule by May 28, 2013. See section VIII of this document for the proposed effective date of a final rule based on this proposed rule. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by March 27, 2013, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0080 and/or Regulatory Information Number (RIN) number 0910–AG48, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document):

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and

Docket No. FDA–2013–N–0080 and RIN 0910–AG48 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), 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:
Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1651, Silver Spring, MD 20993, 301–796–6563; and
Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

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I. Background

A. Current Regulations on Clinical Studies for Medical Devices

1. Clinical Studies Conducted Outside the United States

FDA regulations for PMA of medical devices in part 814 (21 CFR part 814) permit the acceptance of data from clinical studies conducted outside the United States and submitted in support of a PMA application if certain conditions are met. Current § 814.15(a) states that a study conducted outside the United States submitted in support of a PMA and conducted under an IDE shall comply with part 812 (21 CFR part 812). The provision in § 814.15(a) further states that a study conducted outside the United States submitted in support of a PMA and not conducted under an IDE shall comply with the provisions in paragraph (b) or (c) of § 814.15, as applicable.

Under § 814.15(b), FDA will accept studies submitted in support of a PMA which have been conducted outside the United States and begun on or after November 19, 1986, if the data are valid and the investigator has conducted the studies in conformance with the Declaration of Helsinki or the laws and regulations of the country in which the research is conducted, whichever accords greater protection to the human subjects. If the standards of the country are used, the applicant must state in detail any differences between those standards and the Declaration of Helsinki and explain why they offer greater protection to the human subjects.

Under § 814.15(c), FDA will accept studies submitted in support of a PMA that have been conducted outside the United States and begun before November 19, 1986, if FDA is satisfied that the data are scientifically valid and that the rights, safety, and welfare of human subjects have not been violated.

Additionally, § 814.15(d) specifies criteria for acceptance of a PMA application for marketing approval based solely on foreign clinical data, and § 814.15(e) encourages applicants to meet with FDA officials prior to submission of a PMA application that will be based solely on foreign clinical data.

Currently, FDA regulations for premarket notification in part 807, subpart E (21 CFR 807, subpart E), commonly referred to as a ''510(k) submission,'' and investigational device exemptions in part 812 do not address the requirements for FDA acceptance of data from clinical studies conducted outside the United States.

2. Clinical Studies Conducted Inside the United States

FDA's PMA regulations require applications that include the results of clinical investigations involving human subjects to include a statement with respect to each study that: (1) It was conducted in compliance with the institutional review board regulations in part 56 (21 CFR part 56), or was not subject to those regulations under §§ 56.104 or 56.105, and it was conducted in compliance with the informed consent regulations in part 50 (21 CFR part 50); or (2) if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance (see § 814.20(b)(6)(ii)(A)). The regulations also require a statement that each study was conducted in compliance with part 812 concerning sponsors of clinical investigations and clinical investigators, or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance (§ 814.20(b)(6)(ii)(B)).

Currently, FDA's 510(k) and IDE regulations do not address the requirements for FDA acceptance of data from clinical studies conducted inside the United States to support a 510(k) submission or IDE application.

B. Reasons for Proposing To Revise the Regulations

FDA believes that the requirements for FDA's acceptance of data from clinical studies should be consistent regardless of the type of submission or application in which the data are submitted to FDA. For data from clinical studies conducted inside the United States, we propose to require statements in 510(k) submissions and IDE applications that are similar to those currently required for PMA applications, to help ensure the protection of human subjects and the quality and integrity of data obtained from these studies. For data from clinical studies conducted outside the United States, FDA believes that revision of the requirements for FDA acceptance of data from these clinical studies is needed for several reasons, described in this document.

1. Updating Standards for FDA Acceptance of Data From Clinical Studies Conducted Outside the United States

The standards for protecting human subjects have evolved considerably since the issuance of the PMA regulations in 1986. Several notable documents have been published (examples listed in this document) identifying ethical and other principles that provide assurance of the quality and integrity of clinical data and adequate protection of human subjects. As a whole, these documents include principles important to the conduct of clinical trials such as adverse event reporting, sponsor monitoring, and training of study personnel.

- Several documents issued by the International Conference on Harmonisation (ICH) of Technical Requirements for Registration of Pharmaceuticals for Human Use, including the document entitled ''Good Clinical Practice: Consolidated Guideline'' (ICH E6);
- ''Clinical Investigation of Medical Devices for Human Subjects—Good Clinical Practice,'' issued by the International Organization for Standardization, ISO 14155:2011;
- ''Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products,'' issued by the World Health Organization, 1995;
- ''Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries,'' published by the National Bioethics Advisory Commission, 2001;
- ''International Ethical Guidelines for Biomedical Research Involving Human Subjects,'' prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization, 2002;
- ''Good Clinical Practices: Document of the Americas,'' issued by the Pan American Health Organization, 2004; and
- The 1989, 1996, 2000, 2002, 2004, and 2008 amendments to the ''Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects,'' adopted by the World Medical Association.

Many of these documents articulate ethical and policy standards for clinical trials, often referred to as GCP. Generally speaking, GCP is defined by research and regulatory communities as ''a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.'' [1] GCP incorporates important ethical principles, such as review by an IEC; the need for freely given informed consent; conduct of clinical trials only by qualified individuals; and recognition that the rights, safety, and well-being of trial subjects take precedence over the interests of science and society. GCP enumerates specific roles and responsibilities of various parties, including monitoring of the trial and reporting adverse events.

Many of the principles underlying GCP have already been incorporated in FDA's regulations, including parts 50, 56, 812, and 814. For example, the regulations in subpart B of part 50 contain the requirements for obtaining the informed consent of human subjects in clinical investigations. Subparts C and E of part 812 describe the responsibilities of sponsors and investigators, respectively, regarding IDE studies, including conformance to parts 50 and 56 on the use of informed consent and institutional review boards (IRBs), respectively. FDA considers an IRB, as defined in § 56.102(g) and subject to the requirements of part 56, to be one type of IEC (see § 312.3 (21 CFR 312.3)).

We are proposing to revise § 814.15 and to amend parts 807 and 812 to incorporate GCP into the requirements for FDA acceptance of data from clinical studies conducted outside the United States to support an IDE or a device marketing application or submission (an application under sections 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e and 360j, respectively) or a premarket notification submission under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). We believe that the proposed standard helps to ensure adequate human subject protection and the quality and integrity of data obtained from such studies, while also being sufficiently flexible to accommodate differences in how countries regulate the conduct of clinical research and obtain informed consent.

2. Ensuring Quality and Integrity of Data

FDA believes that revising parts 807, 812, and 814 to expressly incorporate GCP will help provide greater assurance of the quality and integrity of the data obtained from clinical studies conducted outside the United States and submitted in support of an application or submission to FDA. It has become increasingly recognized that the development, recording, and reporting of data that are scientifically valid are critical responsibilities of investigators and sponsors and are part of a responsible relationship between these entities and study subjects. The proposed revisions to parts 807, 812, and 814 should help ensure data quality and integrity in several ways. These include: (1) Specifying that GCP includes providing assurance that study data and reported results are credible and accurate and (2) requiring that supporting information on a clinical study conducted outside the United States includes, as appropriate, a description of how the sponsor monitored the trial and ensured that the study was carried out consistent with the study protocol.

The informed consent provisions embodied in GCP also contribute to the integrity of data obtained in clinical studies. The informed consent process enables each subject to receive high-quality information about the implications of participation in the clinical trial. The process also provides an opportunity for the subject and investigator to discuss important information about the subject's condition, potential adverse events, and other factors (such as use of concurrent therapy, illegal drug use, or alcohol abuse) that could confound the study results if they remained undisclosed.

3. Standardizing Human Subject Protections

The current regulations under part 814 require that clinical studies outside the United States submitted in support of a PMA be conducted in conformance with the 1983 version of the Declaration of Helsinki or the laws and regulations of the country in which the research is conducted, whichever accords greater protection to the human subjects. If the standards of the country are used, the applicant is required to state in detail any differences between those standards and the 1983 version of the Declaration of Helsinki and explain why they offer greater protection to the human subjects.

Under the current regulations, in a study involving multinational investigational sites, several different standards may be followed leading to increased complexity in the conduct of the study. The proposal to require that clinical studies conducted outside the United States comply with GCP provides a unifying approach, which may simplify such trials and decrease the regulatory burden on sponsors.

The investigational new drug regulations in part 312 address FDA acceptance of foreign clinical studies not conducted under an investigational new drug application (IND) as support for an IND or marketing application for a drug or biological product. Effective October 27, 2008, foreign clinical studies not conducted under an IND are required to be conducted in accordance with GCP as defined in § 312.120. The proposed revisions to parts 807, 812, and 814 will provide greater consistency with the regulations for drugs and biological products regarding FDA acceptance of foreign clinical studies.

[1] Definition from the ICH document entitled ''Good Clinical Practice: Consolidated Guideline'' (ICH E6), which FDA adopted for use as guidance for industry in 1997 (62 FR 25692, May 9, 1997).

4. Clarifying Requirements for FDA Acceptance of Data From Clinical Studies Submitted in Support of Premarket Notifications and Investigational Device Exemptions

Clinical studies may be used to support a 510(k) submission or an IDE application; however, parts 807 and 812 currently do not address the requirements for FDA acceptance of data from such studies. The proposed revisions will identify the requirements for FDA acceptance of data from clinical studies under these regulations, whether the studies were conducted inside or outside the United States. This proposal is intended to ensure the quality and integrity of clinical data submitted to FDA in 510(k) submissions and IDE applications and to bring consistency in FDA requirements for acceptance of clinical data, whatever the application or submission type.

II. Description of the Proposed Rule

A. Definitions

We propose to add a definition for an IEC to the IDE regulation under § 812.3. We propose to define an IEC as a ''review panel that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection.'' Under the proposal, an adequately constituted IEC includes a reasonable number of members with the qualifications and experience to perform the IEC's functions. The proposed definition of an IEC also specifies that an IRB, as defined in § 56.102(g) and subject to the requirements of part 56, is one type of IEC.

B. Clinical Studies Conducted Outside the United States

We propose to amend the IDE regulations by adding a new section, proposed § 812.28, to address the requirements for FDA acceptance of data from clinical studies conducted outside the United States. An IDE is typically not issued for a clinical study conducted outside the United States; however, there is a small subset of trials conducted outside the United States where IDEs have been issued, for example, certain studies conducted by the Department of Defense. The use of the term ''clinical studies conducted outside the United States'' is intended to address studies not conducted under an IDE and does not indicate a change in overall policy for device studies conducted outside the United States.

The current requirements for FDA acceptance of data from clinical studies conducted outside the United States in support of a PMA application are located at § 814.15, in the PMA regulations. We are proposing to place the revised requirements primarily in the IDE regulations, in part because the requirements for device clinical studies are primarily located in these regulations and in part to create consistency with the drug regulations, which address requirements for FDA acceptance of foreign clinical data in the investigational new drug regulations in part 312. Additionally, similar to these drug regulations, which address requirements for FDA acceptance of foreign clinical data as support for an IND or marketing application for a drug or biological product, the proposed revised device regulations address requirements for FDA acceptance of foreign clinical data as support for not only a PMA but also an IDE or other device marketing application or submission, including a 510(k) or an HDE application.

1. Requirements for FDA Acceptance of Data From Clinical Studies Conducted Outside the United States

Proposed § 812.28(a) would identify requirements for FDA acceptance of data from clinical studies conducted outside the United States to support an IDE or device marketing application or submission. It would rely upon conformance with GCP, including review and approval by an IEC and obtaining and documenting the freely given informed consent of study subjects. Under proposed § 812.28(a)(1), we would require a statement that the study was conducted in accordance with GCP. For purposes of this section, GCP would be defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected. Proposed § 812.28(a)(1) states that GCP includes review and approval (or provision of a favorable opinion) by an IEC before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of a subject (or the subject's legally authorized representative if the subject is unable to provide informed consent) before initiating a study. Proposed § 812.28(a)(1) further states that GCP does not require informed consent in life-threatening situations when the IEC reviewing the study finds, before initiation of the study, that informed consent is not feasible and that either the conditions present are consistent with those described in §§ 50.23 or 50.24(a) of this chapter (concerning exemptions from informed consent requirements in life-threatening situations), or the measures described in the study protocol or elsewhere will protect the rights, safety, and well-being of subjects. This provision would be consistent with the Good Clinical Practice guidance,[2] which recommends that a legally authorized representative provide informed consent or that the requirement of informed consent be waived under such circumstances.

Proposed § 812.28(a)(2) states the second condition for FDA's acceptance of data from a clinical study conducted outside the United States as support for an IDE or a device marketing application or submission to FDA. A statement would be required assuring the availability of the data from the study to FDA for validation through an onsite inspection if the Agency deems it necessary (and an inspection is otherwise authorized by law) or through other appropriate means. FDA may need to inspect records relating to data from a foreign study submitted in support of a PMA, for example, to resolve any uncertainties about whether the study was conducted in accordance with GCP.

2. Requirements for Supporting Information

Proposed § 812.28(b) describes the supporting information to be submitted, in addition to information required elsewhere in parts 807, 812, and 814, when data from clinical studies conducted outside the United States are submitted as support for an IDE or device marketing application or submission. Under proposed § 812.28(b)(1) through (b)(12), the description of the actions the sponsor or applicant took to ensure that the research conformed to GCP as described in § 812.28(a)(1) would include the following information:

- Names and addresses of investigators and research facilities (if an address has changed since the research was conducted, the address where records are maintained should be provided);
- The investigator's qualifications;
- A description of the research facility(ies);
- A detailed summary of the protocol and results of the study, and, should FDA request, certified copies of case

[2] ''Good Clinical Practice: Consolidated Guideline'' (ICH E6), which FDA adopted for use as guidance for industry in 1997 (62 FR 25692, May 9, 1997).

records maintained by the investigator or additional background data such as hospital or other institutional records;

- Either a statement that the device used in the clinical study conducted outside the United States is identical to the device that is the subject of the submission or application, or a detailed description of the device and each important component (including materials and specifications), ingredient, property, and principle of operation of the device used in the clinical study conducted outside the United States and a comparison to the device that is the subject of the submission or application that indicates how the studied device is similar to and/or different from the device that is the subject of the submission or application;
- If the study is intended to support the safety and effectiveness of a device, a discussion demonstrating that the data and information constitute valid scientific evidence within the meaning of § 860.7 (21 CFR 860.7);
- The name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 812.3(t). The sponsor or applicant must maintain records supporting such a statement, including records describing the qualifications of IEC members, and make these records available for Agency review upon request. Although the names of IEC members are required under § 312.120(b)(6) for foreign clinical studies used to support drug and biological product applications, we are proposing to require only the qualifications of the IEC members for device studies due to the reported difficulties of obtaining the names of IEC members in some countries;
- A summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion;
- A description of how informed consent was obtained;
- A description of what incentives, if any, were provided to subjects to participate in the study;
- A description of how the sponsor(s) monitored the study and ensured that the study was carried out consistent with the study protocol; and
- A description of how investigators were trained to comply with GCP (as described in § 812.28(a)(1)) and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained. Any written commitments by investigators to comply with GCP and the study protocol must be maintained by the sponsor or applicant and made available for Agency review upon request.

We believe that the proposed supporting information, combined with an onsite inspection, if necessary, would provide us with the ability to determine whether a particular clinical study conducted outside the United States had been conducted in accordance with GCP.

3. Requirements for Records

Proposed § 812.28(c) describes the retention requirements for records required by this section with regard to a clinical study conducted outside the United States. If the study is submitted in support of an IDE, the records must be retained for 2 years after the termination or completion of the IDE, as described in proposed § 812.28(c)(1). If the study is submitted in support of a premarket notification, premarket approval application, a notice of completion of a product development protocol, or a humanitarian device exemption application, the records must be retained for 2 years after an Agency decision on that submission or application, as described in proposed § 812.28(c)(2).

C. Revisions to § 812.2—Applicability

We propose to amend § 812.2 by removing current paragraphs (b)(2) and (e), which refer to requirements that are no longer necessary because the dates involved have passed. Specifically, paragraph (b)(2) indicated that investigations of a device, except as described in paragraph (e), that were begun on or before July 16, 1980, and were completed on or before January 19, 1981, would be considered to have approved applications for IDEs, unless FDA notified a sponsor under § 812.20(a) that approval of an application was required.

Paragraph (e) required a sponsor who had an IND application for a device in effect on July 16, 1980, and who wished to continue the investigation after 90 days after that date, to comply with paragraph (b)(1) if not a significant risk device or obtain FDA approval under § 812.30 of an IDE application.

To accommodate the proposed removal of paragraph (b)(2), paragraphs (b) and (b)(1) would be combined and proposed paragraph (b) states that unless FDA has notified a sponsor under § 812.20(a) that approval of an application is required, an investigation of a device other than a significant risk device is considered to have an approved application for IDE, if the device is not a banned device and the sponsor complies with paragraphs (b)(1) through (b)(7). Note that paragraphs (b)(1) through (b)(7) are the proposed redesignated paragraphs (b)(1)(i) through (b)(1)(vii).

The current IDE regulations identify varying requirements for clinical investigations of devices based on whether the study is of a significant risk or nonsignificant risk device or would meet the exemption requirements in § 812.2(c). We propose that requirements for clinical studies conducted outside the United States, which are to be submitted to FDA in support of an IDE or a device marketing application or submission, also be subject to varying requirements, depending on whether the study is of a significant risk device or nonsignificant risk device or would meet the exemption requirements in § 812.2(c).

Proposed paragraph (e) identifies these varying requirements. Proposed § 812.2(e)(1) requires studies of a significant risk device, as defined in § 812.3(m), to comply with the requirements of the principles of good clinical practice, as defined in § 812.28(a), maintenance of supporting information as described in § 812.28(b), and records retention as described in § 812.28(c). Proposed § 812.2(e)(2) requires studies of a device, other than a significant risk device, or clinical device investigations that would otherwise meet the exemption requirements in § 812.2(c), to comply with these same requirements concerning good clinical practice and records retention, but with lesser requirements concerning maintenance of the supporting information (i.e., only those requirements at § 812.28(b)(1), (4), (5), (7), (8), (9), and (11)), in recognition of their differing regulatory status compared to significant risk device investigations.

D. Requirements for Report of Prior Investigations in IDE Applications

Current § 812.27(a) requires the report of prior investigations to include reports of all prior clinical, animal, and laboratory testing of the device but does not include specific requirements for reports of clinical testing. Proposed § 812.27(b)(4) would describe the specific requirements for reports of clinical testing conducted both inside and outside the United States.

Proposed (b)(4)(i) requires that, if information on clinical studies conducted in the United States is provided, the report of prior investigations shall include a statement that all such studies have been conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50, the institutional

review boards regulations in part 56, and the investigational device exemptions regulations in part 812, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. It also provides that failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical study.

Proposed § 812.27(b)(4)(ii) states, if information on clinical studies conducted outside the United States is provided to support an IDE, the requirements under § 812.2(e) and § 812.28 of this chapter apply, where the requirements for such studies are detailed. If any such study was not conducted in accordance with GCP as described in § 812.28(a), the report of prior investigations shall include a brief statement of the reason for not conducting the study in accordance with GCP and a description of steps taken to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects were protected. This description is necessary for studies conducted outside the United States because of the greater difficulty in conducting bioresearch monitoring inspections of foreign sites. It further states that failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical study.

We remind sponsors and applicants that they must submit all studies and other information required under applicable FDA regulations for medical devices. For example, as part of our review of an IDE, we consider all relevant data bearing on the safe use of the proposed medical device, including data obtained in any clinical studies conducted outside the United States—even data from studies that are not carried out in accordance with GCP.

E. Requirements for 510(k) Submissions

The requirements for premarket notifications are described in part 807, subpart E. The information required in a premarket notification submission is detailed at § 807.87, but this section does not discuss the requirements relating to clinical data submitted, where applicable, to support a premarket notification submission. Most premarket notifications do not include clinical data and would not be affected by this proposed rule; however, we believe the requirements for FDA acceptance of clinical data should be the same for premarket notifications that do contain clinical data as for other device applications in order to achieve consistency in FDA's clinical data requirements. For 510(k) submissions relying upon literature only, the proposed requirements at new § 807.87(j) would not generally apply.

For the subset of premarket notifications that do contain clinical data, we propose to add a new paragraph (j) to describe requirements relating to clinical data submitted to support a premarket notification and to redesignate existing paragraph (j) as paragraph (k), existing paragraph (k) as paragraph (l), and existing paragraph (l) as paragraph (m).

For a premarket notification submission containing clinical data, proposed paragraph (j)(1) requires, if the data are from clinical studies conducted in the United States, a statement that each study was conducted in compliance with applicable requirements in parts 50, 56, and 812 of this chapter, or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

Proposed paragraph (j)(2) states that, if the data are from clinical studies conducted outside the United States, the requirements under § 812.2(e) and § 812.28 of this chapter apply. If any such study was not conducted in accordance with GCP as described in § 812.28(a), the submission must include a brief statement of the reason for not conducting the study in accordance with GCP and a description of steps taken to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects were protected. This description is necessary for studies conducted outside the United States because of the greater difficulty in conducting bioresearch monitoring inspections of foreign sites. This proposal will help ensure consistency in FDA clinical data requirements, whatever the type of product application or submission at issue.

F. Requirements for PMA Applications

The requirements for premarket approval are described in part 814. The requirements for FDA acceptance of clinical data submitted in support of a PMA from studies conducted outside the United States are currently addressed in § 814.15. As previously indicated, we propose to address these requirements primarily in the IDE regulations. Therefore, removal of current paragraphs (a), (b), and (c) in § 814.15 is proposed. Proposed paragraph (a) will identify the general requirement that a study conducted outside the United States and submitted in support of a PMA shall comply with the relevant provisions of part 812 as set forth in § 812.2(e) and § 812.28. To accommodate this change, current paragraphs (d) and (e) will be redesignated as paragraphs (b) and (c) respectively.

To address the requirements for PMA applications that include data from clinical studies conducted outside the United States, we propose to amend § 814.20(b), the content requirements for a PMA application, specifically the requirements for technical sections containing results of clinical investigations in paragraph (6)(ii). We propose to add a new subparagraph (C) stating that, for clinical studies conducted outside the United States intended to support the PMA, the requirements under § 812.2(e) and § 812.28 of this chapter apply. Required information may be incorporated by cross-reference to another section of the application that contains such information. If any such study was not conducted in accordance with GCP as described in § 812.28(a), the application must include a brief statement of the reason for not conducting the study in accordance with GCP and a description of steps taken to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects were protected. This description is necessary for studies conducted outside the United States because of the greater difficulty in conducting bioresearch monitoring inspections of foreign sites. We remind sponsors and applicants that failure or inability to comply with these requirements does not justify failure to provide information concerning investigations bearing on the safety or effectiveness of a device undergoing PMA review (see § 814.20(b)(8)(ii) and sections 515(c)(1)(A) and 515(c)(2)(A)(v) of the FD&C Act).

We also propose to amend the provisions in § 814.45 concerning denial of approval of a PMA application. We propose to revise paragraph (a)(5) to include as a reason for denial that any clinical investigation involving human subjects described in the PMA application, which was subject to GCP referenced in § 814.15(a) and described in § 812.28(a), was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

Further, we propose to amend § 814.46 regarding withdrawal of approval of a PMA application, specifically to revise paragraph (a)(4) to allow FDA to withdraw approval if FDA

determines that any clinical investigation involving human subjects described in the PMA application, subject to GCP referenced in § 814.15(a) and described in § 812.28(a), was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

Finally, we propose to amend § 814.104 regarding the required contents of HDE applications. Although these applications remain subject to modified requirements for application contents compared to premarket approval applications, we propose that they would not be exempt from the new proposed requirement in § 814.20(b)(6)(ii)(C) regarding submission of data from clinical studies conducted outside the United States. The proposed language also clarifies that, in those situations where data from clinical studies conducted inside the United States are submitted in support of a HDE application, the requirements in § 814.20(b)(6)(ii)(A)–(B) apply.

Premarket approval is considered to include a PDP declared to be completed by FDA (see § 814.19 and section 515(f) of the FD&C Act). Although PDPs are rarely submitted, if a PDP is supported by data from clinical studies conducted outside the United States, the requirements in § 814.15 would apply.

G. Correction to the Regulations Regarding Record Retention for Clinical Studies Conducted Under IDE

When the regulations for premarket approval were amended to address HDE applications, the IDE regulations were not amended because at the time clinical studies supporting an HDE application were not anticipated (largely because of the small numbers of patients affected and the infeasibility of conducting large, randomized clinical trials). Experience has demonstrated that many HDE applications do include data from clinical studies (usually from small, non-randomized studies) in order to meet the required standard for approval. Therefore, we are proposing to revise § 812.140(d) regarding retention of records for clinical research conducted under an IDE to include records supporting an HDE application.

We are similarly proposing to revise § 812.140(d) regarding retention of records for clinical research conducted under an IDE to include records supporting a premarket notification submission, where applicable. Most premarket notification submissions do not include clinical data. For the subset that do contain clinical data, we are proposing that record retention requirements be the same as for other product applications and submissions that contain clinical data, to ensure consistency in FDA clinical data requirements and the integrity and reliability of clinical data submitted. This proposed revision to § 812.140(d) is also consistent with proposed § 812.28(c), described in this document, regarding retention of records for clinical research conducted outside the United States. Each of these proposed revisions would achieve consistency in FDA requirements for clinical data record retention regardless of the application or submission type.

III. Legal Authority

We are proposing to issue this rule under the authority of the provisions of the FD&C Act that apply to medical devices (21 U.S.C. 301 *et seq.*).

To permit devices to be shipped for investigational use, section 520(g) of the FD&C Act authorizes the exemption of investigational devices from otherwise applicable provisions of the FD&C Act relating to misbranding, registration, premarket notification, performance standards, premarket approval, banned devices, records and reporting requirements, good manufacturing practice requirements, and requirements relating to the use of color additives in devices. Under section 520(g) of the FD&C Act, the procedures and conditions that FDA [3] is authorized to prescribe for granting an IDE include the requirement that an application be submitted to FDA, in such form and manner as the Agency shall specify, and other requirements necessary for the protection of the public health and safety. Section 520(g) also requires that the information submitted in support of an IDE application be ''adequate to justify the proposed clinical testing.'' In investigations involving human subjects, the person applying for the exemption (the sponsor) must comply with a number of requirements to assure that the rights and safety of subjects are adequately protected. To provide for flexibility in regulatory requirements, section 520(g) of the FD&C Act permits variations in the procedures and conditions governing IDEs, depending on the nature, scope, duration, and purpose of the study.

Section 515(c)(1)(A) of the FD&C Act requires that PMA applications contain, among other information, full reports of all information, published or known to or which should reasonably be known to the PMA applicant, concerning investigations bearing on the safety or effectiveness of the device for which premarket approval is sought. Section 515(d)(2) of the FD&C Act states that FDA shall deny approval of a PMA application if the Agency finds that ''there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof'' or ''there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof,'' among other reasons. Whether data from an investigation involving human subjects support the safety or effectiveness of a device depends, in part, on whether the study was conducted in accordance with ethical and other principles that provide assurance of the quality and integrity of clinical data and adequate protection of human subjects. Even if the data derive from improperly conducted clinical studies, the data must be submitted in a PMA application under section 515(c)(1)(A) of the FD&C Act.

Under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)), determinations of substantial equivalence include some inquiry into the comparable safety and effectiveness of the device, where appropriate. For devices that have the same intended use as the predicate device but different technological characteristics, information submitted to demonstrate substantial equivalence must include ''appropriate clinical or scientific data[,] if deemed necessary'' by FDA, showing that ''the device is as safe and effective as a legally marketed device'' and ''does not raise different questions of safety and effectiveness than the predicate device.'' As described in this document, whether data from a clinical study support the safety or effectiveness of a device—or, in the context of some premarket notifications, the comparable safety and effectiveness of a device as part of a substantial equivalence demonstration—depends in part on whether the study was conducted in accordance with ethical and other principles that provide assurance of the quality and integrity of clinical data and adequate protection of human subjects.

Under section 520(m) of the FD&C Act, FDA may grant an HDE if FDA finds that: The device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; the device would

[3] In light of section 1003(d) of the FD&C Act (21 U.S.C. 393(d)) and the Secretary of Health and Human Services' (the Secretary's) delegation to the Commissioner of Food and Drugs, statutory references to ''the Secretary'' in the discussion of legal authority have been changed to ''FDA'' or the ''Agency.''

not be available to a person with such disease or condition unless FDA grants the exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition; and the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Again, whether data from clinical studies submitted in an HDE application support that the probable benefits of the device outweigh its risks depends, in part, on whether the study was conducted in accordance with ethical and other principles that provide assurance of the quality and integrity of clinical data and adequate protection of human subjects.

Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes the Agency to issue regulations for the efficient enforcement of the FD&C Act.

These statutory provisions authorize us to issue regulations describing when we may consider data from clinical trials, whether conducted inside or outside the United States, as reliable evidence supporting an IDE, PMA, 510(k), PDP, or HDE application or submission.

IV. Analysis of Economic Impacts

A. Introduction

FDA has examined the impacts of the 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). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the requirements are likely to impose a burden on a substantial number of affected small entities, the Agency projects that the proposed rule, if finalized, will have a significant economic impact on a substantial number of small entities, and has conducted an Initial Regulatory Flexibility Analysis as required under the Regulatory Flexibility Act.

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, 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 $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The proposed rule will require that clinical studies conducted outside the United States and used to support IDE applications, 510(k) submissions, PMA applications, HDE applications, or PDP applications comply with GCP. GCP standards include review and approval by an independent ethics committee and obtaining and documenting human subjects' informed consent. In addition, the proposed rule seeks to amend the 510(k), HDE, and IDE requirements for FDA acceptance of data from clinical studies conducted inside the United States to parallel existing FDA requirements for PMA applications. FDA has not quantified the benefits of the proposed rule that would come from increased collection of information that would provide FDA with greater assurance of clinical data quality and human subject protection, particularly as it pertains to clinical studies conducted outside the United States. Costs would arise from increased labor costs associated with obtaining, documenting, and maintaining records to meet the proposed requirements. The estimated costs of complying with these requirements range from $0.30 million to $24.03 million.

The full analysis of economic impacts is available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm* (See also Ref. 1).

V. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the OMB under the PRA (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting and recordkeeping burden. Included in the 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.

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.

Title: Human Subject Protection; Data Requirements for Medical Device Related Clinical Studies

Description: In this document is a discussion of the regulatory provisions we believe are subject to the PRA and the probable information collection burden associated with these provisions.

Description of Respondents: The reporting and recordkeeping requirements referenced in this document are imposed on a device sponsor or applicant.

Section 807.87 Information Required in a Premarket Notification Submission (OMB Control No. 0910–0120)

Section 807.87 is being amended to address requirements for 510(k) submissions supported by clinical data. For clinical studies conducted in the United States, submitters will be required to submit a statement as described in § 807.87(j)(1). For clinical studies conducted outside the United States, submitters will be required to submit a statement as described in § 807.87(j)(2).

Section 812.2 Clinical Studies Conducted Outside the United States (OMB Control No. 0910–0078)

For any clinical studies conducted outside the United States to be submitted in support of: (1) An IDE, (2) a PMA, (3) a PDP, (4) an HDE or (5) a 510(k), the sponsor or applicant will be required to maintain supporting information and retain records as described in § 812.2(e).

Section 812.27 Report of Prior Investigations (OMB Control No. 0910–0078)

Section 812.27 is being amended to address requirements for IDE applications supported by clinical data. For clinical studies conducted in the United States, sponsors will be required to submit a statement as described in § 812.27(b)(4)(i). For clinical studies conducted outside the United States, sponsors will be required to submit a statement as described in § 812.27(b)(4)(ii).

Section 812.28 Clinical Studies Conducted Outside the United States (OMB Control No. 0910–NEW)

Section 812.28 is being proposed to address the requirements for acceptance of foreign clinical data to support an IDE or a device marketing application or submission. The sponsor or applicant will be required to submit statements as described in § 812.28(a)(1) and (a)(2); provide a description of the actions the sponsor or applicant took to ensure that the research conformed to GCP that includes the information in § 812.28(b)(1) through (b)(12) or a cross-reference to another section of the submission where the information is located; and retain the records as described in § 812.28(c).

Section 812.140 Records Retention (OMB Control No. 0910–0078)

Section 812.140 is being amended to address record retention requirements for investigators and sponsors. An investigator or sponsor will be required to maintain records as described in § 812.140(d).

Section 814.20 Application (OMB Control No. 0910–0231)

Section 814.20 is being amended to address requirements for a PMA supported by data from clinical studies conducted outside the United States. The applicant will be required to submit a statement and information as required by § 814.20(b)(6)(ii)(C).

Section 814.104 Original Applications (OMB Control No. 0910–0332)

Section 814.104 is being amended to address submission of data from clinical studies in an HDE. To the extent the applicant includes clinical information, the applicant will be required to include the information and statements described in § 814.104(b)(4)(i).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.87	1,500	1	1,500	0.25 (15 minutes)	375
812.27(b)(4)(i)	400	1	400	1	400
812.27(b)(4)(ii)	100	1	100	0.25 (15 minutes)	25
812.28(a)(1)	1,500	1	1,500	0.25 (15 minutes)	375
812.28(a)(2)	1,500	1	1,500	0.25 (15 minutes)	375
812.28(b)	1,500	1	1,500	10	15,000
814.20	10	1	10	0.50 (30 minutes)	5
814.104	10	1	10	8	80
Total					16,635

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—(ONGOING) ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
812.2(e)	500	1	500	1	500
812.28(c)	1,500	1	1,500	1	1,500
812.140	10	1	10	1	10
Total					2,010

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The total estimated burden imposed by these information collection requirements is 18,645 annual hours. The estimated burden is based on the most recent empirical data in the relevant collections with the numbers updated to reflect the current burden of these requirements.

It should be noted that while the information collection requirements referenced in this document are revisions to current approved information collections, these collection requirements are being submitted to OMB as a new information collection, with the expectation the currently approved requirements will be amended. As such the following collections of information will be amended and submitted to OMB for approval as revisions to currently approved information collections once the rule is finalized and the collections are due for renewal. The collections to be amended include: Investigational Device Exemptions Reports and Records—21 CFR part 812, OMB control number 0910–0078; Premarket Notification—21 CFR part 807, subpart E, OMB control number 0910–0120; Premarket Approval of Medical Devices—21 CFR part 814, OMB control number 0910–0231; and Medical

Devices: Humanitarian Use Device—21 CFR part 814, subpart H, OMB control number 0910–0332.

To ensure that comments on these new information collection requirements are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Human Subject Protection; Data Requirements for Medical Device Related Clinical Studies.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Proposed Effective Date

We propose that any final rule based on this proposal become effective 180 days after the final rule is published in the **Federal Register**.

IX. Request for Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

X. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. Preliminary Regulatory Impact Analysis of the Proposed Rule to Human Subject Protection; Acceptance of Data From Clinical Studies for Medical Devices, Docket No. FDA–2013–N–0080.

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR parts 807, 812, and 814 be amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 1. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

■ 2. Section 807.87 is amended by redesignating paragraphs (j), (k), and (l) as paragraphs (k), (l), and (m), respectively, and by adding new paragraph (j) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(j) For a submission containing clinical data:

(1) If the data are from clinical studies conducted in the United States, a statement that each study was conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 56 of this chapter, and the investigational device exemptions regulations in part 812 of this chapter, or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(2) If the data are from clinical studies conducted outside the United States, the requirements under §§ 812.2(e) and 812.28 of this chapter apply. If any such study was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a), include a brief statement of the reason for not conducting the study in accordance with GCP and a description of steps taken to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects were protected.

* * * * *

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 3. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383; 42 U.S.C. 216, 241, 262, 263b–263n.

■ 4. Section 812.2 is amended by removing paragraphs (b) introductory text, (b)(1) introductory text, (b)(2), and (e); redesignating paragraphs (b)(1)(i) through (b)(1)(vii) as paragraphs (b)(1) through (b)(7), respectively; and adding new paragraphs (b) introductory text and (e) to read as follows:

§ 812.2 Applicability.

* * * * *

(b) *Abbreviated requirements.* Unless FDA has notified a sponsor under § 812.20(a) that approval of an application is required, an investigation of a device other than a significant risk device is considered to have an approved application for IDE if the device is not a banned device and the sponsor:

* * * * *

(e) *Clinical studies conducted outside the United States.* Clinical studies conducted outside the United States to be submitted in support of an IDE or a device marketing application or submission (an application under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act or a premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act), are subject to the following requirements:

(1) For a significant risk device, as defined in § 812.3(m), the principles of

good clinical practice, as defined in § 812.28(a), maintenance of supporting information as described in § 812.28(b), and records retention as described in § 812.28(c).

(2) For a device, other than a significant risk device, or a device investigation that would otherwise meet the exemption requirements in § 812.2(c), the principles of good clinical practice, as defined in § 812.28(a), maintenance of the supporting information as described in § 812.28(b)(1), (b)(4), (b)(5), (b)(7), (b)(8), (b)(9), and (b)(11), and records retention as described in § 812.28(c).

■ 5. Section 812.3 is amended by adding paragraph (t) to read as follows:

§ 812.3 Definitions.

* * * * *

(t) *Independent ethics committee (IEC)* means a review panel that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection. An institutional review board (IRB), as defined in § 56.102(g) of this chapter and subject to the requirements of part 56 of this chapter, is one type of IEC.

■ 6. Section 812.27 is amended by adding paragraph (b)(4) to read as follows:

§ 812.27 Report of prior investigations.

* * * * *

(b) * * *

(4)(i) If information on clinical studies conducted in the United States is provided, a statement that all such studies have been conducted in compliance with applicable requirements in the protection of human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 56 of this chapter, and the investigational device exemptions regulations in part 812, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical study.

(ii) If information on clinical studies conducted outside the United States is provided to support the IDE, the requirements under §§ 812.2(e) and 812.28 apply. If any such study was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a), the report of prior investigations shall include a brief statement of the reason for not conducting the study in accordance with GCP and a description of steps taken to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects were protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical study.

■ 7. Section 812.28 is added to subpart B to read as follows:

§ 812.28 Clinical studies conducted outside the United States.

(a) *Acceptance of data from clinical studies conducted outside the United States to support an IDE or a device marketing application or submission (an application under section 515 or 520(m) of the Federal Food, Drug, and Cosmetic Act or a premarket notification submission under section 510(k) of the Federal Food, Drug, and Cosmetic Act).* FDA will accept information on clinical studies conducted outside the United States to support an IDE or a device marketing application or submission if the data are valid, the information specified in paragraph (b) of this section and required elsewhere in parts 807, 812, and 814 of this chapter, as applicable, is submitted, and the following conditions are met:

(1) A statement is provided that all such studies have been conducted in accordance with good clinical practice (GCP). For the purposes of this section, GCP is defined as a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials in a way that provides assurance that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects are protected. GCP includes review and approval (or provision of a favorable opinion) by an independent ethics committee (IEC) before initiating a study, continuing review of an ongoing study by an IEC, and obtaining and documenting the freely given informed consent of the subject (or a subject's legally authorized representative, if the subject is unable to provide informed consent) before initiating a study. GCP does not require informed consent in life-threatening situations when the IEC reviewing the study finds, before initiation of the study, that informed consent is not feasible and either that the conditions present are consistent with those described in §§ 50.23 or 50.24(a) of this chapter, or that the measures described in the study protocol or elsewhere will protect the rights, safety, and well-being of subjects.

(2) A statement is provided assuring the availability of the data from the study to FDA for validation through an onsite inspection if the Agency deems it necessary, and if otherwise authorized by law, or through other appropriate means.

(b) *Supporting information.* A sponsor or applicant who submits data from a clinical study conducted outside the United States in support of an IDE or a device marketing application or submission, in addition to information required elsewhere in parts 807, 812, and 814 of this chapter, as applicable, shall provide a description of the actions the sponsor or applicant took to ensure that the research conformed to GCP as described in paragraph (a)(1) of this section. The description is not required to duplicate information already submitted in the application or submission. Instead, the description must provide either the following information or a cross-reference to another section of the application or submission where the information is located:

(1) Names and addresses of investigators and research facilities;

(2) The investigator's qualifications;

(3) A description of the research facility(ies);

(4) A detailed summary of the protocol and results of the study and, should FDA request, certified copies of case records maintained by the investigator or additional background data such as hospital or other institutional records;

(5) Either a statement that the device used in the study conducted outside the United States is identical to the device that is the subject of the submission or application, or a detailed description of the device and each important component (including all materials and specifications), ingredient, property, and principle of operation of the device used in the study conducted outside the United States and a comparison to the device that is the subject of the submission or application that indicates how the studied device is similar to and/or different from the device that is the subject of the submission or application;

(6) If the study is intended to support the safety and effectiveness of a device, a discussion demonstrating that the data and information constitute valid scientific evidence within the meaning of § 860.7 of this chapter;

(7) The name and address of the IEC that reviewed the study and a statement that the IEC meets the definition in § 812.3(t). The sponsor or applicant must maintain records supporting such statement, including records describing

the qualifications of IEC members, and make these records available for Agency review upon request;

(8) A summary of the IEC's decision to approve or modify and approve the study, or to provide a favorable opinion;

(9) A description of how informed consent was obtained;

(10) A description of what incentives, if any, were provided to subjects to participate in the study;

(11) A description of how the sponsor(s) monitored the study and ensured that the study was carried out consistently with the study protocol; and

(12) A description of how investigators were trained to comply with GCP (as described in paragraph (a)(1) of this section) and to conduct the study in accordance with the study protocol, and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained. Any signed written commitments by investigators must be maintained by the sponsor or applicant and made available for Agency review upon request.

(c) *Records.* A sponsor or applicant must retain the records required by this section for a clinical study conducted outside the United States as follows:

(1) If the study is submitted in support of an IDE, for 2 years after the termination or completion of the IDE;

(2) If the study is submitted in support of a premarket notification submission, premarket approval application, a notice of completion of a product development protocol, or a humanitarian device exemption application, for 2 years after an Agency decision on that submission or application.

■ 8. Section 812.140 is amended by revising paragraph (d) to read as follows:

§ 812.140 Records.

* * * * *

(d) *Retention period.* An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application, a notice of completion of a product development protocol, a humanitarian device exemption application, or a premarket notification submission.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 9. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

■ 10. Section 814.15 is amended by removing paragraphs (b) and (c); by redesignating paragraph (d) as paragraph (b) and paragraph (e) as paragraph (c); and by revising paragraph (a) to read as follows:

§ 814.15 Research conducted outside the United States.

(a) A clinical study conducted outside the United States and submitted in support of a PMA shall comply with the relevant provisions of part 812 of this chapter as set forth in §§ 812.2(e) and 812.28 of this chapter.

* * * * *

■ 11. Section 814.20 is amended by adding paragraph (b)(6)(ii)(C) to read as follows:

§ 814.20 Application.

* * * * *

(b) * * *

(6) * * *

(ii) * * *

(C) For clinical studies conducted outside the United States that are intended to support the PMA, the requirements under §§ 812.2(e) and 812.28 of this chapter apply. Required information may be incorporated by cross-reference to another section of the application that contains such information. If any such study was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a) of this chapter, include a brief statement of the reason for not conducting the study in accordance with GCP and a description of steps taken to assure that the data and reported results are credible and accurate and that the rights, safety, and well-being of trial subjects were protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical study.

* * * * *

■ 12. Section 814.45 is amended by revising paragraph (a)(5) to read as follows:

§ 814.45 Denial of approval of a PMA.

(a) * * *

(5) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter or GCP referenced in § 814.15(a) and described in § 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

* * * * *

■ 13. Section 814.46 is amended by revising paragraph (a)(4) to read as follows:

§ 814.46 Withdrawal of approval of a PMA.

(a) * * *

(4) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in part 56 of this chapter or informed consent regulations in part 50 of this chapter or GCP referenced in § 814.15(a) and described in § 812.28(a) of this chapter, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected or the supporting data were determined to be otherwise unreliable.

* * * * *

■ 14. Section 814.104 is amended by revising paragraph (b)(4)(i) to read as follows:

§ 814.104 Original applications.

* * * * *

(b) * * *

(4) * * *

(i) In lieu of the summaries, conclusions, and results from clinical investigations required under § 814.20(b)(3)(v)(B), (b)(3)(vi), and the introductory text of (b)(6)(ii), the applicant shall include the summaries, conclusions, and results of all clinical experience or investigations (whether adverse or supportive) reasonably obtainable by the applicant that are relevant to an assessment of the risks and probable benefits of the device and to the extent the applicant includes such clinical information, the applicant shall include the statements described in § 814.20(b)(6)(ii)(A) and (b)(6)(ii)(B) with respect to clinical investigations conducted in the United States and the information described in § 814.20(b)(6)(ii)(C) with respect to clinical investigations conducted outside the United States; and

* * * * *

Dated: February 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04201 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Parts 585 and 590

[Docket ID: BOEM–2012–0077]

RIN 1010–AD77

Timing Requirements for the Submission of a Site Assessment Plan (SAP) or General Activities Plan (GAP) for a Renewable Energy Project on the Outer Continental Shelf (OCS)

AGENCIES: Bureau of Ocean Energy Management (BOEM); Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the timing requirements for submitting a Site Assessment Plan (SAP) or General Activities Plan (GAP) pursuant to the regulations governing renewable energy and alternate uses of existing facilities on the Outer Continental Shelf (OCS). Under this proposed rule, all OCS renewable energy leases and grants will have a preliminary term of 12 months in which a lessee or grantee must submit a SAP or a GAP. BOEM is taking this action because the current regulations provide timing requirements for submission of SAPs and GAPs that have proven to be impractical.

DATES: *Effective Date:* Submit comments by March 27, 2013. BOEM may not fully consider comments received after this date.

Instructions: Direct your comments to Docket ID No. BOEM–2012–0077. BOEM's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or by email. The www.regulations.gov Web site is an ''anonymous access'' system, which means BOEM will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to BOEM without going through www.regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, BOEM recommends that you include your name and other contact information in the body of your comment along with any disk or CD–ROM you submit. If BOEM cannot read your comment due to technical difficulties and cannot contact you for clarification, BOEM may not be able to consider your comment. Electronic files should avoid the use of special characters or any form of encryption, and be free of any defects or viruses.

ADDRESSES: Please use the Regulation Identifier Number (RIN) 1010–AD77 for comments directed to BOEM.

You may submit comments on the rulemaking by any of the following methods. See also Public Availability of Comments under Procedural Matters.

- *Federal eRulemaking Portal: http://www.regulations.gov.* In the entry titled ''Enter Keyword or ID,'' enter BOEM–2012–0077, then click search. Follow the instructions to submit public comments and view supporting and related materials available for this rulemaking. We will post all comments.
- *Mail or hand-carry BOEM comments to the Department of the Interior; Bureau of Ocean Energy Management; Attention:* Office of Policy, Regulations and Analysis (OPRA); 381 Elden Street, MS–4001, Herndon, Virginia 20170–4817. Please reference ''Timing Requirements for the Submission of a Site Assessment Plan (SAP) or a General Activities Plan (GAP) for a Renewable Energy Project on the Outer Continental Shelf (OCS)'' in your comments and include your name and return address.
- *If you believe that this rule imposes any new information collection requirement(s), send your comments on the information collection in this rule to:* Interior Desk Officer 1010–AD77, Office of Management and Budget; 202–395–5806 (fax); email: *oira_docket@omb.eop.gov.* Please also send a copy of these comments to BOEM. *Docket:* All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy during normal business hours at the Office of Policy, Regulations and Analysis, Bureau of Ocean Energy Management, U.S. Department of the Interior, 381 Elden Street, Herndon, Virginia 20170.

FOR FURTHER INFORMATION CONTACT: Jennifer Golladay, Office of Renewable Energy Programs, at *jennifer.golladay@boem.gov* or 703–787–1688; or Peter Meffert, BOEM, Office of Policy, Regulations and Analysis, at *Peter.Meffert@boem.gov* or 703–787–1610.

SUPPLEMENTARY INFORMATION: This rule is designed to increase efficiency and reduce the burden of regulations, since it extends the timeframes for lessees and operators to submit plans and makes it possible for a Right-of-Use and Easement (RUE) to be approved while a GAP is still pending.

Summary of Proposed Changes

30 CFR Part 585

This proposed rule would amend the timing requirements for submitting a Site Assessment Plan (SAP) or General Activities Plan (GAP) pursuant to the regulations governing renewable energy and alternate uses of existing facilities on the Outer Continental Shelf in 30 CFR part 585. Under the proposed rule, all OCS renewable energy leases and grants would have a preliminary term of 12 months in which the lessee or grantee must submit a SAP or a GAP. BOEM is proposing these changes because the current regulations specify timing requirements for submission of SAPs and GAPs that have proven to be impractical.

The current regulations require a lessee to submit a SAP or a GAP, and a grantee to submit a GAP, within six months of lease or grant issuance in cases where the lease or grant is issued following completion of a competitive process. In cases where a lease or grant is issued noncompetitively, the current regulations require the requestor to submit a SAP or GAP within 60 days after BOEM issues a determination of no competitive interest and before the issuance of either a grant or a lease. In communications with BOEM, prospective OCS renewable energy lessees and grantees have indicated that these timeframes—especially the 60-day requirement—are too short, and that most developers intend to request departures from the regulatory requirements pertaining to the timing of SAP and GAP submission. Moreover, seasonal weather conditions may exacerbate time constraints associated with the preparation of a SAP or GAP.

The proposed rule would create additional flexibility for the program by amending pertinent sections of the regulations at 30 CFR part 585 as follows:

(1) Deleting the requirement for submission of a SAP within 60 days of

a notice of a determination of no competitive interest and removing related references (§§ 585.212 and 585.231) to that requirement;

(2) Changing the preliminary lease term from six months to 12 months and deleting the statements that leases issued noncompetitively do not have a preliminary term (§§ 585.235 and 585.236); removing the current (a)(2) in § 585.235 and redesignating (a)(3) as (a)(2).

(3) Providing a preliminary grant term of 12 months (§ 585.303);

(4) Deleting the requirement for submission of a GAP within 60 days of a notice of determination of no competitive interest (§ 585.306);

(5) Deleting the requirement for approving a GAP before issuing a grant (§ 585.309);

(6) Replacing references to the six-month preliminary lease term with references to the 12-month preliminary term in the sections pertaining to payment of rent (§§ 585.500, 585.503, and 585.505); and

(7) Changing the deadline for SAP and GAP submission for leases and grants. Currently, for commercial leases issued competitively, there is a six months deadline after lease issuance to submit a SAP or a GAP. For a non-competitive lease, the current requirement is that a SAP or GAP be submitted 60 days after the determination of no competitive interest (DNCI). Both of these timeframes would be changed under this rule, which would provide that any lease or grant have a preliminary term of 12 months for submitting the required plan. In addition, some minor revisions or deletions of related references are made in §§ 585.601, 585.611, 585.612, 585.640, 585.646, and 585.647. Related provisions and references concerning compliance with Coastal Zone Management Act (CZMA) federal consistency requirements would be revised in these sections, as well as in §§ 585.230 and 585.305.

The original timing requirements were designed to encourage diligent development and to enable efficient review and approval processes for lease issuance and plan approval. The original timeframes and approaches still may be achieved under the amended regulations. Since lessees or grantees would have up to 12 months to submit a SAP or a GAP, any person who wishes to do so within the original timeframes may still do so. Likewise, if a prospective lessee or grantee desires and is able to take advantage of the efficiency associated with coupling review and approval of a lease or grant request with a SAP or GAP, by submitting the plan soon after a DNCI, in the case of a non-competitive lease, or upon lease execution, in the case of a competitive lease, it still may do so. The new timing requirements in this proposed rule are intended to strike a proper balance between promoting diligent activity on OCS renewable energy leases and grants and aligning with the needs and expectations of OCS renewable energy developers in planning and implementing their projects. Comments are requested as to whether the proposed amendments would provide adequate time for project planning and implementation, and, if not, how much time should be provided.

The proposed amendment to part 585, to provide a preliminary term of 12 months for all OCS renewable energy leases and grants, would affect many sections. Provisions in §§ 585.212, 585.230, 585.231, 585.235, and 585.236 would be changed to implement the universal 12-month preliminary lease term and to revise the related lease issuance process accordingly. Sections 585.303, 585.305, 585.306, and 585.309 would be changed to implement the universal 12-month preliminary grant term and revise the related grant issuance process accordingly. Sections 585.500, 585.503, and 585.505 would be changed to provide for the submission of rent payments in accordance with the new 12-month term. Sections 585.601, 585.611, 585.612, 585.640, 585.646, and 585.647 would be changed to reflect the effects of providing the universal 12-month preliminary term and to revise the related plan review and approval processes accordingly.

In addition to the changes described above, the proposed rule would make conforming changes to part 585 that would incorporate the Coastal Zone Management Act (CZMA) terminology included in part 500 to assure that BOEM coordinates with the appropriate State CZMA agencies. Sections affected would include: §§ 585.102, 585.203, 585.211, 585.238, 585.306, and 585.902.

Section 585.112. ''CZMA State'' Definition

The proposed rule would add a new definition of the term ''CZMA State'' to delineate more accurately which States can review an OCS activity for consistency with a State's approved coastal zone management program under the Coastal Zone Management Act, 16 U.S.C. 1451 *et seq.* The proposed rule would provide that a ''CZMA State'' means any State in which a particular activity on the OCS would have a reasonably foreseeable direct or indirect effect on any coastal use or resource of that State. The definition would contain a cross reference to the National Oceanic and Atmospheric Administration (NOAA) regulation, 15 CFR 930.11(g), defining the term ''effect on any coastal use or resource.''

The Federal consistency concept under the CZMA is different from the ''Affected State'' concept under the Outer Continental Shelf Lands Act (OCSLA), 43 U.S.C. 1331 *et seq.* The CZMA does not use the term ''Affected State;'' the phrase in the CZMA is ''affects any land or water use or natural resource of the coastal zone,'' 16 U.S.C. 1456(c). The proposed rule is based on CZMA regulations that use the phrase ''effects on any coastal use or resource,'' 15 CFR 930.11 and 930.33. Under the CZMA, only a State that demonstrates a reasonably foreseeable coastal effect from a particular activity can review an activity for consistency with its approved coastal management program (CMP) (this is the ''effects test''). As NOAA stated in the preamble to its 2006 regulations, ''[t]here are no geographical boundaries to the application of the effects test.'' (71 FR 788 (2006)).

OCSLA, however, uses the term ''Affected State'' to identify which States are entitled to participate in BOEM's leasing program. OCSLA defines ''Affected State'' to include any State for which an activity would be within the State ''if its boundaries were extended seaward to the outer margin of the outer Continental Shelf,'' 43 U.S.C. 1331 and 1333(a)(2)(A). OCSLA uses the words ''Affected State'' whenever it intends to invoke that definition. But significantly, when OCSLA refers to compliance with the CZMA, it does not use the term ''Affected State;'' instead, it uses the language of the CZMA. *See* 43 U.S.C. 1351(d).

BOEM's current regulations do not make clear the distinction between CZMA and OCSLA requirements. When the current BOEM regulations implement the sections of OCSLA that mention the CZMA, they use the term ''Affected State'' instead of the CZMA concept ''affecting any land use or water use in the coastal zone of a State.'' The dual usage of this term is seen, for example, in § 585.611 or § 585.628, because these sections attempt to implement 43 U.S.C. 1351(a)(3)—concerning sending a SAP or COP to an ''affected State'' under the OCSLA—and 43 U.S.C. 1351(d)—concerning sending consistency certifications to States when their land use or water use in the coastal zone is affected under the CZMA. Although BOEM is already required by statute to comply with the terms of the CZMA, adding conforming terminology

in these regulations is intended to provide clarity and avoid confusion.

In addition to proposing a new definition, we propose to substitute the newly defined term ''CZMA State'' for the term ''Affected State'' in a number of regulatory sections in part 585 that are intended to implement the CZMA requirements rather than OCSLA requirements.

The proposed rule would also revise the definition of the terms *You* and *your* to include contractors and subcontractors of the listed entities.

Section 585.500(a).

The proposed rule would revise § 585.500(a) by providing the correct Web site to the BOEM *Fees for Services* page (application fees) for electronic payments.

Section 590.4(b)(1).

The proposed rule would provide the correct Web site to the BOEM *Fees for Services* page (application fees) for electronic payments.

Legal Authority

The authority for this rulemaking is the broad rulemaking provision of OCSLA, as set forth in 43 U.S.C. 1334(a), that authorizes the Secretary of the Interior to prescribe and amend such rules and regulations as may be necessary to administer a leasing program, or necessary and proper in order to provide for the prevention of waste and conservation of natural resources of the OCS.

The authority for the portion of this rulemaking dealing with the production, transportation, or transmission of energy from sources other than oil and gas, and alternate uses of the OCS, is Section 8(p)(8) of OCSLA (43 U.S.C. 1337(p)(8)), which authorizes the Secretary to issue any necessary regulations to carry out Subsection 8(p) of OCSLA.

Procedural Matters

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is not significant.

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

This proposed rule is not a significant rule as determined by the Office of Management and Budget (OMB) and is not subject to review under E.O. 12866. For the most part, this rule proposes administrative corrections and clarifications to the existing regulations. Other changes consist of the reorganization of selected renewable energy regulations.

Because this proposed rule otherwise does not propose to alter or change requirements for leasing, compliance, or enforcement from those set forth in existing regulations, no costs are estimated for this rulemaking. We welcome comments on any unidentified new compliance costs or benefits expected to be realized by this proposed rule.

(1) This proposed rule would not have an annual effect of $100 million or more on the economy. It would not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) This proposed rule would not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This proposed rule would not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This proposed rule would not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

Regulatory Flexibility Act

The Department of the Interior certifies that this proposed rule would not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rulemaking would affect large and small entities through the clarification of the existing regulatory requirements under the reorganized regulations of part 585.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and ten Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of BOEM, call 1–888–734–3247. You may comment to the Small Business Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

Small Business Regulatory Enforcement Fairness Act

This proposed rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*). This proposed rule:

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

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

(c) Would not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. The requirements apply to all entities operating to develop renewable resources on the OCS.

Unfunded Mandates Reform Act of 1995

This proposed rule would not impose an unfunded mandate on state, local, or tribal governments, or the private sector, of more than $100 million per year. This proposed rule would not have a significant or unique effect on state, local, or tribal governments, or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this proposed rule would not have significant takings implications. This proposed rule would not be a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this proposed rule would not have federalism implications. This proposed rule would not substantially affect the relationship between the Federal and state governments. To the extent that

state and local governments have a role in OCS activities, this proposed rule would not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This proposed rule would comply with the requirements of E.O. 12988. Specifically, this rule:

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

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

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, BOEM has evaluated this proposed rule and determined that it would have no substantial effects on federally recognized Indian tribes.

Paperwork Reduction Act (PRA) of 1995

This proposed rule does not contain new information collection requirements, and a submission under the PRA is not required. Therefore, an information collection request is not being submitted to the Office of Management and Budget (OMB) for review and approval under 44 U.S.C. 3501 *et seq.* The rule refers to, but does not change, the information collection requirements in 30 CFR 585. The OMB has approved the referenced information collection under OMB Control Number 1010–0176 (31,124 hours and $3,816,000 non-hour cost burden).

National Environmental Policy Act of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. BOEM evaluated this rule under the criteria of the National Environmental Policy Act, 43 CFR part 46 and 516 Departmental Manual 15. This rule would meet the criteria for categorical exclusion set forth in 43 CFR 46.210(i) in that this proposed rule is '' * * * of an administrative, financial, legal, technical, or procedural nature * * *'' Furthermore, we have evaluated this proposed rule to determine if it involves any of the extraordinary circumstances that would require an environmental assessment or an environmental impact statement as set forth in 43 CFR 46.215. We concluded that this rule does not meet any of the criteria for extraordinary circumstances as set forth in 516 Departmental Manual 2 (Appendix 2).

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554, app. C § 515, 114 Stat. 2763, 2763A–153–154).

Effects of the Nation's Energy Supply (E.O. 13211)

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

Clarity of This Regulation

We are required by E.O. 12866, E.O. 12988, and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

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

(c) Use clear language rather than jargon;

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

(e) Use lists and tables wherever such lists or tables would be more helpful.

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

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we would be able to do so.

List of Subjects

30 CFR Part 585

Bonding, Coastal zone, Continental shelf, Electric power, Energy, Environmental impact statements, Environmental protection, Incorporation by Reference, Marine resources, Natural resources, Payments, Public lands, Public lands—rights-of-way, Reporting and recordkeeping requirements, Revenue sharing, Solar energy.

30 CFR Part 590

Administrative practice and procedure.

Dated: February 14, 2013.

Tommy P. Beaudreau

Principal Deputy Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Bureau of Ocean Energy Management (BOEM) proposes to amend Chapter V as follows:

PART 585—RENEWABLE ENERGY AND ALTERNATE USES OF EXISTING FACILITIES ON THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 585 continues to read as follows:

Authority: 43 U.S.C. 1331 *et seq.*; 43 U.S.C. 1337.

■ 2. Revise § 585.102 paragraph (e) to read as follows:

§ 585.102 What are BOEM's responsibilities under this part?

* * * * *

(e) BOEM will provide for coordination and consultation with the Governor of any State, the State CZMA agency of any CZMA State, or the executive of any local government or Indian Tribe that may be affected by a lease, easement, or ROW under this subsection. BOEM may invite any affected State Governor, a State CZMA agency, an affected Indian Tribe, and/or an affected local government executive to join in establishing a task force or other joint planning or coordination agreement in carrying out our responsibilities under this part.

■ 3. Amend § 585.112 by adding the definitions of CZMA State and State CZMA Agency in alphabetical order and by revising the definition of *You* and *your* to read as follows:

§ 585.112 Definitions.

* * * * *

CZMA State means any State in which an activity on the OCS would have a reasonably foreseeable direct or indirect effect on any coastal use or resource of that State. See 15 CFR 930.11(g).

* * * * *

State CZMA Agency means the agency within a CZMA State responsible for making Federal consistency decisions under the State Coastal Management Program (CMP) approved under the Coastal Zone Management Act (CZMA), 16 U.S.C. 1451 *et seq.*

* * * * *

You and *your* refer to an applicant, lessee, the operator, a designated agent of the lessee(s) or designated operator, ROW grant holder, RUE grant holder, or Alternate Use RUE grant holder under this part, or the possessive of each, depending on the context. The terms *You* and *your* also includes contractors and subcontractors of the entities specified in the preceding sentence.

* * * * *

■ 4. Revise § 585.203 to read as follows:

§ 585.203 With whom will BOEM consult before issuance of a lease?

For leases issued under this part, through either the competitive or noncompetitive process, BOEM, prior to issuing the lease, will coordinate and consult with relevant Federal agencies (including, in particular, those agencies involved in planning activities that are undertaken to avoid or minimize conflicts among users and maximize the economic and ecological benefits of the OCS, including multifaceted spatial planning efforts), the Governor of any CZMA State or of any affected State, the State CZMA agency, the executive of any affected local government, and any affected Indian Tribe, as directed by subsections 8(p)(4) and (7) of the OCS Lands Act or other relevant Federal laws. Federal statutes that require BOEM to consult with interested parties or Federal agencies or to respond to findings of those agencies, include the Endangered Species Act (ESA) and the Magnuson-Stevens Fishery Conservation and Management Act (MSA). BOEM also engages in consultation with state and tribal historic preservations officers pursuant to the National Historic Preservation Act (NHPA).

■ 5. Revise § 585.211 paragraph (c) to read as follows:

§ 585.211 What is the process for the competitive issuance of leases?

* * * * *

(c) Proposed Sale Notice. BOEM will publish the Proposed Sale Notice in the **Federal Register**, and send it to the Governor of any CZMA State or of any affected State, the State CZMA agency, an affected Indian Tribe, and the executive of any local government that might be affected. The comment period following issuance of a Proposed Sale Notice will be 60 days.

* * * * *

■ 6. Revise § 585.212 paragraph (a) to read as follows:

§ 585.212 What is the process BOEM will follow if there is reason to believe that competitors have withdrawn before the Final Sale Notice is issued?

* * * * *

(a) If, after reviewing comments in response to the notice of Request for Interest, BOEM determines that there is no competitive interest in the lease area, and one party wishes to acquire a lease, we will discontinue the competitive process and will proceed with the noncompetitive process set forth in § 585.231(d) through (i) following receipt of the acquisition fee specified in § 585.502(a).

* * * * *

■ 7. In § 585.230 redesignate paragraphs (e) through (g) as paragraphs (f) through (h) and add new paragraph (e) to read as follows:

§ 585.230 May I request a lease if there is no Call?

* * * * *

(e) A copy of your consistency certification and necessary data and information as submitted to the State CZMA agency pursuant to 15 CFR part 930, subpart D.

* * * * *

■ 8. Revise § 585.231 paragraphs (d), (e), (f) and (g)(2) to read as follows:

§ 585.231 How will BOEM process my unsolicited request for a noncompetitive lease?

* * * * *

(d) If BOEM determines that there is no competitive interest in a lease, we will publish in the **Federal Register** a notice of Determination of No Competitive Interest.

(e) BOEM will coordinate and consult with affected Federal agencies, CZMA states, and any affected state and local governments, and affected Indian tribes in the review of noncompetitive lease requests.

(f) After completing the review of your lease request, BOEM may offer you a noncompetitive lease.

(g) * * *

(2) Within 45 days after you receive the lease copies, you must pay the first 12-months rent, as required in § 585.503.

* * * * *

■ 9. Revise § 585.235 paragraph (a) to read as follows:

§ 585.235 If I have a commercial lease, how long will my lease remain in effect?

(a) For commercial leases, the lease terms and applicable automatic extensions are as shown in the following table:

Lease term	Automatic extensions	Requirements
(1) Each commercial lease will have a preliminary term of 12 months, within which must be submitted: (i) a SAP; or (ii) a combined SAP and Construction and Operations Plan (COP). The preliminary term begins on the effective date of the lease.	If BOEM receives a SAP that satisfies the requirements of §§ 585.605 through 585.613 or a SAP/COP that satisfies the requirements of §§ 585.605 through 585.613 and §§ 585.620 through 585.629, the preliminary term will be extended for the time necessary for us to conduct technical and environmental reviews of the SAP or SAP/COP.	The SAP must meet the requirements of §§ 585.605 through 585.613. The SAP/COP must meet the requirements of §§ 585.605 through 585.613 and §§ 585.620 through 585.629.
(2) A commercial lease will have a site assessment term of five years to conduct site assessment activities and to submit a COP, if a SAP/COP has not been submitted. Your site assessment term begins when BOEM approves your SAP or SAP/COP.	If we receive a COP that satisfies the requirements of §§ 585.620 through 585.629, the site assessment term will be automatically extended for the period of time necessary for us to conduct technical and environmental reviews of the COP.	The COP must meet the requirements of §§ 585.620 through 585.629 of this part.

Lease term	Automatic extensions	Requirements
(3) A commercial lease will have an operations term of 25 years, unless a longer term is negotiated by the parties. A request for lease renewal must be submitted two years before the end of the operations term. If you submit a COP, your operations term begins on the date that BOEM approves the COP. If you submit a SAP/COP, your operations term begins five years after the earliest of the following dates: when BOEM approves the SAP/COP; when fabrication begins; or, when installation commences.	.....	The lease renewal request must meet the requirements, as provided in §§ 585.425 through 585.429.
(4) A commercial lease may have additional time added to the operations term through a lease renewal. The term of the lease renewal will not exceed the original term of the lease, unless a longer term is negotiated by the parties. The lease renewal term begins upon expiration of the original operations term.	NOTE: BOEM may order or grant a suspension of the operations term, as provided in §§ 585.415 through 585.421 thereby effectively extending the term of the lease.	

* * * * *

■ 10. Revise § 585.236 paragraph (a) to read as follows:

§ 585.236 If I have a limited lease, how long will my lease remain in effect?

(a) For limited leases, the lease terms are as shown in the following table:

Lease term	Extension or suspension	Requirements
(1) Each limited lease has a preliminary term of 12 months to submit a GAP. The preliminary term begins on the effective date of the lease.	If we receive a GAP that satisfies the requirements of §§ 585.640 through 585.648 of this part, the preliminary term will be automatically extended for the period of time necessary for us to conduct a technical and environmental review of the plans.	The GAP must meet the requirements of §§ 585.640 through 585.648.
(2) Each limited lease has an operations term of five years for conducting site assessment, technology testing, or other activities. The operations term begins on the date that we approve your GAP.	We may order or grant a suspension of the operations term as provided in §§ 585.415 through 585.421.	

* * * * *

■ 11. Revise § 585.238 paragraph (b) to read as follows:

§ 585.238 Are there any other renewable energy research activities that will be allowed on the OCS?

* * * * *

(b) In issuing leases, ROW grants, or RUE grants to a Federal agency or a State on the OCS for renewable energy research activities under this provision, BOEM will coordinate and consult with other relevant Federal agencies, the State CZMA agency of each CZMA state, any other affected State(s), affected local government executives, and affected Indian Tribes.

* * * * *

■ 12. Amend § 585.303 by:

■ a. Redesignating the existing text as paragraph (b); and

■ b. Adding new paragraph (a) to read as follows:

§ 585.303 How long will my ROW grant or RUE grant remain in effect?

(a) Each ROW or RUE grant will have a preliminary term of 12 months from the date of issuance of the ROW or RUE grant within which to submit a GAP. The preliminary term begins on the effective date of the grant. You must submit a GAP no later than the end of the preliminary term to continue your grant in effect. However you may submit a GAP prior to the issuance of your ROW or RUE grant.

* * * * *

■ 13. Amend § 585.305 by adding a new paragraph (e) to read as follows:

§ 585.305 How do I request an ROW grant or RUE grant?

* * * * *

(e) A copy of your consistency certification and necessary data and information as submitted to the State CZMA agency pursuant to 15 CFR part 930, subpart D.

■ 14. Amend § 585.306 by revising the introductory text, paragraph (b) and by removing paragraph (c) to read as follows:

§ 585.306 What action will BOEM take on my request?

BOEM will consider requests for ROW grants and RUE grants on a case-by-case basis and may issue a grant competitively, as provided in § 585.308, or noncompetitively if BOEM determines, after public notice, that there is no competitive interest. BOEM will coordinate and consult with relevant Federal agencies, with the State CZMA agency in any CZMA State, the Governor of any affected State, and the executive of any affected local government.

* * * * *

(b) If BOEM determines that there is no competitive interest in a ROW grant or RUE grant, we will publish a notice in the **Federal Register** of such determination. We will establish terms and conditions for the grant in consultation with you.

■ 15. In § 585.309 revise the introductory paragraph to read as follows:

§ 585.309 When will BOEM issue a noncompetitive ROW grant or RUE grant?

After completing the review of your grant request, BOEM may offer you a noncompetitive grant.

* * * * *

■ 16. Revise § 585.500 paragraphs (a) and (b) to read as follows:

§ 585.500 How do I make payments under this part?

(a) For acquisition fees or the initial 12-months rent paid for the preliminary term of your lease, you must make your electronic payments through the *Fees for Services* page on the BOEM Web site at *http://www.boem.gov,* and you must include one copy of the *Pay.gov* confirmation receipt page with your unsolicited request or signed lease instrument.

(b) For rent during the preliminary term or for any period subsequent to the first 12-months rent or the site assessment term; or operating fees during the operations term, you must make your payments as required in 30 CFR 1218.51.

* * * * *

■ 17. Revise § 585.503 paragraph (a)(1) to read as follows:

§ 585.503 What are the rent and operating fee requirements for a commercial lease?

(a) * * *

(1) You must pay ONRR the first 12-months' rent, as provided in § 585.500, 45 days after BOEM issues your lease, in accordance with the payment methodology outlined in ONRR regulations at 30 CFR §§ 1218.301 and 1218.302, excluding any requirements not applicable to renewable energy.

* * * * *

■ 18. Revise § 585.505 paragraph (b) to read as follows:

§ 585.505 What are the rent and operating fee requirements for a limited lease?

* * * * *

(b) You must pay ONRR, in accordance with the payment methodology outlined in ONRR regulations at 30 CFR §§ 1218.301 and 1218.302, the first 12-months' rent when BOEM issues your limited lease, as provided in § 585.500, excluding any requirements not applicable to renewable energy.

* * * * *

■ 19. Amend § 585.601 by:

■ a. Revising both the introductory paragraph and paragraph (a);

■ b. Removing paragraph (b);

■ c. Redesignating paragraphs (c) and (d) as paragraphs (b) and (c), to read as follows:

§ 585.601 When am I required to submit my plans to BOEM?

You must submit your plans as follows:

(a) You may submit your SAP or GAP prior to lease or grant issuance but must submit your SAP or your GAP no later than 12 months from the date of the lease or grant issuance.

* * * * *

■ 20. Revise § 585.611 to read as follows:

§ 585.611 What information and certifications must I submit with my SAP to assist BOEM in complying with NEPA and other relevant laws?

You must submit, with your SAP, detailed information to assist BOEM in complying with NEPA and other relevant laws as appropriate.

(a) A SAP submitted for an area in which site assessment activities have not previously been reviewed under NEPA or other applicable Federal laws by BOEM, must describe those resources, conditions, and activities listed in the following table that could be affected by your proposed activities or that could affect the activities proposed in your SAP.

(b) For a SAP submitted for an area in which site assessment activities have previously been considered by BOEM under applicable Federal law (*e.g.,* a NEPA analysis and CZMA consistency determination for site assessment activities), BOEM will review the SAP to determine if its impacts are consistent with those previously considered. If the anticipated impacts of your SAP are substantially inconsistent with those previously anticipated, we may determine that new NEPA and other relevant Federal reviews are required. In that case, BOEM will notify you of such determination and you must submit a SAP that describes those resources, conditions, and activities listed in the following table that could be affected by your proposed activities or that could affect the activities proposed in your SAP, including:

Type of information:	Including:
(1) Hazard information	Meteorology, oceanography, sediment transport, geology, and shallow geological or manmade hazards.
(2) Water quality	Turbidity and total suspended solids from construction.
(3) Biological resources	Benthic communities, marine mammals, sea turtles, coastal and marine birds, fish and shellfish, plankton, sea grasses, and other plant life.
(4) Threatened or endangered species	As required by the Endangered Species Act (ESA) of 1973 (16 U.S.C. 1531 *et seq.*).
(5) Sensitive biological resources or habitats.	Essential fish habitat, refuges, preserves, special management areas identified in coastal management programs, sanctuaries, rookeries, hard bottom habitat, chemosynthetic communities, and calving grounds; barrier islands, beaches, dunes, and wetlands.
(6) Archaeological resources	As required by the NHPA (16 U.S.C. 470 *et seq.*), as amended.
(7) Social and economic conditions	Employment, existing offshore and coastal infrastructure (including major sources of supplies, services, energy, and water), land use, subsistence resources and harvest practices, recreation, recreational and commercial fishing (including typical fishing seasons, location, and type), minority and lower income groups, coastal zone management programs, and viewshed.
(8) Coastal and marine uses	Military activities, vessel traffic, and energy and nonenergy mineral exploration or development.
(9) Consistency Certification	If required by CZMA, as appropriate: (i) 15 CFR part 930, subpart D, if the SAP is submitted prior to lease issuance; (ii) 15 CFR part 930, subpart E, if the SAP is submitted after lease issuance.
(10) Other resources, conditions, and activities.	As identified by BOEM.

■ 21. Revise § 585.612 to read as follows:

§ 585.612 How will my SAP be processed for Federal consistency under the Coastal Zone Management Act?

Your SAP will be processed based on whether it is submitted before or after your lease is issued:

If your SAP is submitted:	Your SAP will be handled as follows:
(a) Before lease issuance,	You will furnish a copy of your SAP, consistency certification, and necessary data and information pursuant to 15 CFR part 930, subpart D, to the State's CZMA agency and BOEM at the same time.
(b) After lease issuance, ..	You will submit a copy of your SAP, consistency certification, and necessary data and information pursuant to 15 CFR 93, subpart E to BOEM. BOEM will forward to the State CZMA agency one paper copy and one electronic copy of your SAP, consistency certification, and necessary data and information required under 15 CFR part 930, subpart E, after BOEM has determined that all information requirements for the SAP are met.

■ 22. Revise § 585.640 paragraph (b) to read as follows:

§ 585.640 What is a General Activities Plan (GAP)?

* * * * *

(b) You must receive BOEM approval of your GAP before you can begin any of the approved activities on your lease or grant. You must submit your GAP no later than 12 months from the date of the lease or grant issuance.

■ 23. Revise § 585.646 to read as follows:

§ 585.646 What information and certifications must I submit with my GAP to assist BOEM in complying with NEPA and other relevant laws?

You must submit, with your GAP, detailed information to assist BOEM in complying with NEPA and other relevant laws as appropriate.

(a) A GAP submitted for an area in which GAP activities have not previously been reviewed by BOEM under NEPA/CZMA or other applicable Federal laws must describe those resources, conditions, and activities listed in the following table that could be affected by your proposed activities or that could affect the activities proposed in your GAP.

(b) For a GAP submitted for an area in which GAP activities have previously been considered by BOEM under applicable Federal law (*e.g.,* a NEPA analysis and CZMA consistency determination for the GAP activities), BOEM will review the GAP to determine if its impacts are consistent with those previously considered. If the anticipated impacts of your GAP are substantially inconsistent with those previously anticipated, we may determine that new NEPA/CZMA and other relevant Federal reviews are required. In that case, BOEM will notify you of such determination, and you must submit a GAP that describes those resources, conditions, and activities listed in the following table that could be affected by your proposed activities or that could affect the activities proposed in your GAP, including:

Type of information:	Including:
(1) Hazard information	Meteorology, oceanography, sediment transport, geology, and shallow geological or manmade hazards.
(2) Water quality	Turbidity and total suspended solids from construction.
(3) Biological resources	Benthic communities, marine mammals, sea turtles, coastal and marine birds, fish and shellfish, plankton, sea grasses, and other plant life.
(4) Threatened or endangered species	As required by the ESA (16 U.S.C. 1531*et seq.*).
(5) Sensitive biological resources or habitats.	Essential fish habitat, refuges, preserves, special management areas identified in coastal management programs, sanctuaries, rookeries, hard bottom habitat, chemosynthetic communities, and calving grounds; barrier islands, beaches, dunes, and wetlands
(6) Archaeological resources	As required by NHPA (16 U.S.C. 470 *et seq.*), as amended.
(7) Social and economic conditions	Employment, existing offshore and coastal infrastructure (including major sources of supplies, services, energy, and water), land use, subsistence resources and harvest practices, recreation, recreational and commercial fishing (including typical fishing seasons, location, and type), minority and lower income groups, coastal zone management programs, and viewshed.
(8) Coastal and marine uses	Military activities, vessel traffic, and energy and nonenergy mineral exploration or development.
(9) Consistency Certification	If required by CZMA, as appropriate: (A) 15 CFR part 930, subpart D, if the GAP is submitted prior to lease or grant issuance; (B) 15 CFR part 930, subpart E, if the GAP is submitted after lease or grant issuance.
(10) Other resources, conditions, and activities.	As required by BOEM.

■ 24. Revise § 585.647 to read as follows:

§ 585.647 How will my GAP be processed for Federal consistency under the Coastal Zone Management Act?

Your GAP will be processed based on whether it is submitted before or after your lease or grant is issued:

If your GAP is submitted . . .	Your GAP will be handled as follows:
(a) Before lease or grant issuance	You will furnish a copy of your GAP, consistency certification, and necessary data and information pursuant to 15 CFR part 930, subpart D, to the State's CZM agency and BOEM at the same time.
(b) After lease or grant issuance	You will submit a copy of your GAP, consistency certification, and necessary data and information pursuant to 15 CFR 93, subpart E to BOEM. BOEM will forward to the State CZMA agency one paper copy and one electronic copy of your GAP, consistency certification, and necessary data and information required under 15 CFR part 930, subpart E, after BOEM has determined that all information requirements for the GAP are met.

■ 25. Revise § 585.902 paragraph (f) to read as follows:

§ 585.902 What are the general requirements for decommissioning facilities authorized under my SAP, COP, or GAP?

* * * * *

(f) Provide BOEM with documentation of any coordination efforts you have made with the State CZMA agencies, and any affected States, local, and Tribal governments.

PART 590—APPEAL PROCEDURES

■ 26. The authority citation for part 590 is revised to read as follows:

Authority: 5 U.S.C. 301 *et seq.;* 31 U.S.C. 9701; 43 U.S.C. 1334.

■ 27. Revise § 590.4 paragraph (b)(1) to read as follows:

§ 590.4 How do I file an appeal?

* * * * *

(b) * * *

(1) You must pay electronically through the *Fees for Services* page on the BOEM Web site at *http://www.boem.gov,* and you must include a copy of the *Pay.gov* confirmation receipt page with your Notice of Appeal.

* * * * *

[FR Doc. 2013–03992 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2012–0727; FRL–9376–7]

RIN 2070–AB27

Proposed Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 37 chemical substances which were the subject of premanufacture notices (PMNs). Seventeen of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action would require persons who intend to manufacture, import, or process any of these 37 chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

DATES: Comments must be received on or before April 26, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2012–0727, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA–HQ–OPPT–2012–0727. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPPT–2012–0727. EPA's policy is that all comments received will be included in the docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at *http://www.regulations.gov,* or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection

Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–9232; email address: *moss.kenneth@epa.gov.*

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances in this proposed rule. The following list of North American 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:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a final SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What action is the agency taking?

These proposed SNURs would, when finalized, require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of the specific chemical substances identified in the PMNs for any activity designated by these SNURs as a significant new use. Receipt of such notices allows EPA to assess risks that may be presented by the intended uses and, if appropriate, to regulate the proposed use before it occurs. Additional rationale and background to these rules are more fully set out in the preamble to EPA's first direct final SNUR published in the **Federal Register** of April 24, 1990 (55 FR 17376). Consult that preamble for further information on the objectives, rationale, and procedures for SNURs and on the basis for significant new use designations, including provisions for developing test data.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) and 40 CFR part 721 require persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule. Provisions relating to user fees appear at 40 CFR part 700.

According to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.

• The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the 37 chemical substances that are the subject of these proposed SNURs, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Proposed Rule

EPA is proposing to establish significant new use and recordkeeping requirements for 37 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

• PMN number.

• Chemical name (generic name, if the specific name is claimed as CBI).

• Chemical Abstracts Service (CAS) number (if assigned for non-confidential chemical identities).

• Basis for the TSCA section 5(e) consent order or, for TSCA non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).

• Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).

• CFR citation assigned in the regulatory text section of this proposed rule.

This proposed rule includes 14 PMN substances whose reported chemical names include the term ''carbon nanotube'' or ''carbon nanofibers.'' Because of a lack of established nomenclature for carbon nanotubes, the TSCA Inventory names for carbon nanotubes are currently in generic form, e.g., carbon nanotube (CNT), multi-walled carbon nanotube (MWCNT), double-walled carbon nanotube (DWCNT), or single-walled carbon nanotube (SWCNT). EPA uses the specific structural characteristics provided by the PMN submitter to more specifically characterize the TSCA Inventory listing for an individual CNT. All submitters of new chemical notices for CNTs have claimed those specific structural characteristics as CBI. EPA is publishing the generic chemical name along with the PMN number to identify that a distinct chemical substance was the subject of the PMN without revealing the confidential chemical identity of the PMN substance. Confidentiality claims preclude a more detailed description of the identity of these CNTs. If an intended manufacturer, importer, or processor of CNTs is unsure of whether its CNTs are subject to this proposed SNUR or any other SNUR, the company can either contact EPA or obtain a written determination from EPA pursuant to the bona fide procedures at § 721.11. EPA is using the specific structural characteristics for all CNTs submitted as new chemical substances under TSCA to help develop standard nomenclature for placing these chemical substances on the TSCA Inventory. EPA has compiled a generic list of those structural characteristics entitled ''Material Characterization of Carbon Nanotubes for Molecular Identity (MI) Determination & Nomenclature.'' A copy of this list is available in the docket for these proposed SNURs under docket ID number EPA–HQ–OPPT–2012–0727. If EPA develops a more specific generic chemical name for these materials, that name will be made publicly available.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including exceeding production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this proposed rule, may be claimed as CBI.

This proposed rule includes 17 PMN substances for which EPA determined, pursuant to TSCA section 5(e), that uncontrolled manufacture, import, processing, distribution in commerce, use, and disposal may present an unreasonable risk of injury to human health or the environment. Accordingly, these substances are subject to ''risk-based'' consent orders under TSCA section 5(e)(1)(A)(ii)(I). Those consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called ''section 5(e) SNURs'' on these PMN substances are proposed pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The section 5(e) SNURs designate as a ''significant new use'' the absence of the protective measures required in the corresponding consent orders.

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA section 5(e) consent order usually requires, among other things, that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL) that is established by EPA to provide adequate protection to human health. In addition to the actual NCEL concentration, the comprehensive NCELs provisions in TSCA section 5(e) consent orders, which are modeled after Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs) provisions, include requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. However, no comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will normally state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the § 721.63 respirator requirements may request to do so under § 721.30. EPA expects that persons whose § 721.30 requests to use the NCELs approach for SNURs are approved by EPA will be required to comply with NCELs provisions that are comparable to those contained in the corresponding TSCA section 5(e) consent order for the same chemical substance.

This proposed rule also includes SNURs on 20 PMN substances that are not subject to consent orders under TSCA section 5(e). In these cases, for a variety of reasons, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a ''significant new use.'' These so-called ''non-section 5(e) SNURs'' are promulgated pursuant to § 721.170. EPA has determined that every activity designated as a ''significant new use'' in all non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, ''(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified'' for the PMN substance.

PMN Number P–00–835

Chemical name: Substituted picolinate (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the substance will be used as an intermediate in the manufacture of agricultural chemicals. Based on ecological structure activity relationship (EcoSAR) analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 90 parts per billion (ppb) of the PMN substance in surface waters. As described in the PMN, releases to surface water are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 90 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (Office of Chemical Safety and Pollution Prevention (OCSPP) Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10637.

PMN Number P–02–167

Chemical name: Lithium metal phosphate (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an electrode material. Based on EcoSAR analysis of test data on analogous inorganic phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases to water are not expected to exceed 1 ppb. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance presents an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075); an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10638.

PMN Number P–02–668

Chemical name: Siloxanes and Silicones, di-Me, polymers with Ph silsesquioxanes, hydrolyzed, reaction products with 2-[[3-(trimethoxysilyl) propoxy]methyl]oxirane.

CAS number: 478823–10–8.

Basis for action: The PMN substance will be used as a binder for silicone coatings. Based on structure activity relationship (SAR) analysis of test data on analogous epoxides and alkoxysilanes, EPA identified concerns for mutagenicity, oncogenicity, reproductive toxicity, developmental toxicity, lung toxicity, and sensitization from dermal and inhalation exposures to the PMN substance. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of impervious gloves and a National Institute for Occupational Safety and Health (NIOSH)-certified respirator with an assigned protection factor (APF) of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that manufacturing, processing, and use of the substance may present an unreasonable risk. EPA has determined, however, that use of the substance without impervious gloves where there is a potential for dermal exposure; any use of the substance without a NIOSH-certified respirator with an APF of at least 10; or any use of the substance in consumer products may result in serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(1)(i)(C) and (b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465), with attention to the pathology of the reproductive organs, and a carcinogenicity test (OPPTS Test Guideline 870.4200) would help to characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10639.

PMN Number P–03–135

Chemical name: 1,2-Cyclohexanedicarboxylic acid, 1-(2-ethylhexyl) 2-(2-methylpropyl) ester.

CAS number: 252958–29–5.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a compressor lubricant. Based on EcoSAR analysis of test data on analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, the substance is not released to surface waters. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. There are two other chemical substances identified in the PMN that are already on the TSCA Inventory. The SNUR does not apply to those chemical substances. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help to characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10640.

PMN Number P–03–255

Chemical name: Phenol and vinyltoluene based hydrocarbon resin (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a diluent for coatings. Based on EcoSAR analysis of test data on analogous neutral organics, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb of the PMN substance in surface waters. As described in the PMN, releases to water are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance resulting in surface water concentrations exceeding 1 ppb may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish early-life stage toxicity test (OPPTS Test Guideline 850.1400); a daphnid chronic toxicity test (OPPTS Test Guideline 850.1300); and an algal toxicity test (OCSPP Test Guideline 850.4500) would help to characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10641.

PMN Numbers P–03–762 and P–03–763

Chemical name: Modified polyisocyanates (generic).

CAS number: Claimed as confidential.

Basis for action: The consolidated PMN states that the generic (non-confidential) use of the substances will be as hardeners. Based on SAR analysis of test data on analogous isocyanates, EPA has identified concerns for sensitization and irritation from dermal and inhalation exposure to the PMN substances. For the use described in the PMN, significant occupational inhalation and dermal exposures are not expected due to no domestic manufacture, use of impervious gloves, and no use of the substances involving an application method that generates a vapor, mist, or aerosol. Further, consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed processing or use of the substances may present an unreasonable risk. EPA has determined, however, that any domestic manufacture of the substances; any use of the substances without impervious gloves where there is a potential for dermal exposures; any use of the substance in consumer products; or any use of the substances involving an application method that generates a vapor, mist, or aerosol may result in serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substances.

CFR citation: 40 CFR 721.10642.

PMN Number P–04–640

Chemical name: Diisocyanate terminated polycarbodiimide (generic).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: February 1, 2006.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinking agent for solvent-based inks; a monomer for polymerization; and a water scavenger for producing anhydrous polymers. The PMN did not identify consumer uses for the PMN substance. Based on SAR analysis of test data on structurally similar diisocyanates, EPA identified concerns for dermal sensitization, respiratory sensitization, and pulmonary toxicity from exposure to the PMN substance by the inhalation and dermal routes. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health. To protect against these risks, the order requires:

1. Use of personal protective equipment including impervious gloves (when there is potential dermal exposure) and either a NIOSH-certified respirator with an APF of at least 2,000, or compliance with a NCEL of 0.05 mg/m^3 as an 8-hour time-weighted average (when there is potential inhalation exposure).

2. Establishment and use of a hazard communication program. The SNUR would designate as a ''significant new use'' the absence of these protective measures and consumer use of the PMN substance.

Recommended testing: EPA has determined that data from worker exposure to the PMN substance (such as inhalation monitoring data generated according to the NCELs section of the consent order) or a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance. The order does not require submission of the testing at any specified time or production volume. However, the order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10643.

PMN Number P–07–553

Chemical name: Reaction product of aluminum hydroxide and modified alkoxysilane (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the substance will be used as a flame retardant. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates, EPA identified concerns for lung toxicity from inhalation exposures to the PMN substance. At an annual production volume of 100,000 kilograms (kgs), significant occupational inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposure; or any increase of the annual 100,000 kg production volume may result in increased exposure to the PMN substance, which may cause serious human health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) with a 60-day holding period would help characterize the health effects of the PMN substance.

CFR citation: 40 CFR 721.10644.

PMN Number P–08–392

Chemical name: Multi-walled carbon nanotube (generic) (P–08–392).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: November 14, 2008.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) use of the substance will be as an antistatic, reinforcement additive. Based on test data on the PMN substance, and SAR analysis of test data on structurally similar respirable, poorly soluble particulates, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA, based on a finding that the PMN substance may present an unreasonable risk of injury to human health. To protect against these risks, the order:

1. Requires use of personal protective equipment including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an APF of at least 50 (when there is potential inhalation exposure).

2. Prohibits manufacture of the PMN substance in the United States.

3. Restricts processing and use of the PMN substance to those uses specified in the consent order.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or Organisation for Economic Co-operation and Development (OECD) Test Guideline 413) in rats with a post exposure observation period of up to 3 months, including bronchoalveolar lavage fluid (BALF) analysis and certain material characterization data, would help characterize possible effects of the substance. In the consent order, the PMN submitter has agreed to perform these tests within 18 months of commencing non-exempt commercial manufacture.

CFR citation: 40 CFR 721.10645.

PMN Number P–09–257

Chemical name: Multi-walled carbon nanotube (generic) (P–09–257).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: August 11, 2009.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) uses of the substance will be as an electric conductive filler to replace conventional material such as carbon black or carbon fiber in matrixes such as polymer resin for conductive applications, and an additive for elastomers, polymers, and resins to enhance mechanical properties. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and other CNTs, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNTs, may induce cardiovascular toxicity if inhaled. Although there are no environmental toxicity studies on CNTs available, EPA expects that some fraction of the CNTs, if released into the environment, will eventually be suspended in water. There have been sublethal effects observed for single walled CNTs in rainbow trout at levels as low as 100 ppb. The order was issued under section 5(e)(1)(A)(i) and (e)(1)(A)(ii)(I) of TSCA based on a finding that this substance may present an unreasonable risk of injury to human health and the environment. To protect against these risks, the order:

1. Requires use of personal protective equipment including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an APF of at least 50 (when there is potential inhalation exposure).

2. Prohibits manufacture of the PMN substance in the United States.

3. Restricts processing and use of the PMN substance to those uses specified in the consent order.

4. Prohibits release to water during processing and use.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats with a post exposure observation period of up to 3 months (including BALF analysis, a determination of cardiovascular toxicity (clinically-based blood/plasma protein analyses), and histopathology of the heart) and development of data on certain physical/chemical properties would help characterize possible effects of the substance. In the consent order, the PMN submitter has agreed not to exceed a specified production volume/time limit (whichever comes first) without performing the 90-day test on the PMN substance. In addition, in the consent order, the PMN submitter agreed to provide the physical/chemical properties data within a specified time limit.

CFR citation: 40 CFR 721.10646.

PMN Numbers P–10–115, P–10–116, P–10–117, P–10–118, P–10–119, P–10–120, P–10–121, P–10–122, P–10–123, P–10–124, P–10–125, and P–10–126

Chemical name: Multi-walled carbon nanofibers (generic).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: May 9, 2011.

Basis for TSCA section 5(e) consent order: The PMNs state that the uses of the substances will be as electrical and thermal conductivity additives, mechanical reinforcement additives, energy storage additives, and chemical intermediates. Based on SAR analysis of test data on analogous respirable, poorly soluble particulates and other CNTs, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity. Further, available data suggests that pulmonary deposition of some nanoparticles, including CNTs may induce cardiovascular toxicity if inhaled. Although there are no environmental toxicity studies on CNTs available, EPA expects that some fraction of the CNTs, if released into the environment, will eventually be suspended in water. There have been sub-lethal effects observed for single walled CNTs in rainbow trout at levels as low as 100 ppb. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that these substances may present an unreasonable risk of injury to human health and the environment. To protect against this risk, the order:

1. Requires use of personal protective equipment including impervious gloves and protective clothing (when there is a potential dermal exposure) and a NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an APF of at least 50 (when there is potential inhalation exposure).

2. Restricts use of the PMN substances to use only as electrical and thermal conductivity additives, mechanical reinforcement additives, energy storage additives, and chemical intermediates as specified in the consent order.

3. Restricts processing and use of the PMN substances to industrial settings.

4. Prohibits release of the PMN substances into the waters of the United States during processing and use activities.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain physical/chemical properties data, workplace exposure monitoring and characterization testing, and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465 or OECD Test Guideline 413) in rats would help characterize the human health effects of the PMN substances. The PMN submitter agreed to provide the physical/chemical properties data for the PMN substances within one year after submitting the notice of commencement. The consent order contains two additional production volume limits. The PMN submitter agreed not to exceed the first production volume limit without submitting workplace exposure monitoring and characterization testing (including byproducts) as well as quantification and characterization of substances that may be released during exposures typical during the use phase, such as handling, tearing and cutting the PMN substances. The PMN submitter has also agreed not to exceed the second production volume limit without performing two 90-day inhalation toxicity tests, with a post-exposure observation period of up to 3 months, BALF analysis, aggregation/agglomeration state, shape, size/size particle distribution and surface properties of materials as administered, aggregation/agglomeration state, shape, size/size particle distribution and surface properties of materials of the

delivered materials after administration, determination of cardiovascular toxicity, heart histopathology, and data on pulmonary deposition. One 90-day inhalation toxicity test will be conducted from a representative PMN substance in the group P–10–115, P–10–116, P–10–117, P–10–118, P–10–119, and the other 90-day inhalation toxicity test will be conducted from a representative PMN substance in the group P–10–120, P–10–121, P–10–122, P–10–123, P–10–124, P–10–125, and P–10–126.

CFR citation: 40 CFR 721.10647.

PMN Numbers P–10–545 and P–10–546

Chemical name: Modified lithium iron phosphates (generic).

CAS number: Claimed as confidential.

Effective date of TSCA section 5(e) consent order: December 10, 2010.

Basis for TSCA section 5(e) consent order: The consolidated PMN states that the generic (non-confidential) use of the substances will be as battery electrode components, contained use. Based on test data on analogous respirable, poorly soluble particulates, there is potential risk for adverse lung effects including cancer, lung fibrosis, lung inflammation and systemic effects, including immunotoxicity. EPA has identified concerns for these health effects from exposures to the PMN substances. Based on EcoSAR analysis of test data on analogous phosphates, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters. The order was issued under sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) of TSCA based on a finding that these substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the consent order:

1. Restricts manufacturing, processing, and use of the substances to a fully-enclosed and automated process, including all loading and unloading activities.

2. Restricts use of the PMN substances to use only as specified in the consent order.

3. Prohibits release of the PMN substances into the waters of the United States during processing and use activities.

The SNUR would designate as a ''significant new use'' the absence of these protective measures.

Recommended testing: EPA has determined that the results of a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) in rats with a post-exposure observation period of up to 3 months, including BALF analysis; an algal toxicity test (OCSPP Test Guideline 850.5400); and physical/chemical properties testing for: Water solubility (OECD Test Guideline 105); surface chemistry, particle size distribution of the PMN substances, dustiness test (European Standard 15051); and particle size distribution, aggregation state, and porosity would help characterize the human health and environmental effects of the PMN substances. The PMN submitter has agreed not to exceed the confidential production volume in the consent order without performing the 90-day inhalation toxicity test and the physical/chemical properties tests.

CFR citation: 40 CFR 721.10648.

PMN Number P–11–115

Chemical name: MDI modified polyalkylene glycol adipate polyester (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10649.

PMN Number P–11–155

Chemical name: Polyether substituted anthraquinone derivative (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be used as a colorant for cleaners and detergents. Based on EcoSAR analysis of test data on analogous aromatic amines and nonionic dyes, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 2 ppb of the PMN substance in surface waters for greater than 20 days per year. This 20-day criterion is derived from partial life cycle tests (daphnid chronic and fish early life stage tests) that typically range from 21 to 28 days in duration. EPA predicts toxicity to aquatic organisms may occur if releases of the PMN substance to surface water, from uses other than as described in the PMN, exceed releases from the use described in the PMN. For the use described in the PMN, environmental releases did not exceed 1 ppb for more than 20 days per year.

Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance other than as a colorant for cleaners and detergents may cause significant adverse environmental effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(4)(ii).

Recommended testing: EPA has determined that the results of a fish acute toxicity test, freshwater and marine (OPPTS Test Guideline 850.1075) and an aquatic invertebrate acute toxicity test, freshwater daphnids (OPPTS Test Guideline 850.1010) would help characterize the environmental effects of the PMN substance.

CFR citation: 40 CFR 721.10650.

PMN Number P–11–290

Chemical name: Carbide derived nanocarbon (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a sensor element in an electrochemical sensor. Based on SAR analysis of test data on respirable, poorly soluble particulates, EPA identified concerns for pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity if the substances were manufactured by a method other than described in the PMN. Further, available data suggests that pulmonary deposition of some carbon-based nanoparticles, may induce cardiovascular toxicity if inhaled. EPA identified concerns for lung toxicity to workers from inhalation exposures to the PMN substance. For the manufacture method described in the PMN, significant dermal and inhalation exposures are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an

unreasonable risk. EPA has determined, however, that manufacture of the substance by a method other than as described in the PMN may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that inhalation monitoring data collected during the manufacturing process according to the EPA draft Inhalation Monitoring Data Collection Guidelines (located in the docket under docket ID number EPA–HQ–OPPT–2012–0727) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10651.

PMN Numbers P–11–309, P–11–311, P–11–312, P–11–313, and P–11–314

Chemical names: (P–11–309) Hexanedioic acid, polymer with polyether polyol, 1,1′-methylenebis[4-isocyanatobenzene] and dihydroxydialkyl ether (generic); (P–11–311) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1′-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic); (P–11–312) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1′-methylenebis[isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic); (P–11–313) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1′-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether, reaction products with dialkylcarbinol (generic); and (P–11–314) Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1′-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether reaction products with dialkylcarbinol (generic).

CAS numbers: Claimed as confidential.

Basis for action: The PMNs state that the generic (non-confidential) use of the substances will be as industrial adhesives. Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances. For the use described in the PMNs, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substances may present an unreasonable risk. EPA has determined, however, that any use of the substances without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substances in consumer products may cause serious health effects. Based on this information, the PMN substances meet the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substances.

CFR citations: 40 CFR 721.10652 (P–11–309); 40 CFR 721.10653 (P–11–311); 40 CFR 721.10654 (P–11–312); 40 CFR 721.10655 (P–11–313); and 40 CFR 721.10656 (P–11–314).

PMN Number P–12–73

Chemical name: Castor oil, polymer with hydrogenated vegetable oil, 1,1′-methylenebis[isocyanatobenzene] and isocyanate (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance is as an industrial adhesive. Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for sensitization. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substances in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization (OPPTS Test Guideline 870.2600) and a 90-day subchronic inhalation toxicity test (OPPTS Test Guideline 870.3465) in rodents would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10657.

PMN Number P–12–133

Chemical name: 2-Oxepanone, polymer with 1,6-diisocyanatohexane, 2,2″dimethyl-1;3-propanediol and 2,2′-oxybis[ethanol].

CAS number: 1313708–90–5.

Basis for action: The PMN states that the substance will be used as a coating for wind craft wings. Based on SAR analysis of test data on structurally similar chemicals submitted under TSCA section 8(e), EPA identified concerns for oncogenicity and mutagenicity. Additionally, based on the isocyanate moiety, the Agency identified concerns for sensitization. For the use described in the PMN, significant occupational inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity study (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10658.

PMN Number P–12–143

Chemical name: Poly(oxy-1,4-butanediyl), -hydro—hydroxy-, polymer with alkyldiisocyanates (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a crosslinking resin. Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and respiratory exposures to the PMN substance. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore,

EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures, or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10659.

PMN Number P–12–274

Chemical name: Aliphatic diisocyanate adduct with substituted amino alkyl silane (generic).

CAS number: Claimed as confidential.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as an adhesive. Based on SAR analysis of test data on analogous isocyanates, EPA identified concern for sensitization from dermal and inhalation exposure to the PMN substance. Additionally, liquid and vapor contact with the eye can cause moderate to severe irritation. For the use described in the PMN, significant occupational dermal and inhalation exposures are not expected due to the use of a NIOSH-certified respirator with an APF of at least 10, and consumer exposures are not expected as the substance is not used in consumer products. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without a NIOSH-certified respirator with an APF of at least 10, where there is a potential for inhalation exposures; or any use of the substance in consumer products may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170(b)(3)(ii).

Recommended testing: EPA has determined that the results of a skin sensitization test (OPPTS Test Guideline 870.2600) and a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10660.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are subject to these proposed SNURs, EPA concluded that for 17 of the 37 chemical substances regulation was warranted under TSCA section 5(e) pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit IV. Based on these findings, TSCA section 5(e) consent orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. The proposed SNUR provisions for these chemical substances are consistent with the provisions of the TSCA section 5(e) consent orders. These SNURs are being proposed pursuant to § 721.160.

In the other 20 cases, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met, as discussed in Unit IV.

B. Objectives

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA would be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA would ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at *http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html.*

VI. Notice and Comment Procedures

EPA is issuing these SNURs by notice and comment procedure, as described in § 721.170(d)(4). In accordance with § 721.170(d)(4)(ii)(A), persons are being given the opportunity to submit comments on or before April 26, 2013 on whether EPA should establish notification requirements.

VII. Applicability of Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant ''new'' use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for 17 chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. EPA is soliciting comments on whether any of the uses proposed as significant new uses are ongoing.

As discussed in the **Federal Register** of April 24, 1990 SNUR, EPA has decided that the intent of TSCA section 5(a)(1)(B) is best served by designating a use as a significant new use as of the date of publication of this proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements because a person could defeat the SNUR by initiating the significant new use before the rule became final, and then argue that the use was ongoing before the effective date of the final rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances that would be regulated through these proposed SNURs will have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including any extensions, expires.

EPA has promulgated provisions to allow persons to comply with these proposed SNURs before the effective date. If a person meets the conditions of advance compliance under § 721.45(h), the person would be considered exempt from the requirements of the SNUR.

VIII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).

2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for non-5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.'' The Organisation for Economic Co-operation and Development (OECD) test guidelines are available from the OECD Bookshop at *http://www.oecdbookshop.org* or Source OECD at *http://www.sourceoecd.org.* To access the European Standard, EN 15051 method, issued by The European Committee for Standardization (CEN), please go to *http://www.cen.eu/cen/products.*

In the TSCA section 5(e) consent orders for several of the chemical substances regulated under this proposed rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Listings of the tests specified in the TSCA section 5(e) consent orders are included in Unit IV. The SNURs contain the same production volume limits as the TSCA section 5(e) consent orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

When physical/chemical properties of test material and/or material characterization tests are recommended for nanoscale substances that are the subject of this proposed rule, you should take into consideration the characterizations identified in the Guidance Manual for the Testing of Manufactured Nanomaterials: OECD's Sponsorship Programme, which is available at *http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)20/rev&doclanguage=en.*

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

IX. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and § 721.25. E–PMN software is available electronically at *http://www.epa.gov/opptintr/newchems.*

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2012–0727.

XI. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for several new chemical substances that were the subject of PMNs, and, in some cases, TSCA section 5(e) consent orders. 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).

B. Paperwork Reduction Act (PRA)

According to PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA would amend the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this proposed rule, if the SNUR is subsequently issued as a final rule. This listing of the OMB control numbers and their subsequent codification in the CFR satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320. This Information Collection Request (ICR) was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is ''good cause'' under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table without further notice and comment.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a

SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of these SNURS would not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUR submitted by any small entity would not cost significantly more than $8,300.

A copy of that certification is available in the docket for this proposed rule.

This proposed rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit X. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than $8,300.

Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

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), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), does not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: February 15, 2013.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add § 721.10637 to subpart E to read as follows:

§ 721.10637 Substituted picolinate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted picolinate (PMN P–00–835) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=90).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 3. Add § 721.10638 to subpart E to read as follows:

§ 721.10638 Lithium metal phosphate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as lithium metal phosphate (PMN P–02–167) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 4. Add § 721.10639 to subpart E to read as follows:

§ 721.10639 Siloxanes and Silicones, di-Me, polymers with Ph silsesquioxanes, hydrolyzed, reaction products with 2-[[3-(trimethoxysilyl)propoxy]methyl]oxirane.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as siloxanes and silicones, di-Me, polymers with Ph silsesquioxanes, hydrolyzed, reaction products with 2-[[3-(trimethoxysilyl)propoxy]methyl]oxirane (PMN P–02–668; CAS No. 478823–10–8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (a)(4), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 5. Add § 721.10640 to subpart E to read as follows:

§ 721.10640 11,2-Cyclohexanedicarboxylic acid, 1-(2-ethylhexyl) 2-(2-methylpropyl) ester.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 1,2-cyclohexanedicarboxylic acid, 1-(2-ethylhexyl) 2-(2-methylpropyl) ester (PMN P–03–135; CAS Nos. 252958–29–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 6. Add § 721.10641 to subpart E to read as follows:

§ 721.10641 Phenol and vinyltoluene based hydrocarbon resin (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol and vinyltoluene based hydrocarbon resin (PMN P–03–255) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=1).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 7. Add § 721.10642 to subpart E to read as follows:

§ 721.10642 Modified polyisocyanates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as modified polyisocyanates (PMNs P–03–762 and P–03–763) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(3), (b) (concentration set at 0.1 percent), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (o), and (y)(l).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 8. Add § 721.10643 to subpart E to read as follows:

§ 721.10643 Diisocyanate terminated polycarbodiimide (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as diisocyanate terminated polycarbodiimide (PMN P–04–640) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The

requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(3), (a)(4), and (a)(6)(ii). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a tight-fitting full facepiece with an assigned protection factor (APF) of at least 2,000 meets the minimum requirements § 721.63(a)(4). As an alternative to the respiratory requirements listed here, a manufacturer, importer, or processor may choose to follow the new chemical exposure limit (NCEL) provisions listed in the TSCA section 5(e) consent order for this substance. The NCEL is 0.05 mg/m^3. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will receive NCELs provisions comparable to those contained in the corresponding section 5(e) consent order.

(ii) *Hazard communication program.* Requirements as specified in § 721.72 (a), (b), (c), (d), (f), (g)(1)(i), (g)(1)(ii), (g)(2)(i), (g)(2)(ii), (g)(2)(iii), (g)(2)(iv) (use respiratory protection or maintain airborne concentrations at or below an 8-hour time-weighted average of 0.05 mg/m^3), (g)(2)(v), and (g)(5).

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 9. Add § 721.10644 to subpart E to read as follows:

§ 721.10644 Reaction product of aluminum hydroxide and modified alkoxysilane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as reaction product of aluminum hydroxide and modified alkoxysilane (PMN P–07–553) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (b) (concentrations set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(s) (100,000 kilograms).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 10. Add § 721.10645 to subpart E to read as follows:

§ 721.10645 Multi-walled carbon nanotube (generic) (P–08–392).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotube (PMN P–08–392) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been completely reacted (cured); or embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (a)(6) (particulate, including solids or liquid droplets). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 meet the minimum requirements of § 721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), and (q) (within 18 months of commencing non-exempt commercial manufacture).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions

of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

■ 11. Add § 721.10646 to subpart E to read as follows:

§ 721.10646 Multi-walled carbon nanotube (generic) (P–09–257).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanotube (PMN P–09–257) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substance that have been completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been completely reacted (cured); embedded in a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing; or incorporated into an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (a)(6) (particulate, including solids or liquid droplets). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 meets the minimum requirements of § 721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (f), (k), and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

■ 12. Add § 721.10647 to subpart E to read as follows:

§ 721.10647 Multi-walled carbon nanofibers (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as multi-walled carbon nanofibers (PMNs P–10–115, P–10–116, P–10–117, P–10–118, P–10–119, P–10–120, P–10–121, P–10–122, P–10–123, P–10–124, P–10–125, and P–10–126) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured); incorporated or embedded into a polymer matrix that itself has been reacted (cured); embedded into a permanent solid polymer form that is not intended to undergo further processing except for mechanical processing; or incorporated into an article as defined at 40 CFR 720.3(c).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(1), (a)(2)(i), (a)(2)(ii), (a)(3), (a)(4), and (a)(6)(i). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(1) and (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. A National Institute for Occupational Safety and Health (NIOSH)-certified air-purifying, tight-fitting full-face respirator equipped with N100 filters with an assigned protection factor (APF) of at least 50 meets the minimum requirements of § 721.63(a)(4).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (k) (electrical and thermal conductivity additive in encapsulated thermoplastics, thermosets, elastomers, glass, metals, and ceramics; mechanical reinforcement additive in encapsulated thermoplastics, thermosets, elastomers, glass, metals, and ceramics; energy storage additive; or chemical intermediate), (l) and (q).

(iii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), (e), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

■ 13. Add § 721.10648 to subpart E to read as follows:

§ 721.10648 Modified lithium iron phosphates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as modified lithium iron phosphates (PMNs P–10–545 and P–10–546) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this rule do not apply to quantities of the PMN substances after they have been completely reacted (cured), embedded or incorporated into a polymer matrix that has been reacted (cured), or embedded in a permanent solid polymer form that is not intended to undergo further processing, except mechanical.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80 (a), (b), (c), (k), and (q).

(ii) *Release to water.* Requirements as specified in § 721.90 (b)(1) and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (i), and (k) are applicable to manufacturers, importers, and processors of these substances.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

■ 14. Add § 721.10649 to subpart E to read as follows:

§ 721.10649 MDI modified polyalkylene glycol adipate polyester (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as MDI modified polyalkylene glycol adipate polyester (PMN P–11–115) is subject to reporting under this section for the significant

new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 15. Add § 721.10650 to subpart E to read as follows:

§ 721.10650 Polyether substituted anthraquinone derivative (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polyether substituted anthraquinone derivative (PMN P–11–155) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (colorant for cleaners and detergents).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 16. Add § 721.10651 to subpart E to read as follows:

§ 721.10651 Carbide derived nanocarbon (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carbide derived nanocarbon (PMN P–11–290) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (manufacture of the substance by the method described in the premanufacture notice).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

■ 17. Add § 721.10652 to subpart E to read as follows:

§ 721.10652 Hexanedioic acid, polymer with polyether polyol, 1,1′-methylenebis[4-isocyanatobenzene] and dihydroxydialkyl ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with polyether polyol, 1,1′-methylenebis[4-isocyanatobenzene] and dihydroxydialkyl ether (PMN P–11–309) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 18. Add § 721.10653 to subpart E to read as follows:

§ 721.10653 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1′-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1′-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (PMN P–11–311) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 19. Add § 721.10654 to subpart E to read as follows:

§ 721.10654 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[isocyanatobenzene], dihydroxydialkyl ether and dialkanol ether (PMN P–11–312) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63 (a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 20. Add § 721.10655 to subpart E to read as follows:

§ 721.10655 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether, reaction products with dialkylcarbinol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether, reaction products with dialkylcarbinol (PMN P–11–313) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a

loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 21. Add § 721.10656 to subpart E to read as follows:

§ 721.10656 Hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether reaction products with dialkylcarbinol (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as hexanedioic acid, polymer with .alpha.-hydro-.omega.-hydroxypoly[oxy(methyl-1,2-ethanediyl)],1,1'-methylenebis[4-isocyanatobenzene], dihydroxydialkyl ether reaction products with dialkylcarbinol (PMN P–11–314) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 22. Add § 721.10657 to subpart E to read as follows:

§ 721.10657 Castor oil, polymer with hydrogenated vegetable oil, 1,1'-methylenebis[isocyanatobenzene] and isocyanate (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as castor oil, polymer with hydrogenated vegetable oil, 1,1'-methylenebis[isocyanatobenzene] and isocyanate (PMN P–12–73) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 23. Add § 721.10658 to subpart E to read as follows:

§ 721.10658 2-Oxepanone, polymer with 1,6-diisocyanatohexane, 2,2-dimethyl-1,3-propanediol and 2,2'-oxybis[ethanol].

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2-oxepanone, polymer with 1,6-diisocyimatohexane, 2,2-dimethyl-1,3-propanediol and 2,2'-oxybis[ethanol] (PMN P–12–133; CAS No. 1313708–90–5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general

and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 24. Add § 721.10659 to subpart E to read as follows:

§ 721.10659 Poly(oxy-1,4-butanediyl), -hydro—hydroxy-, polymer with alkyldiisocyanates (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as poly(oxy-1,4-butanediyl), -hydro—hydroxy-, polymer with alkyldiisocyanates (PMN P–12–143) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63 (a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

■ 25. Add § 721.10660 to subpart E to read as follows:

§ 721.10660 Aliphatic diisocyanate adduct with substituted amino alkyl silane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as aliphatic diisocyanate adduct with substituted amino alkyl silane (PMN P–12–274) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(4), (a)(6)(i), (a)(6)(ii), (a)(6)(v), (b) (concentration set at 0.1 percent), and (c). When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering control measures (e.g., enclosure or confinement of the operation, general and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. The following National Institute for Occupational Safety and Health (NIOSH)-certified respirators with an assigned protection factor (APF) of at least 10 meet the requirements of § 721.63(a)(4):

(A) NIOSH-certified air-purifying, tight-fitting half-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(B) NIOSH-certified air-purifying, tight-fitting full-face respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters;

(C) NIOSH-certified powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate air (HEPA) filters;

(D) NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (either half-face or full-face) and HEPA filters; and

(E) NIOSH-certified supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet, or tight-fitting facepiece (either half-face or full-face).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125 (a), (b), (c), (d), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

[FR Doc. 2013–04298 Filed 2–22–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 70

[Docket No. CDC–2012–0016]

RIN 0920–AA22

Control of Communicable Diseases: Interstate; Scope and Definitions

AGENCY: Centers for Disease Control and Prevention (HHS/CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking; withdrawal.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is withdrawing a previously published Notice of Proposed Rulemaking (NPRM) that solicited public comment on updates to the Scope and Definitions for its regulations.

DATES: The Notice of Proposed Rulemaking published at 77 FR 75936, December 26, 2012, is withdrawn, effective immediately.

FOR FURTHER INFORMATION CONTACT: For questions concerning this notice: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION: On December 26, 2012, HHS/CDC published a Notice of Proposed Rulemaking (NPRM) amending 42 CFR part 70 to update the Scope and Definitions to reflect modern terminology and plain language used by private industry and public health partners. (77 FR 75936). On the same date, HHS/CDC simultaneously published a companion direct final rule that proposed identical updates in this **Federal Register** because it believed that the proposed revisions were non-controversial and unlikely to generate significant adverse comment. (77 FR 75880). In the NPRM, HHS/CDC indicated that if we did not receive any significant adverse comments on the direct final rule by January 25, 2013, we would publish a document in the **Federal Register** withdrawing this notice of proposed rulemaking and confirming the effective date of the direct final rule within 30 days after the comment period on the direct final rule ends. HHS/CDC received one public comment that was not a significant, adverse comment, but rather was in support of the companion NPRM. Because HHS/CDC did not receive any significant adverse comments to the NPRM within the specified comment period, we hereby withdraw this NPRM from rulemaking.

Dated: February 13, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–04139 Filed 2–22–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC–2012–0017]

RIN 0920–AA12

Control of Communicable Diseases: Foreign; Scope and Definitions

AGENCY: Centers for Disease Control and Prevention (HHS/CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking; withdrawal.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is withdrawing a previously published Notice of Proposed Rulemaking (NPRM) that solicited public comment on updates to the Scope and Definitions for its regulations.

DATES: The Notice of Proposed Rulemaking published at 77 FR 75939, December 26, 2012, is withdrawn, effective immediately.

FOR FURTHER INFORMATION CONTACT: For questions concerning this notice: Ashley A. Marrone, JD, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop E–03, Atlanta, Georgia 30333; telephone 404–498–1600.

SUPPLEMENTARY INFORMATION: On December 26, 2012 HHS/CDC published a Notice of Proposed Rulemaking (NPRM) amending 42 CFR part 71 to update the Scope and Definitions to reflect modern terminology and plain language used globally by industry and public health partners. (77 FR 75939). On the same date, HHS/CDC simultaneously published a companion direct final rule that proposed identical updates in this **Federal Register** because it believed that the proposed revisions were non-controversial and unlikely to generate significant adverse comment. (77 FR 75885). In the NPRM, HHS/CDC indicated that if we did not receive any significant adverse comments on the direct final rule by January 25, 2013, we would publish a document in the **Federal Register** withdrawing this notice of proposed rulemaking and confirming the effective date of the direct final rule within 30 days after the comment period on the direct final rule ends. HHS/CDC received two comments to the companion NPRM. One comment pertained to food safety that raised issues unrelated to the companion NPRM and appears to have been submitted in error. The second comment was a general comment on immigration and was outside the scope of this rulemaking. HHS/CDC did not consider this comment to be a significant, adverse comment because it did not raise any issues that were relevant to the subject matter under consideration. Because HHS/CDC did not receive any relevant significant adverse comments within the specified comment period, we hereby withdraw this NPRM from rulemaking.

Dated: February 13, 2013.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2013–04131 Filed 2–22–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

RIN 0648–XT12

Endangered and Threatened Species; Proposed Rule To List 66 Reef-Building Coral Species; Proposed Reclassification of Elkhorn Acropora palmata and Staghorn Acropora cervicornis Under the Endangered Species Act (ESA); Extension of Public Comment Period and Notice of Public Hearing

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

ACTION: Extension of public comment period; notice of public hearing.

SUMMARY: NMFS hereby extends the comment period on the proposed listing determinations of 66 reef-building coral species and the proposed reclassifications of elkhorn (*Acropora palmata*) and staghorn (*Acropora cervicornis*) corals under the ESA until April 6, 2013, and announces a public hearing to be held in Silver Spring, MD, on March 12, 2013.

DATES: Comments and information regarding this proposed rule must be received by April 6, 2013. The public hearing will be held on Tuesday, March 12, 2013, from 6 to 9 p.m. in Silver Spring, MD.

ADDRESSES: The March 12, 2013, hearing will be held at NOAA Headquarters, Building 4, NOAA Science Center, 1301 East-West Highway, Silver Spring, MD 20910.

You may submit comments, identified by NOAA–NMFS–2010–0036, by any of the following methods:

- *Electronic submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=[NOAA–NMFS–2010–0036*], click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Regulatory Branch Chief, Protected Resources Division, National Marine Fisheries Service, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814; or Assistant Regional Administrator, Protected Resources, National Marine Fisheries Service, Southeast Regional Office, 263 13th Avenue South, Saint Petersburg, FL 33701, Attn: 82 coral species proposed listing.
- *Fax:* 808–973–2941; Attn: Protected Resources Regulatory Branch Chief; or 727–824–5309; Attn: Protected Resources Assistant Regional Administrator.

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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

You can obtain the petition and reference materials regarding this determination via the NMFS Pacific Island Regional Office Web site: *http://www.fpir.noaa.gov/PRD/PRD_coral.html;* NMFS Southeast Regional Office Web site: *http://sero.nmfs.noaa.gov/pr/esa/82CoralSpecies.htm;* NMFS HQ Web site: *http://www.nmfs.noaa.gov/stories/2012/11/82corals.html;* or by submitting a request to the Regulatory Branch Chief, Protected Resources Division, National Marine Fisheries Service, Pacific Islands Regional Office, 1601 Kapiolani Blvd., Suite 1110, Honolulu, HI 96814, Attn: 82 coral species.

FOR FURTHER INFORMATION CONTACT: Chelsey Young, NMFS, Pacific Islands Regional Office, 808–944–2137; Lance Smith, NMFS, Pacific Island Regional Office, 808–944–2258; Jennifer Moore, NMFS, Southeast Regional Office, 727–824–5312; or Marta Nammack, NMFS, Office of Protected Resources, 301–427–8469.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, we published a proposed rule in the **Federal Register** (77 FR 73219) in response to a petition submitted by the Center for Biological Diversity to list 83 reef-building coral species as threatened or endangered under the ESA. We concluded that 12 of the petitioned coral species warrant listing as endangered (5 Caribbean and 7 Indo-Pacific), 54 coral species warrant listing as threatened (2 Caribbean and 52 Indo-Pacific), and 16 coral species (all Indo-Pacific) do not warrant listing as threatened or endangered under the ESA. We also determined that two Caribbean coral species currently listed warrant reclassification from threatened to endangered.

We subsequently received requests to extend the public comment period for an additional 90 days. We have determined that an extension of 30 days, until April 6, 2013, making the full comment period 120 days, will allow adequate time for the public to thoroughly review and comment on the proposed rule while still providing the agency with sufficient time to meet our statutory deadlines.

Public Hearing

Joint Commerce-Interior ESA implementing regulations state that the Secretary shall promptly hold at least one public hearing if any person requests one within 45 days of publication of a proposed regulation to list a species or to designate critical habitat (see 50 CFR 424.16(c)(3)). We received a request for a public hearing to be held in the DC area. In addition to the 20 public hearings we held in Puerto Rico, the U.S. Virgin Islands, Florida, Hawaii, Guam, the Northern Mariana Islands, and American Samoa, we will hold an additional public hearing in Silver Spring, MD.

In past ESA rule-makings we have conducted traditional public hearings, consisting of recorded oral testimony from interested individuals. This format, although providing a means for public input, does not provide opportunities for dialogue and information exchange. We believe that the traditional public hearing format can be improved upon by also including a brief presentation on the results of the status review of 83 species of reef-building corals and other topics of interest.

The preferred means for providing public comment to the official record is via written testimony prepared in advance of the hearing which may also be presented orally. Blank ''comment sheets'' will be provided at the hearing for those without prepared written comments, and opportunity will also be provided for additional oral testimony. There is no need to register for this hearing.

In scheduling this additional public hearing, we have anticipated that many affected stakeholders and members of the public may prefer to discuss the proposed listing directly with staff during the public comment period. However, this public hearing is not the only opportunity for the public to provide input on this proposal. The public and stakeholders are encouraged to continue to comment and provide input to NMFS on the proposal (via the Federal e-Rulemaking Portal *www.regulations.gov,* correspondence, or fax; see **ADDRESSES**) up until the scheduled close of the comment period on April 6, 2013.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: February 19, 2013.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–04150 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–BC38

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Amendment to the Corals and Reef Associated Plants and Invertebrates Fishery Management Plan of Puerto Rico and the U.S. Virgin Islands

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

ACTION: Notice of availability; request for comments.

SUMMARY: The Caribbean Fishery Management Council (Council) has submitted Amendment 4 to the Fishery Management Plan (FMP) for Corals and Reef Associated Plants and Invertebrates of Puerto Rico and the U.S. Virgin Islands (USVI) (Coral FMP) for review, approval, and implementation by NMFS. Amendment 4 to the Coral FMP proposes to modify management of seagrasses in the U.S. Caribbean exclusive economic zone (EEZ). The intent of Amendment 4 to the Coral FMP is to address the future management of seagrasses in the U.S. Caribbean EEZ in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Written comments must be received on or before April 26, 2013.

ADDRESSES: You may submit comments on Amendment 4 to the Coral FMP, identified by ''NOAA–NMFS–2013–0021'', 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–2013–0021,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Maria del Mar Lopez, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Electronic copies of the amendment may be obtained from the Southeast Regional Office Web site at: *http://sero.nmfs.noaa.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Maria del Mar Lopez, Southeast Regional Office, NMFS, telephone: 727–824–5305, email: *Maria.Lopez@noaa.gov.*

SUPPLEMENTARY INFORMATION: Seagrasses in the EEZ off Puerto Rico and the USVI are managed under the Coral FMP. The Coral FMP was prepared by the Council and is implemented under the authority of the Magnuson-Stevens Act by regulations at 50 CFR part 622. The Magnuson-Stevens Act also requires that NMFS, upon receiving a plan or amendment, publish an announcement in the **Federal Register** notifying the public that the plan or amendment is available for review and comment.

Background

The Magnuson-Stevens Act requires the establishment of annual catch limits (ACLs) and accountability measures (AMs) to end overfishing and prevent overfishing from occurring. Annual catch limits are levels of annual catch of a stock or stock complex that are set to prevent overfishing from occurring. Accountability measures are management controls to prevent ACLs from being exceeded, and to correct or mitigate overages of the ACL if they occur.

To address the requirements of the Magnuson-Stevens Act, NMFS published a final rule to implement the 2011 Caribbean ACL Amendment on December 30, 2011 (76 FR 82414), which included Amendment 3 to the Coral FMP. However, ACLs and AMs for seagrasses, which are included in the Coral FMP, were not established at that time. In Amendment 4 to the Coral FMP, the Council considered whether to set an ACL for seagrasses, designate seagrasses as ecosystem component (EC) species, or remove seagrasses from the Coral FMP.

Action Contained in the Amendment

Amendment 4 to the Coral FMP proposes to modify the management of seagrass species included in the Coral FMP. The Coral FMP currently includes four individual species of seagrasses: turtle grass (*Thalassia testudinum*), manatee grass (*Syringodium filiforme*), shoal grass (*Halodule wrightii*), widgeon grass (*Ruppia maritima*), and one group of species, the sea vines (*Halophila* spp., including *H. decipiens, H. baillonis, H. engelmannii,* and *H. stipulacea* (exotic)), all of which occur in U.S. Caribbean waters. Seagrasses were included in 1994 as members of the coral reef resources fishery management unit (FMU) of the Coral FMP. The Coral FMP defined the coral reef resources FMU to include a vast array of plants and invertebrates that provide habitats that are essential to the growth, development, and survival of managed finfish and other marine organisms.

The location, presence, and distribution of seagrasses in the EEZ are not well known. The best available scientific information indicates that the vast majority of seagrasses occur in shallower waters of Puerto Rico and the USVI due to depth associated light limitations found in the EEZ. Both Puerto Rico and the USVI regulate activities involving seagrasses through their respective coastal zone management programs. Seagrasses have been identified as essential fish habitat (EFH) for stocks within the four Council FMPs (Reef Fish, Queen Conch, Spiny Lobster, and Coral). Essential fish habitat is defined by the Magnuson-Stevens Act as those waters and substrates necessary to fish for spawning, breeding, feeding or for growth to maturity. Additionally, seagrasses have also been identified as habitat areas of particular concern (HAPC) within special areas in Puerto Rico commonwealth and USVI territorial waters (state waters).

There is presently no known targeted or indirect harvest of any of the seagrass species included in the Coral FMP, either from the EEZ or from state waters, and future harvest is not anticipated.

In Amendment 4 to the Coral FMP, the Council considered whether to take no action, set an ACL for seagrasses, designate seagrasses as EC species, or remove seagrasses from the Coral FMP. The Magnuson-Stevens Act's National Standard 7 guidelines (50 CFR 600.340) require Councils to prepare FMPs only for overfished fisheries and other fisheries where regulation would serve some useful purpose, and where the present or future benefit of regulation would justify the costs. Because there is no known harvest of seagrass species, and these species occur predominantly in state waters, the Council determined that Federal management of seagrasses is unnecessary. Further, removing seagrasses from the Coral FMP would not affect the designation of seagrasses as EFH and HAPC for stocks within the Queen Conch Resources of Puerto Rico and the USVI FMP, Reef Fish Fishery of Puerto Rico and the USVI FMP, FMP for the Spiny Lobster Fishery of Puerto Rico and the USVI, and Coral FMP. Seagrasses would continue to be protected by these designations, which require, among other things, that FMPs to minimize to the extent practicable adverse effects on EFH caused by fishing. In addition, other management measures currently in place, such as gear restrictions and closed areas, would continue protection to these important habitats.

Proposed Rule for Amendment 4 to the Coral FMP

A proposed rule that would implement Amendment 4 to the Coral FMP has been drafted. In accordance with the Magnuson-Stevens Act, NMFS is evaluating Amendment 4 to the Coral FMP to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law. If the determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Consideration of Public Comments

The Council submitted Amendment 4 to the Coral FMP for Secretarial review, approval, and implementation. NMFS' decision to approve, partially approve, or disapprove Amendment 4 to the Coral FMP will be based, in part, on consideration of comments, recommendations, and information received during the comment period on this notice of availability.

Comments received by April 26, 2013, whether specifically directed to the amendment or the proposed rule, will be considered by NMFS in its decision to approve, disapprove, or partially approve the amendment. Comments received after that date will not be considered by NMFS in this decision. All comments received by NMFS on the amendment or the proposed rule during their respective comment periods will be addressed in the final rule.

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

Dated: February 20, 2013.

Kara Meckley,

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

[FR Doc. 2013–04266 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 121101598–3124–01]

RIN 0648–XC334

Atlantic Highly Migratory Species; North and South Atlantic 2013 Commercial Swordfish Quotas

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

ACTION: Proposed rule; request for comments.

SUMMARY: This proposed rule would adjust the 2013 fishing season quotas for North and South Atlantic swordfish based upon 2012 commercial quota underharvests and international quota transfers consistent with the International Commission for the Conservation of Atlantic Tunas (ICCAT) Recommendations 11–02 and 12–01. This proposed rule could affect commercial and recreational fishing for swordfish in the Atlantic Ocean, including the Caribbean Sea and Gulf of Mexico. This action implements ICCAT recommendations, consistent with the Atlantic Tunas Convention Act (ATCA), and furthers domestic management objectives under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Written comments must be received by 5 p.m., local time, on March 27, 2013.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2013–0030, 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–2013–0030,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

Mail: Submit written comments to Margo Schulze-Haugen, NMFS/SF1, 1315 East West Highway, National Marine Fisheries Service, SSMC3, Silver Spring, MD 20910.

Fax: 301–713–1917, Phone: 301–427–8503; *Attn:* Margo Schulze-Haugen.

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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

NMFS will hold one public hearing on this proposed rule on March 14, 2013. The public hearing will be held in Silver Spring, MD and may be combined with a hearing for another relevant action. For specific location, date, and time, see the **SUPPLEMENTARY INFORMATION** section of this document.

Copies of the supporting documents—including the 2012 Environmental Assessment (EA), Regulatory Impact Review (RIR), and Initial Regulatory Flexibility Analysis (IRFA) for North Atlantic swordfish, the 2007 EA, RIR, and IRFA for South Atlantic swordfish, and the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan—are available from the HMS Management Division Web site at *http://www.nmfs.noaa.gov/sfa/hms/* or by contacting Jennifer Cudney by phone at 301–427–8503 or Steve Durkee by phone at 202–670–6637.

FOR FURTHER INFORMATION CONTACT: Jennifer Cudney by phone at 301–427–8503 or Steve Durkee by phone at 202–670–6637, or by fax: 301–713–1917.

SUPPLEMENTARY INFORMATION:

Background

The U.S. Atlantic swordfish fishery is managed under the 2006 Consolidated Highly Migratory Species (HMS) Fishery Management Plan (FMP). Implementing regulations at 50 CFR part 635 are issued under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.,* and ATCA, 16 U.S.C. 971 *et seq.* The United States implements ICCAT recommendations under ATCA, through regulations as may be necessary and appropriate.

North Atlantic Swordfish Quota

At the 2011 ICCAT meeting, Recommendation 11–02 was adopted, maintaining the North Atlantic swordfish total allowable catch (TAC) of 10,301 metric tons (mt) dressed weight (dw) (13,700 mt whole weight (ww)) through 2013. Of this TAC, the United States baseline quota is 2,937.6 mt dw (3,907 mt ww) per year. ICCAT Recommendation 11–02 also includes a 112.8 mt dw (150 mt ww) annual quota transfer from the United States to Morocco and limits allowable underharvest carryover to 25 percent of a contracting party's baseline quotas. Therefore, the United States may carry over a maximum of 734.4 mt dw (976.8 mt ww) of underharvest from the previous year (2012) to be added to the 2013 baseline quota. This proposed rule would adjust the U.S. baseline quota for the 2013 fishing year to account for the annual quota transfer to Morocco and the 2012 underharvest.

The 2013 North Atlantic swordfish baseline quota is 2,937.6 mt dw (3,907 mt ww). The preliminary North Atlantic swordfish underharvest for 2012 was 1,209.4 mt dw (1,608.5 mt ww) as of December 31, 2012, which exceeds the

maximum carryover cap of 734.4 mt dw (976.8 mt ww). Therefore, NMFS is proposing to carry forward the maximum amount allowed per ICCAT Recommendation 11–02. The 2,937.6 mt dw (3,907 mt ww) baseline quota would be reduced by the 112.8 mt dw (150 mt ww) annual quota transfer to Morocco and increased by the underharvest carryover maximum of 734.4 mt dw (976.8 mt ww), resulting in 3,559.2 mt dw (4733.7 mt ww), which is the proposed adjusted North Atlantic swordfish quota for the 2013 fishing year. From that proposed adjusted quota, the directed category would be allocated 3,209.2 mt dw (4,268.2 mt ww), which would be split equally into two seasons in 2013 (January through June, and July through December). Fifty mt dw (66.5 mt ww) would be allocated to the reserve category for inseason adjustments and research, and 300 mt dw (399 mt ww) would be allocated to the incidental category, which includes recreational landings and catch by incidental swordfish permit holders, for the 2013 fishing season, per § 635.27(c)(1)(i)(B) (Table 1).

The landings and proposed quota for North Atlantic swordfish are based on commercial dealer reports and reports by anglers in the HMS Non-Tournament Recreational Swordfish and Billfish Landings Database and the Recreational Billfish Survey received as of December 31, 2012, and do not include dead discards. We will adjust the quotas in the final rule based on updated data, including dead discard data, if available. Thus, while the 2013 proposed North Atlantic swordfish quota is subject to further adjustments and we are notifying the public of that potential change, we do not expect the final quota to change from the proposed quota. The United States has carried over the full amount of underharvest allowed under ICCAT recommendations for the past several years, and we do not expect fishing activity to vary significantly from these past years. For the final quota to deviate from the proposed quota, the sum of updated landings data (from late reports) and dead discard estimates would need to reach or exceed 475 mt dw. In 2011, dead discards were estimated to equal 101.5 mt dw and late reports equaled 108.4 mt dw. Consequently, we do not believe updated data and dead discard estimates will change the adjusted quota.

South Atlantic Swordfish Quota

In 2006, ICCAT Recommendation 06–03 established the South Atlantic swordfish TAC at 17,000 mt ww for 2007, 2008, and 2009. Of this, the United States received 75.2 mt dw (100 mt ww). As with the North Atlantic swordfish recommendation, ICCAT Recommendation 06–03 limited the amount of underharvest that can be carried forward. For South Atlantic swordfish, the United States may carry forward up to 100 percent of the base quota (75.2 mt dw). In 2009, Recommendation 09–03 reduced the South Atlantic swordfish TAC to 15,000 mt ww but maintained the U.S. quota share of 75.2 mt dw (100 mt ww) and underharvest carryover limit through 2012. Recommendation 09–03 also included a total of 75.2 mt dw (100 mt ww) of quota transfers from the U.S. to other countries. These transfers were 37.6 mt dw (50 mt ww) to Namibia, 18.8 mt dw (25 mt ww) to Côte d'Ivore, and 18.8 mt dw (25 mt ww) to Belize. In November 2012, ICCAT Recommendation 12–01 extended the U.S. baseline quota, underharvest carryover limit, and international quota transfer amounts and provisions through 2013.

In 2012, U.S. fishermen did not land any South Atlantic swordfish as of December 31, 2012. Therefore, 75.2 mt dw (100 mt ww) of underharvest is available to carry over to 2013 and can cover the entire 75.2 mt dw (100 mt ww) of annual international quota transfers outlined above. As a result, the 2013 adjusted quota for South Atlantic swordfish is 75.2 mt dw (100 mt ww) (Table 1).

The landings and proposed quota for South Atlantic swordfish are based on dealer reports received as of December 31, 2012, and do not include dead discards. We will adjust the quotas in the final rule based on updated data, including dead discard data, if available. Thus, the 2013 proposed South Atlantic swordfish quota is subject to further adjustments. However, the United States has only landed South Atlantic swordfish once in the past several years (0.2 mt dw in April 2010) and is unlikely to do so during the remainder of 2012. For this reason, we do not expect the final quota to change from the proposed quota.

Impacts

Impacts resulting from the 2013 North Atlantic swordfish specifications are analyzed in the EA, RIR, and IRFA that were prepared for the 2012 Swordfish Quota Specifications Final Rule (July 31, 2012; 77 FR 45273). The impacts resulting from the 2013 South Atlantic swordfish specifications were analyzed in the EA, RIR, and IRFA that were prepared for the 2007 Swordfish Quota Specification Final Rule (October 5, 2007; 72 FR 56929). The proposed quota adjustments would not increase overall quotas and are not expected to increase fishing effort, protected species interactions, or environmental effects beyond those considered in the 2012 and 2007 EAs. Therefore, because there would be no changes to the North or South Atlantic swordfish management measures in this proposed rule, or the affected environment or any environmental effects that have not been previously analyzed, NMFS has determined that the North and South Atlantic swordfish specifications and impacts to the human environment as a result of the proposed quota adjustments do not require additional NEPA analysis beyond that discussed in the 2012 and 2007 EAs.

TABLE 1—2013 NORTH AND SOUTH ATLANTIC SWORDFISH QUOTAS

North Atlantic Swordfish Quota (mt dw)	2012	2013
Baseline Quota	2,937.6	2,937.6
Quota Transfer to Morocco	(−)112.8	(−)112.8
Total Underharvest from Previous Year+	1,388.5	1,209.4
Underharvest Carryover from Previous Year+	(+)734.4	(+)734.4
Adjusted Quota	3,559.2	3,559.2
Quota Allocation:		
Directed Category	3,209.2	3,209.2
Incidental Category	300	300
Reserve Category	50	50

South Atlantic Swordfish Quota (mt dw)	2012	2013
Baseline Quota	75.2	75.2
International Quota Transfers*	(−)75.2	(−)75.2
Total Underharvest from Previous Year+	75.2	75.2
Underharvest Carryover from Previous Year+	75.2	75.2
Adjusted quota	75.2	75.2

+ Underharvest carryover is capped at 25 percent of the baseline quota allocation for the North Atlantic and 75.2 dw (100 mt ww) for the South Atlantic. 2012 underharvest current as of December 31, 2012; does not include dead discards.

* Under Recommendation 12–01, 100 mt ww of the U.S. underharvest and base quota, as necessary, was transferred to Namibia (37.6 mt dw, 50 mt ww), Cote d'Ivore (18.8 mt dw, 25 mt ww), and Belize (18.8 mt dw, 25 mt ww).

NMFS determined that the proposed rules to implement the North Atlantic swordfish quota framework (77 FR 25669, May 1, 2012) and South Atlantic swordfish quota framework (75 FR 35432, June 22, 2010) are consistent to the maximum extent practicable with the enforceable policies of the approved coastal management program of coastal states on the Atlantic including the Gulf of Mexico and the Caribbean Sea. Pursuant to 15 CFR 930.41(a), NMFS provided the Coastal Zone Management Program of each coastal state a 60-day period to review the consistency determination and to advise the Agency of their concurrence. NMFS received concurrence with the consistency determinations from several states and inferred consistency from those states that did not respond within the 60-day time period. This proposed action to establish the 2013 North and South Atlantic swordfish quotas does not change the framework previously consulted upon; therefore, no additional consultation is required.

Public Hearings

Comments on this proposed rule may be submitted via *http://www.regulations.gov,* mail, or fax; comments may also be submitted at the public hearing. NMFS solicits comments on this proposed rule by *March 27, 2013.* During the comment period, NMFS will hold one public hearing for this proposed rule. The public hearing will be held at the NMFS Science Center at 1301 East-West Highway, Silver Spring MD on March 14, 2013, from 1:00–4:00 p.m. This hearing may be combined with a hearing for another relevant action. The hearing location will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Steve Durkee at 202–670–6637, at least 7 days prior to the meeting.

The public is reminded that NMFS expects participants at the public hearings to conduct themselves appropriately. At the beginning of each public hearing, a representative of NMFS will explain the ground rules (*e.g.,* alcohol is prohibited from the hearing room; attendees will be called to give their comments in the order in which they registered to speak; each attendee will have an equal amount of time to speak; and attendees should not interrupt one another). The NMFS representative will attempt to structure the meeting so that all attending members of the public will be able to comment, if they so choose, regardless of the controversial nature of the subject(s). Attendees are expected to respect the ground rules, and, if they do not, they will be asked to leave the hearing.

Classification

Pursuant to the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that the proposed rule is consistent with the 2006 Consolidated HMS FMP and its amendments, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

The Chief Council for Regulation of the Department of Commerce certified to the Chief Council for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities because the proposed quota adjustments are the same as in 2012 and the United States is not expected to catch its entire quota in 2013.

This proposed rule would adjust the 2013 baseline quota for North Atlantic swordfish (January 1, 2013, through December 31, 2013) to account for 2012 underharvests and international quota transfers per § 635.27(c)(1)(i) based on ICCAT recommendation 11–02. The United States can carry over 2012 underharvest at a level not to exceed 25 percent of the baseline quota. Additionally, ICCAT Recommendation 11–02 stipulates that the United States transfer 112.8 mt dw (150 mt ww) of quota to Morocco.

In 2012, U.S. fishermen landed 2,349.8 mt dw (3,125.2 mt ww) of North Atlantic swordfish as of December 31, 2012, leaving 1,209.4 mt dw (1,608.5 mt ww) of quota underharvest. This underharvest amount exceeds the maximum underharvest carryover of 734.4 mt dw (976.8 mt ww), therefore, 734.4 mt dw (976.8 mt ww) of 2012 underharvest would be carried over and added to the 2013 baseline quota. The quota transfer of 112.8 mt dw (150 mt ww) to Morocco would be deducted, leaving a proposed 2013 North Atlantic swordfish adjusted quota of 3,559.2 mt dw (4733.7 mt ww) (Table 1).

This proposed rule would also adjust the 2013 baseline quota for South Atlantic swordfish (January 1, 2013, through December 31, 2013) to account for 2012 underharvests and international quota transfers per § 635.27(c)(1)(ii) based on ICCAT recommendation 12–01. The United States can carry over 2012 underharvest at a level not to exceed 100 percent of the baseline quota. Additionally, ICCAT Recommendation 12–01 stipulates that the United States transfer the following quota amounts to other countries: 37.6 mt dw (50 mt ww) to Namibia; 18.8 mt dw (25 mt ww) to Côte d'Ivore; and 18.8 mt dw (25 mt ww) to Belize.

In 2012, U.S. fishermen did not land any South Atlantic swordfish as of December 31, 2012. Therefore, 75.2 mt dw (100 mt ww) of underharvest is available to carry over to 2013 and can cover the entire 75.2 mt dw (100 mt ww) of annual international quota transfers outlined above. As a result, the 2013 adjusted quota for South Atlantic swordfish is 75.2 mt dw (100 mt ww) (Table 1).

The commercial swordfish fishery is comprised of fishermen who hold one of three swordfish limited access permits (LAP) (i.e., directed, incidental, or handgear), fishermen who hold an HMS incidental squid trawl permit, and the related industries including processors, bait houses, and equipment suppliers. NMFS considers all participants in the commercial swordfish fishery to be small entities, based on the relevant NAICS codes and size standards set by

the Small Business Administration. As of November 2012, there were approximately 180 vessels with a directed swordfish LAP, 75 vessels with an incidental swordfish LAP, and 77 vessels with a handgear LAP for swordfish. Additionally, there were approximately 71 HMS incidental squid trawl permit holders, which allow vessels in the *Illex* squid fishery to retain up to 15 incidentally-caught swordfish while trawling for squid. Based on the 2011 swordfish ex-vessel price of $4.44/lb, the 2013 North and South Atlantic swordfish baseline quotas could result in gross revenues of $28,754,470 (2937.6 mt dw (6,476,232 lbs dw) * $4.44/lb) and $734,132 (75.2 mt dw (165,345 lbs dw) * $4.44), respectively, if the quotas were fully utilized. Under the adjusted quotas of 3,559.2 mt dw (7,846,612 lbs dw) for North Atlantic swordfish and 75.2 mt dw (165,345 lbs dw) for South Atlantic swordfish, the gross revenues could be $34,838,957 and $734,132, respectively, for fully utilized quotas.

Potential revenues per vessel resulting from full utilization of the adjusted quotas, could be $86,449 for the North Atlantic swordfish fishery and $1,821 for the South Atlantic swordfish fishery, considering a total of 403 swordfish permit holders. These estimates, however, represent an average across all permit types, despite permit differences in retention limits, target species, and geographical range. For North Atlantic swordfish, directed swordfish permit holders would likely experience higher than average per-vessel revenue due to the use of pelagic longlines and the lack of a retention limit per trip. At the other extreme, HMS incidental squid trawl permit holders would likely experience per vessel revenue well below the average due to the low retention limit per trip (15 swordfish) and because these vessels do not target swordfish and only catch them incidentally. For South Atlantic swordfish, only directed swordfish permit holders would be likely to interact with this stock; therefore, potential revenue is higher than the average for these directed swordfish permit holders, and near zero for the other permit types. Additionally, U.S. fishermen rarely catch South Atlantic swordfish. Over the past 5 years, only 0.2 mt dw of South Atlantic swordfish catch has been reported.

Because the United States' commercial swordfish fishery is not expected to catch its entire quota in 2013, these adjustments will not have a significant impact on a substantial number of small entities. As a result, no initial regulatory flexibility analysis is required, and none has been prepared.

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

Dated: February 15, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2013–04156 Filed 2–22–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 121126649–3123–01]

RIN 0648–BC79

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Monkfish Fishery; Emergency Action

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

ACTION: Proposed rule; request for comment.

SUMMARY: NMFS proposes to implement a temporary emergency action that would suspend existing monkfish possession limits for vessels issued both a Federal limited access Northeast multispecies permit and a limited access monkfish Category C or D permit that are fishing under a Northeast multispecies day-at-sea in the monkfish Northern Fishery Management Area for 180 days beginning on May 1, 2013. This action is necessary to help mitigate expected adverse economic and social harm resulting from substantial reductions to the 2013 annual catch limits for several groundfish stocks managed under the Northeast Multispecies Fishery Management Plan. The intended effect of this action is to provide additional fishing opportunities to vessels affected by reductions to groundfish catch limits, without resulting in overfishing monkfish within the Northern Fishery Management Area.

DATES: Comments must be received by March 12, 2013.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2012–0240, 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-2012-0240,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930–2276. Mark the outside of the envelope: ''Comments on Monkfish Emergency Action.''

• *Fax:* (978) 281–9135; Attn: Douglas Christel.

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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA), which is contained in the environmental assessment (EA) prepared for this action and summarized in the Classification section of this proposed rule. Copies of the supporting biological, economic, and social impact analysis for this action is contained in the EA prepared for this rule, and may be found at the following Internet address: *http://www.nero.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Douglas Christel, Fishery Policy Analyst, (978) 281–9141, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Background

The monkfish fishery is jointly managed by the New England Fishery Management Council (NEFMC) and the Mid-Atlantic Fishery Management Council. The fishery extends from Maine to North Carolina out to the continental margin. The Councils manage the fishery as two stocks, with the Northern Fishery Management Area (NFMA) covering the Gulf of Maine (GOM) and northern part of Georges Bank (GB), and the Southern Fishery Management Area (SFMA) extending from the southern flank of GB through

the Mid-Atlantic Bight to North Carolina. The monkfish fishery is primarily managed by possession limits, in conjunction with a yearly allocation of monkfish days-at-sea (DAS) calculated to enable vessels participating in the fishery to catch, but not exceed, the target total allowable landings (TAL) limit and the annual catch target (ACT, the TAL plus an estimate of expected discards) in each management area. Both the ACT and the TAL are calculated to maximize yield in the fishery over the long term.

Monkfish are often caught while fishing for Northeast (NE) multispecies (i.e., groundfish), particularly in the NFMA. Both monkfish and groundfish are bottom-dwelling species comingling in the same fishing locations and susceptible to gear types used in both fisheries. Because a majority of vessels operating in the NFMA are issued both monkfish and groundfish permits, the two fisheries are closely related, and influence one another in both the nature of fishing operations (which species to target and where to fish) and resulting economic and social impacts of applicable management measures.

Recent groundfish stock assessments indicate that substantial reductions in the fishing mortality rate for several groundfish stocks are necessary to prevent overfishing and rebuild overfished stocks, consistent with rebuilding plans required under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Accordingly, the NEFMC developed Framework Adjustment (FW) 48 to the NE Multispecies Fishery Management Plan (FMP) to specify annual catch limits (ACLs) for several groundfish stocks based upon the updated stock assessments, among other measures. The NEFMC ultimately split FW 48 into two separate actions, with updated ACLs adopted as part of FW 50 at its January 2013 meeting. The proposed ACLs for several stocks, particularly those caught in the GOM and GB, are substantially reduced compared to ACLs specified for fishing year (FY) 2012 (see Table 1). A proposed rule to implement these proposed ACLs, along with other management measures, is expected to be published in the **Federal Register** shortly. If approved, such ACLs would likely become effective by the start of FY 2013 on May 1, 2013, and may result in substantial adverse economic impacts to vessels participating in the groundfish fishery. To help mitigate the adverse economic impacts of reduced fishing opportunities in the groundfish fishery during FY 2013, at its November 2012 meeting, the NEFMC requested that NMFS implement an emergency action to eliminate monkfish possession limits for groundfish sector vessels fishing under a groundfish DAS in the NFMA, an area that includes the entire GOM and northern portions of GB.

TABLE 1—PROPOSED REDUCTIONS OF 2013 GROUNDFISH ACLS COMPARED TO 2012 ACLS

Groundfish stock	Reduction of FY 2013 ACL compared to FY 2012 (percent)
GB cod	55
GOM cod	77
GOM haddock	71
GB yellowtail flounder	62
Cape Cod/GOM yellowtail flounder	53
American plaice	57
Witch flounder	52

According to the latest monkfish stock assessment conducted in August 2010 (50th Stock Assessment Workshop), monkfish in the NFMA are neither overfished, nor subject to overfishing. Based on this assessment and an evaluation by the NEFMC Scientific and Statistical Committee, the Councils adopted FY 2011–2013 monkfish ACTs and TALs for the NFMA as part of FW 7 to the Monkfish FMP (October 26, 2011; 76 FR 66192). These catch limits were set below the overfishing level for NFMA monkfish to account for both scientific and management uncertainty, and to minimize the risk that overfishing will occur. In recent years, monkfish landings have fallen short of monkfish target total allowable catch amounts specified for the NFMA (see Table 2), with FY 2012 landings levels also projected to be below the TAL. As a result, monkfish landings could be increased as a means of providing additional fishing opportunities for groundfish vessels, with little risk of overfishing NFMA monkfish.

TABLE 2—RECENT NFMA MONKFISH LANDINGS COMPARED TO ASSOCIATED TARGET TOTAL ALLOWABLE CATCH AMOUNTS FOR EACH YEAR

Fishing year	Target total allowable catch (mt)	Amount landed (mt)	Percent of target total allowable catch landed
2008	5,000	3,528	71
2009	5,000	3,344	67
2010	5,000	2,834	57
2011	5,854	3,699	63

Justification for Emergency Action

Section 305(c) of the Magnuson-Stevens Act authorizes the Secretary to promulgate emergency regulations to address an emergency for any fishery. NMFS policy guidelines for determining whether an emergency rule is justified were published on August 21, 1997 (62 FR 44421). The guidelines state that the implementation of an emergency action should be limited to special circumstances where substantial harm or disruption of the resource, fishery, or community would be caused in the time it would take to follow standard rulemaking procedures. The emergency action guidelines define the existence of an emergency as a situation that: ''(1) Results from recent, unforeseen events or recently discovered circumstances; and (2) presents serious conservation or management problems in the fishery; and (3) if the opportunity for prior public notice and comment is being waived, can be addressed through emergency regulations for which the immediate benefits outweigh the value of advance notice, public comment, and deliberative consideration of the impacts on participants to the same

extent as would be expected under the normal rulemaking process.'' The justifications described in the guidelines include the prevention of significant direct economic loss, or to preserve a significant economic opportunity that otherwise might be foregone, and the prevention of significant community impacts. This action meets the first two guidelines; the third guideline is not relevant because the opportunity for prior public comment is not being waived.

As discussed more thoroughly in the EA developed to support this action (see **ADDRESSES**), the combined effect of several issues facing the groundfish fishery for FY 2013 present recently discovered circumstances that would likely cause serious management problems and result in substantial economic and social harm for the groundfish and monkfish fisheries and associated communities. These issues include a series of recent groundfish stock assessment updates indicating the poor condition of some stocks and the need to reduce fishing mortality for these stocks starting in FY 2013, a late decision by the NEFMC to adopt substantially lower groundfish ACLs for certain stocks for FY 2013 as part of FW 48B to the NE Multispecies FMP, and the lack of time to develop additional measures to mitigate the economic and social impacts of reduced FY 2013 groundfish ACLs through the conventional fishery management council management process. These issues can, at least in part, be addressed through an emergency action to suspend existing monkfish possession limits for vessels issued both a limited access groundfish and monkfish permit in the NFMA.

An emergency action would provide additional fishing opportunities to help mitigate expected substantial adverse economic and social harm resulting from reduced groundfish ACLs in FY 2013, without significantly increasing the risk of overfishing monkfish in the NFMA. These measures can be developed and implemented by NMFS more swiftly than a Council action that is subject to procedural and other requirements not applicable to NMFS. Implementing such measures under emergency action would help to preserve an economic opportunity that otherwise might be foregone if the NEFMC attempted to implement such measures under the normal, slower Council process. Although some of the groundfish stock assessments were completed earlier in 2012, final ACLs were not formally adopted by the NEFMC until January 2013 following the completion of the stock assessment update for GOM and GB cod in December 2012. Thus, the full scope of potential adverse economic impacts for FY 2013 was not realized until very recently. Therefore, the potential impact of the proposed reductions in groundfish ACLs for several groundfish stocks combined represents recently discovered circumstances that could result in substantial harm to the groundfish fishery and associated fishing communities. Further, because the NEFMC needed to prioritize adopting ACLs before the start of FY 2013, there was not enough time to fully develop measures that would help mitigate expected economic impacts of reduced ACLs in FY 2013 as part of FW 48B. Accordingly, NMFS finds that this proposed emergency action, as further described below, is consistent with section 305(c) of the Magnuson-Stevens Act and NMFS guidance regarding the use of emergency actions.

Proposed Management Measures

Pursuant to section 305(c)(3) of the Magnuson-Stevens Act, the management measures proposed in this rule would remain in effect for 180 days, and are likely to be extended an additional 185 days, as allowed by this section of the Magnuson-Stevens Act, unless new information indicates that the NFMA monkfish TAL for FY 2013. If extended, these measures would be effective for the duration of FY 2013 (through April 30, 2014).

1. Monkfish Possession Limits in the NFMA

This emergency action would suspend existing monkfish possession limits for vessels issued a Federal limited access monkfish Category C or D permit (i.e., those also issued a Federal limited access NE multispecies permit) that are fishing under a groundfish DAS or both a groundfish and monkfish DAS in the NFMA during FY 2013. Vessels would still be required to declare a trip under a groundfish or monkfish DAS at the dock prior to starting a trip in order to be exempt from the monkfish possession limits; a vessel that does not declare a trip under a groundfish or monkfish DAS at the dock prior to starting a trip would not be exempt from the monkfish possession limits under this action. Existing monkfish possession limits for vessels issued a limited access monkfish Category A or B permit and fishing under only a monkfish DAS, or vessels issued an open access monkfish Category E permit (i.e., vessels that catch monkfish while targeting other fisheries) would remain the same, as specified in Table 3. In addition, the overfishing level, acceptable biological catch level, ACL, ACT, and TAL would remain as 19,557 mt, 7,592 mt, 6,567 mt, and 5,854 mt, respectively, as implemented in either Amendment 5 (May 25, 2011; 76 FR 30265) or FW 7 to the Monkfish FMP.

TABLE 3—PROPOSED MONKFISH POSSESSION LIMITS IN THE NFMA FOR 2013

Sector participation status	DAS type	Monkfish permit category	Possession limit (tail weight)
Non-sector (Common Pool)	No DAS	A, B, or E	Up to 5% of total weight of fish onboard; or 50 lb (23 kg) per day, up to 150 lb (68 kg) per trip based on gear used.
	Monk	A	1,250 lb (567 kg)/DAS.
		B	600 lb (272 kg)/DAS.
	NE Mults A	E	Up to 25% of total weight of fish onboard, not to exceed 300 lb (136 kg).
	DAS only	C or D	Unlimited.
	NE Mults A & Monk DAS	C or D	Unlimited.
Sector	Non-DAS	E	Up to 5% of total weight of fish onboard; or 50 lb (23 kg) per day, up to 150 lb (68 kg) per trip based on gear used.
	NE Mults A	E	Up to 25% of total weight of fish onboard, not to exceed 300 lb (136 kg).
	DAS only	C or D	Unlimited.
	NE Mults A & Monk DAS	C or D	Unlimited.

These proposed measures differ from those requested by the NEFMC in that the suspension of existing monkfish possession limits would apply to both sector and non-sector vessels instead of just sector vessels. Suspending monkfish possession limits for both sector and non-sector groundfish vessels is proposed as being necessary to ensure that the proposed measures fairly and equitably allocate fishing privileges among affected entities, consistent with National Standard 4 of the Magnuson-Stevens Act. This emergency action would not apply to vessels issued a limited access monkfish Category A or B permit, because they are not issued a limited access groundfish permit and are not directly affected by reductions to groundfish ACLs during FY 2013, or to those issued a Category H permit, because they cannot fish within the NFMA.

We expect these proposed measures to more closely achieve, but not exceed, the FY 2013 TAL for monkfish in the NFMA. Using recent landings patterns by limited access monkfish Category C and D vessels, we expect that the proposed measures would result in monkfish landings of approximately 5,430 mt during FY 2013, or 93 percent of the FY 2013 monkfish TAL in the NFMA. This represents an increase of 608,530 lb (276,024 kg) of monkfish landings compared to landings expected under the current possession limits. If fishing patterns shift as a result of these proposed measures, and such a shift results in increased targeting of monkfish, there is a risk that monkfish landings from the NFMA could exceed the FY 2013 TAL.

2. Regional Administrator Authority to Reinstate Existing Monkfish Possession Limits

This action proposes to authorize the Regional Administrator to reinstate monkfish possession limits for limited access monkfish Category C and D vessels fishing under a groundfish DAS or both a monkfish and groundfish DAS in the NFMA at any time within 180 days following the implementation of this action if available data indicate that the NFMA monkfish TAL or ACT may be exceeded during FY 2013. Further, NMFS may modify or not extend this action after the initial 180 days. This is necessary to ensure that unexpected changes in fishing behavior in response to this emergency action do not cause monkfish landings or catch, when discards are included, to exceed the FY 2013 NFMA monkfish TAL or ACT, respectively, and result in overfishing for NFMA monkfish. If necessary, NMFS shall reinstate monkfish possession limits in the NFMA consistent with the Administrative Procedure Act.

Request for Comments

The public is invited to comment on any of the measures proposed in this rule. NMFS is especially interested in receiving comments on the likelihood that these measures may result in changes to recent fishing behavior, including whether more groundfish DAS would be used in FY 2013, and whether vessels would use groundfish DAS to specifically target monkfish.

Classification

At this time, the NMFS Assistant Administrator has made a preliminary determination that the emergency measures that this proposed rule would implement are consistent with the Monkfish FMP, provisions of the Magnuson-Stevens Act, agency guidelines on emergency rules, and other applicable laws. NMFS, in making a final determination, will take into account the data, views, and comments received during the comment period.

This proposed rule has been determined to be not significant for the purposes of Executive Order (E.O.) 12866.

This proposed rule does not contain policies with Federalism or takings implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

NMFS prepared an IRFA as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the legal basis for this action are contained in the preamble to this proposed rule and in the background, purpose, and need discussion (Section 2.0) of the EA prepared for this action. This proposed action does not contain any new recordkeeping or reporting requirements, and does not impose any additional costs to affected vessels.

As described above, this action is necessary to help mitigate substantial economic and social impacts to the groundfish fishery and associated fishing communities resulting from substantially reduced ACLs for several groundfish stocks during FY 2013. This action would suspend existing monkfish possession limits for vessels issued a Federal limited access monkfish Category C or D permit fishing under either a monkfish or groundfish DAS in the NFMA. The objective of this emergency action is to increase monkfish fishing opportunities and associated revenue for affected groundfish vessels. The proposed measures are expected to facilitate an increase in NFMA monkfish landings during FY 2013, while minimizing the risk of overfishing monkfish in the NFMA.

NMFS fully analyzed and considered three principal alternatives, including the No Action Alternative, Alternative 1, and the proposed action. The No Action Alternative would have retained the existing monkfish possession limits, while Alternative 1 would have suspended monkfish possession limits for vessels issued a Federal limited access monkfish Category C or D permit when fishing under both a monkfish and groundfish DAS in the NFMA. NMFS also considered, but did not fully analyze, several additional alternatives that were rejected because they were beyond the scope of the purpose and need for this action. The proposed action, Alternative 2 in the EA developed for this action, would likely result in the greatest economic benefit to affected entities among the alternatives considered, as described further below. For a more complete description of the alternatives considered in this action, refer to the EA prepared for this action (see **ADDRESSES**).

The economic value of monkfish landings depends upon the market category landed due to price variation among the various monkfish market categories. To more effectively compare the economic impacts among alternatives considered in this action, expected revenues associated with each alternative are estimated using the average price of monkfish landed when all landings of all market categories are converted to live weight equivalents using established conversion factors. It is important to recognize that realized revenues during FY 2013 will change in proportion to any deviation from the average price reported during the first part of FY 2012 ($1.22 per lb ($2.69 per kg)), as well as the amount of each monkfish market category that is landed.

Description of and Estimate of the Number of Small Entities to Which the Proposed Rule Would Apply

The preferred alternative would affect any vessel issued a valid Federal limited access monkfish Category C or D permit that fishes under a monkfish or groundfish DAS in the NFMA. All of the vessels affected by this action are considered small entities under the Small Business Administration size standards for small fishing businesses ($4.0 million in gross sales). Therefore, there are no disproportionate impacts

between small and large entities associated with this proposed action. Available data are not adequate to identify affiliated vessels, so each operating unit (vessel) is considered a small entity for purposes of the RFA. For a more detailed description of the affected entities, refer to the EA prepared for this action (see **ADDRESSES**).

As of December 7, 2012, 2,212 vessels were issued a Federal monkfish permit, of which 558 were issued limited access monkfish Category C or D permits during FY 2012. However, only a fraction of these vessels will likely actually fish in the NFMA during FY 2013. During FY 2008, 400 Category C or D vessels fished in the NFMA out of a total of 690 vessels that were issued a limited access monkfish Category C or D permit (58 percent). During FY 2011, a total of 189 monkfish Category C or D vessels fished exclusively in the NFMA, or in both the NFMA and SFMA during the same trip, out of 586 permits issued (32 percent). Assuming more recent fishing activity is a better predictor of fishing operations during FY 2013, it is expected that between 175–200 vessels would be affected by this action. The average size and horsepower of vessels affected by this action is 60 ft (18 m) and 540 horsepower. Because over 80 percent of NFMA monkfish landings in recent years were landed by trawl vessels, trawl vessels would be most affected by this action.

Economic Impacts of the Proposed Action

Assuming that higher monkfish landings do not depress monkfish ex-vessel prices during FY 2013, the proposed action is expected to provide opportunities for increased fishing revenue for affected vessels. The maximum potential revenue that could be realized from the proposed action would be approximately $15.7 million for monkfish landings alone. This assumes that the entire NFMA monkfish TAL (5,854 mt, or 12.9 million lb) would be landed during FY 2013 at the average monkfish price observed during FY 2012 ($1.22 per lb ($2.69 per kg) when landings are converted to live weight equivalents).

Realized revenues from the proposed action are estimated to be approximately $14.6 million from monkfish landings alone during FY 2013 based on a projection of monkfish landings and using the average monkfish price observed to date during FY 2012 ($1.22 per lb ($2.69 per kg) live weight equivalent). That projection estimated that the proposed action would increase monkfish landings by approximately 608,000 lb (275,737 kg) compared to the No Action Alternative. The proposed action would increase monkfish fishing revenue by $742,000 compared to the No Action Alternative, while it would increase monkfish revenue by $568,000 compared to Alternative 1. Additional fishing revenue would also be expected based on landings of other species.

Measures that restrict fishing effort in the groundfish fishery will likely be the primary factor affecting how much additional monkfish fishing revenue would be realized from the proposed action. As noted above, substantial reductions in the FY 2013 ACLs for several groundfish stocks are proposed as part of FW 48 to the NE Multispecies FMP. It is likely that these substantially-reduced groundfish ACLs could cause groundfish vessels to fully harvest their groundfish allocations (sector annual catch entitlements (ACE), or non-sector trimester total allowable catch (TAC) amounts) before the end of FY 2013, triggering reactive accountability measures that would cease groundfish fishing operations temporarily, or for the duration of FY 2013. This would prevent the monkfish and groundfish fisheries from fully realizing the potential economic benefits of suspending monkfish possession limits for vessels fishing under a monkfish or groundfish DAS in the NFMA. If groundfish vessels can avoid exceeding their sector ACE or non-sector trimester TACs, then monkfish landings will likely more closely approach the FY 2013 NFMA monkfish TAL and ACT, resulting in greater economic benefits to affected vessels.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: February 19, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons stated in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. In § 648.94, suspend paragraphs (b)(1)(i), (b)(1)(ii), and (b)(3)(i); and add paragraphs (b)(1)(iii) through (v), (b)(3)(iv), and (h) to read as follows:

§ 648.94 Monkfish possession and landing restrictions.

* * * * *

(b) * * *

(1) * * *

(iii) *Category A vessels.* A limited access monkfish Category A vessel that fishes under a monkfish DAS exclusively in the NFMA may land up to 1,250 lb (567 kg) tail weight or 3,638 lb (1,650 kg) whole weight of monkfish per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). For every 1 lb (0.45 kg) of tail only weight landed, the vessel may land up to 1.91 lb (0.87 kg) of monkfish heads only, as described in paragraph (a) of this section.

(iv) *Category B vessels.* A limited access monkfish Category B vessel that fishes under a monkfish DAS exclusively in the NFMA may land up to 600 lb (272 kg) tail weight or 1,746 lb (792 kg) whole weight of monkfish (gutted) per DAS (or any prorated combination of tail weight and whole weight based on the conversion factor for tail weight to whole weight of 2.91). For every 1 lb (0.45 kg) of tail only weight landed, the vessel may land up to 1.91 lb (0.87 kg) of monkfish heads only, as described in paragraph (a) of this section.

(v) *Category C and D vessels.* Unless otherwise specified pursuant to paragraph (h) of this section, there is no monkfish trip limit for limited access monkfish Category C or D vessels that are fishing under a monkfish DAS exclusively in the NFMA.

* * * * *

(3) * * *

(iv) *NFMA*—(A) *Category C and D vessels.* Unless otherwise specified pursuant to paragraph (h) of this section, there is no monkfish trip limit for limited access monkfish Category C or D vessels that are fishing under a NE multispecies DAS exclusively in the NFMA.

(B) *Category F vessels.* A limited access monkfish Category F vessel that is fishing under a NE multispecies DAS, and not a monkfish DAS, exclusively in the NFMA is subject to the incidental catch limit specified in paragraph (c)(1)(i) of this section.

(C) *Vessels participating in the NE Multispecies Regular B DAS Program.* Category C, D, F, G, and H vessels participating in the NE Multispecies Regular B DAS Program, as specified under § 648.85(b)(6), are subject to the incidental catch limit specified in paragraph (c)(1)(i) of this section.

* * * * *

(h) *Regional Administrator authority to reinstate monkfish possession limits.*

Based upon available information, if the Regional Administrator projects that monkfish landings on trips that fished in the NFMA may exceed the fishing year 2013 target total allowable landing limit of 5,854 mt or, when combined with an estimate of discards, the 6,567 mt annual catch target, before the end of fishing year 2013 on April 30, 2014, the Regional Administrator shall reinstate monkfish possession limits for Category C and D vessels in a manner consistent with the Administrative Procedure Act. If monkfish possession limits are reinstated pursuant to this paragraph (h), Category C vessels shall be subject to the possession limits specified in paragraphs (b)(1)(iii) and (c)(1)(i) of this section, while Category D vessels shall be subject to the possession limits specified in paragraphs (b)(1)(iv) and (c)(1)(i) of this section.

[FR Doc. 2013–04265 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

RIN 0648–XC469

Pacific Fishery Management Council; Public Meetings and Hearings

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

ACTION: Notice of opportunities to submit public comments.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) has announced its annual preseason management process for the 2013 ocean salmon fisheries. This notice informs the public of opportunities to provide comments on the 2013 ocean salmon management measures which will publish as a final rule and be effective May 1, 2013.

DATES: Written comments on the salmon management alternatives adopted by the Pacific Council at its March 2013 meeting, and described in Preseason Report II, submitted electronically or in hard copy by 11:59 p.m. Pacific Time, March 31, 2013 will be considered in the Pacific Council's final recommendation for the 2013 management measures.

ADDRESSES: Documents will be available from Mr. Dan Wolford, Chairman, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384, telephone: 503–820–2280 (voice) or 503–820–2299 (fax), and posted on the Pacific Council web site at *http://www.pcouncil.org.* You may submit comments, identified by NOAA–NMFS–2012–0248, by any one of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2012-0248,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Mr. Dan Wolford, Chairman, Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.
- *Fax:* 503–820–2299, Attn: Mr. Mike Burner.
- Comments can also be submitted via email at *PFMC.comments@noaa.gov.*

Instructions: Comments sent by any other method, to any other address or individual may not be considered by NMFS or the Pacific Council. 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 and the Pacific Council will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Burner, telephone: 503–820–2280. For information on submitting comments via the Federal e-Rulemaking portal, contact Peggy Mundy, telephone: 206–526–4323.

SUPPLEMENTARY INFORMATION: The Pacific Council has published its annual notice of availability of reports; public meetings, and hearings for the 2013 ocean salmon fisheries (77 FR 73987, December 12, 2012). The Pacific Council will adopt alternatives for 2013 ocean salmon fisheries at its meeting, March 6–11, 2013 at the Hotel Murano in Tacoma, Washington. Details of this meeting are available on the Pacific Council's Web site (*www.pcouncil.org*) and will be published in the **Federal Register** in February 2013. On March 20, 2013, ''Preseason Report II-Proposed Alternatives and Environmental Assessment Part 2 for 2013 Ocean Salmon Fishery Regulations'' and public hearing schedule will be mailed to the public that have requested to receive these documents (see **ADDRESSES**) and posted on the Pacific Council Web site at *http://www.pcouncil.org.* The report will include a description of the salmon management alternatives and a summary of their biological and economic impacts.

Comments on the alternatives the Pacific Council adopts at its March 2013 meeting, and described in Preseason Report II, may be submitted in writing or electronically as described under Addresses, above, or verbally or in writing at any of the public hearings held on March 25–26, 2013, or at the Pacific Council's meeting, April 5–11, 2013, at the Sheraton Portland Airport Hotel in Portland, Oregon. Written and electronically submitted comments must be received no later than 11:59 p.m. Pacific Time, March 31, 2013 in order to be included in the briefing book for the April Council meeting where they will be considered in the adoption of the Pacific Council's final recommendation for the 2013 salmon fishery management measures. All comments received accordingly will be reviewed and considered by the Pacific Council and NMFS.

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

Dated: February 20, 2013.

Kara Meckley,

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

[FR Doc. 2013–04264 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 78, No. 37
Monday, February 25, 2013

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

Forest Service

Intermountain Region, Payette National Forest, New Meadows Ranger District, Idaho; Lost Creek-Boulder Creek Landscape Restoration Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an Environmental Impact Statement.

SUMMARY: The New Meadows Ranger District of the Payette National Forest will prepare an Environmental Impact Statement (EIS) for the Lost Creek-Boulder Creek Landscape Restoration Project. The Lost Creek-Boulder Creek Landscape Restoration Project area is located approximately 10 miles north and west of New Meadows, Idaho in in Boulder Creek, a tributary to the Little Salmon, and in the headwaters of the Weiser River and the West Fork of the Weiser River. It comprises approximately 80,000 acres and is within the boundaries of the New Meadows District of the Payette National Forest, in Adams County Idaho. The project is designed to improve wildlife habitat, reduce forest fuels, and improve watershed conditions through a variety of activities including commercial and noncommercial vegetation management and road system modifications and maintenance.

DATES: Comments concerning the project must be received by March 27, 2013. The draft environmental statement is expected in July 2013 and the final Environmental Impact Statement is expected in November 2013.

ADDRESSES: Send written comments to Keith Lannom, Forest Supervisor, 800 W. Lakeside Avenue, McCall, Idaho 83638. Comments may also be sent via email to *comments-intermtn-payette-newmeadows@fs.fed.us,* or via facsimile to 208–634–0744.

FOR FURTHER INFORMATION CONTACT: Ken Meyers, Project Team Leader, 208–347–0344. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose of the project is to: (1) Improve habitat for specific wildlife species of concern such as the ESA-listed northern Idaho ground squirrel and white-headed woodpecker; (2) maintain and promote large tree forest structure, early seral species composition and forest resiliency; (3) reduce the risk of uncharacteristic and undesirable wildland fire; (4) restore habitat connectivity, especially in streams occupied by ESA-listed fishes and in designated critical habitat; (5) reduce road-related accelerated sediment and other road related impacts; (6) restore riparian vegetation and floodplain function; (7) better manage recreation use in the vicinity of Lost Valley Reservoir and Boulder Creek, and (8) contribute to the economic vitality of communities adjacent to the Payette National Forest.

Proposed Action

The Proposed Action includes vegetative treatments to improve wildlife habitat for the Northern Idaho Ground Squirrel and species that rely on habitat similar to the white-headed woodpecker, and to move vegetation toward the desired conditions specified in the Payette National Forest Plan. The project would harvest an estimated 20 million board feet (MMBF) of timber (all figures are approximations and may change as the project is refined). Commercial vegetative treatments would include commercial thin-free thin (13,700 acres); free thin-patch cut (1,700 acres); and commercial thin-mature plantations (8,400 acres). Non-commercial vegetative treatments include: Non-commercial thinning (16,000 acres); and prescribed burning (45,000 acres).

The proposal includes changes to the Forest System Road network to reduce road-related impacts to water quality and fish habitat, as well as reduce overall road density. Specific road actions include: 70 miles of system road decommissioning; 60 miles of roads moved to long term closure status (all currently closed to the public); 12 miles of seasonally open road converted to ATV trails; restoration of 90 miles of unauthorized roads; and relocation of 1 ½ half miles of road scheduled for decommissioning. The project includes 40 opportunities for replacement of culverts and other aquatic organism passages. No new roads will be built under this proposal.

Recreation actions will occur in the Lost Valley reservoir area and in the Boulder Creek subwatershed. Work includes rerouting trails, installing trail signs, installing toilets, improving and constructing trailhead parking, installing information kiosks, and graveling campsites and campground access roads. In addition to the open roads converted to ATV trails, twenty new miles of ATV routes will be designated and signed.

A range of reasonable alternatives will be considered. The no-action alternative will serve as a baseline for comparison of alternatives. The proposed action will be considered along with additional alternatives developed that meet the purpose and need and address major issues identified during scoping. Alternatives may have different amounts, locations, and types of project activities.

Responsible Official

The Forest Supervisor of the Payette National Forest is the Responsible Official.

Nature of Decision To Be Made

Based on the purpose and need for the proposed action, the Responsible Official will determine whether to proceed with the action, as proposed, as modified by another alternative or not at all. If an action alternative is selected, the Responsible Official will determine what design features, mitigation measures and monitoring to require.

Preliminary Issues

Preliminary issues for this project include effects on water quality, soil productivity, wildlife habitat, recreation, access management, and fish habitat.

Addresses

Additional project information is available on the Payette National Forest Web site at *http://www.fs.fed.us/nepa/fs-usda-pop.php/?project=33830.*

Scoping Process

This notice of intent initiates the scoping process, which guides the development of the Environmental Impact Statement. It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the environmental impact statement. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will become part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered, however.

Dated: February 13, 2013.

Keith Lannom,

Forest Supervisor.

[FR Doc. 2013–04182 Filed 2–22–13; 8:45 am]

BILLING CODE 3410–11–P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Meetings

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice of meetings.

SUMMARY: The Architectural and Transportation Barriers Compliance Board (Access Board) plans to hold its regular committee and Board meetings in Washington, DC, Monday through Wednesday, March 11–13, 2013 at the times and location listed below.

DATES: The schedule of events is as follows:

Monday, March 11, 2013

10:30–3:30 p.m.—Ad Hoc Rulemaking Committees: Closed to Public

3:30–4:00—Ad Hoc Committee on Accessible Design in Education

Tuesday, March 12, 2013

9:30 a.m.–11:00—Ad Hoc Committee on Frontier Issues

11:00–Noon—Presentation on Accessibility of Mobile Devices

1:30–2:00 p.m.—Budget Committee

2:00–2:45—Planning and Evaluation Committee

3:00–4:00—Technical Programs Committee

Wednesday, March 13, 2013

9:30 a.m.–10:30—Ad Hoc Committee on Transportation Vehicles: Closed to Public

10:30–Noon—Presentation on Accessible Transportation Research

1:30–3:00 p.m.—Board Meeting

ADDRESSES: Meetings will be held at the Access Board Conference Room, 1331 F Street NW., suite 800, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: For further information regarding the meetings, please contact David Capozzi, Executive Director, (202) 272–0010 (voice); (202) 272–0054 (TTY).

SUPPLEMENTARY INFORMATION: At the Board meeting scheduled on the afternoon of Wednesday, March 13, the Access Board will consider the following agenda items:

- Administer Oath of Office to new appointee
- Approval of the draft January 9, 2013 meeting minutes (vote)
- Budget Committee Report
- Technical Programs Committee Report
- Planning and Evaluation Committee Report
- Ad Hoc Committee Reports: Emergency Transportable Housing and Information and Communications Technology (votes)
- Election Assistance Commission Report
- Prescription Drug Labeling Working Group Report
- ADA and ABA Guidelines; Federal Agency Update
- Election of Officers (votes)
- Executive Director's Report
- Public Comment, Open Topics

All meetings are accessible to persons with disabilities. An assistive listening system, computer assisted real-time transcription (CART), and sign language interpreters will be available at the Board meeting and committee meetings. Persons attending Board meetings are requested to refrain from using perfume, cologne, and other fragrances for the comfort of other participants (see *www.access-board.gov/about/policies/fragrance.htm for more information*).

David M. Capozzi,

Executive Director.

[FR Doc. 2013–04260 Filed 2–22–13; 8:45 am]

BILLING CODE 8150–01–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: National Oceanic and Atmospheric Administration (NOAA).

Title: Groundfish Tagging Program.

OMB Control Number: 0648–0276.

Form Number(s): NA.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 380.

Average Hours per Response: Spaghetti tags returns, 5 minutes; archival tag returns, 20 minutes.

Burden Hours: 78.

Needs and Uses: This request is for extension of a current information collection.

The groundfish tagging program provides scientists with information necessary for effective conservation, management, and scientific understanding of the groundfish fishery off Alaska and the Northwest Pacific. The program area includes the Pacific Ocean off Alaska (the Gulf of Alaska, the Bering Sea and Aleutian Islands Area, and the Alexander Archipelago of Southeast Alaska), California, Oregon, and Washington. Fish movement information from recovered tags is used in population dynamics models for stock assessment. There are two general categories of tags. Simple plastic tags (spaghetti tags) are external tags approximately two inches long printed with code numbers. When a tag is returned the tag number is correlated with databases of released, tagged fish to determine the net movement and growth rate of the tagged fish. Archival tags are microchips with sensors encased in plastic cylinders that record the depth, temperature or other data, which can be downloaded electronically from the recovered tags. The groundfish tagging and tag recovery program is part of the fishery resource assessment and data collection that the National Marine Fisheries Service conducts under the Magnuson-Stevens Act authority as codified in 16 U.S.C. 1801(a)(8).

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: *OIRA_Submission@omb.eop.gov.*

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482–0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

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.*

Dated: February 19, 2013.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2013–04185 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1884]

Expansion of Foreign-Trade Zone 49 Newark/Elizabeth, New Jersey

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 Port Authority of New York and New Jersey, grantee of Foreign-Trade Zone 49, submitted an application to the Board for authority to expand FTZ 49, to add a new site (Site 13) in the Newark/Elizabeth, New Jersey, area within the New York/Newark Customs and Border Protection port of entry (FTZ Docket 78–2011, filed 12/07/11);

Whereas, notice inviting public comment has been given in the **Federal Register** (76 FR 77770, 12/14/11) 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, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to expand FTZ 49 is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit, and to a sunset provision that would terminate authority on February 28, 2018 for Site 13 if no activity has occurred under FTZ procedures before that date. Existing Sites 1–6 would also be subject to a sunset provision that would terminate authority where no activity has occurred under FTZ procedures by February 28, 2018.

Signed at Washington, DC, this 6th day of February 2013.

Paul Piquado,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

Attest:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2013–04269 Filed 2–22–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1880]

Reorganization of Foreign-Trade Zone 204 Under Alternative Site Framework Tri-Cities, Tennessee/Virginia

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Board adopted the alternative site framework (ASF) (74 FR 1170–1173, 01/12/2009; correction 74 FR 3987, 01/22/2009; 75 FR 71069–71070, 11/22/2010) as an option for the establishment or reorganization of general-purpose zones;

Whereas, the Tri-Cities Airport Commission, grantee of Foreign-Trade Zone 204, submitted an application to the Board (FTZ Docket 19–2012, filed 03/20/2012) for authority to reorganize under the ASF with a service area of the Counties of Sullivan, Hawkins, Greene, Washington, Unicoi, Carter, Hamblen and Johnson, Tennessee and the Counties of Buchanan, Dickenson, Wise, Lee, Russell, Scott and Washington, Virginia and the Cities of Norton and Bristol, Virginia, within and adjacent to the Tri-Cities Customs and Border Protection port of entry. FTZ 204's Sites 1 through 9 and 11 would be categorized as magnet sites;

Whereas, notice inviting public comment was given in the **Federal Register** (77 FR 17408, 03/26/2012) 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, and that the proposal is in the public interest;

Now, therefore, the Board hereby orders:

The application to reorganize FTZ 204 under the alternative site framework is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, to the Board's standard 2,000-acre activation limit for the zone, and to a five-year ASF sunset provision for magnet sites that would terminate authority for Sites 2 through 9 and 11 if not activated by January 31, 2018.

Signed at Washington, DC, this 6th day of February 2013.

Paul Piquado,

Assistant Secretary of Commerce for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2013–04279 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–916; C–570–917]

Laminated Woven Sacks From the People's Republic of China: Negative Final Determination of Circumvention

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (''the Department'') continues to determine that the laminated woven sacks subject to this inquiry are not circumventing the antidumping and countervailing duty orders on laminated woven sacks from the People's Republic of China (''PRC''), as provided in section 781(d) of the Tariff Act of 1930, as amended (''the Act'').[1]

DATES: *Effective Date:* February 25, 2013.

FOR FURTHER INFORMATION CONTACT: Irene Gorelik, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–6905.

SUPPLEMENTARY INFORMATION:

[1] *See Notice of Antidumping Duty Order: Laminated Woven Sacks From the People's Republic of China,* 73 FR 45941 (August 7, 2008); *see also Laminated Woven Sacks From the People's Republic of China: Countervailing Duty Order,* 73 FR 45955 (August 7, 2008), (collectively, ''*Orders*'').

Scope of the Orders

The merchandise covered by the orders [2] is laminated woven sacks. Laminated woven sacks are bags or sacks consisting of one or more plies of fabric consisting of woven polypropylene strip and/or woven polyethylene strip, regardless of the width of the strip; with or without an extrusion coating of polypropylene and/or polyethylene on one or both sides of the fabric; laminated by any method either to an exterior ply of plastic film such as biaxially-oriented polypropylene (''BOPP'') or to an exterior ply of paper that is suitable for high quality print graphics.[3] Effective July 1, 2007, laminated woven sacks are classifiable under Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings 6305.33.0050 and 6305.33.0080. Laminated woven sacks were previously classifiable under HTSUS subheading 6305.33.0020.[4] The HTSUS subheadings are provided for convenience and customs purposes only; the written product description of the scope of the orders is dispositive.

Scope of the Anti-Circumvention Inquiry

The merchandise subject to the anti-circumvention inquiry is laminated woven sacks produced with two ink colors printed in register and a screening process (''screening-process sacks''). Petitioners allege that PRC producers of screening-process sacks have adapted the screening process to create graphics that appear to have three or more distinct colors visible, although, they are produced using only two inks and a screen. Petitioners contend that such graphics would normally be printed using three inks printed in register at three different print stations, which would then make them subject merchandise. However, by adapting the screening process, Petitioners state that PRC producers of screening-process sacks are able to produce similar graphics while only using two inks, thus, making merchandise that is out of scope and not subject to antidumping and countervailing duties.

The screening process at issue, as described by interested parties, only uses two ink colors printed in register at two different print stations. However, the artwork, by use of a screen, allows for different shades of a single color to appear on the bag. Thus, when printed, the screening-process sacks appear to have been printed with more than two colored inks because more than two distinct colors are visible on the finished product. As an example of the screening-process sacks, the Department placed on the record of both proceedings five laminated woven sacks imported by Shapiro: Two individual Manna Pro Horse Feed sacks, two individual Red Head Deer Corn sacks, and one Manna Pro Calf-Manna sack.[5] Following the *Negative Preliminary Determination,*[6] an additional sack was placed on the record,[7] referred to as the ''Manna Pro Complete Sack,'' as an example of a two-ink, screened sack imported by Shapiro and addressed in the Post-Preliminary Determination.

Methodology

The Department has conducted this proceeding in accordance with section 781(d)(1) of the Act.[8] For a full description of the methodology underlying our conclusions, please see the Final Decision Memo,[9] dated concurrently with this final determination and hereby adopted by this notice. The Final Decision Memo is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). Access to IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Final Decision Memo can be accessed directly on the Internet at *http://www.trade.gov/ia/.* The signed Final Decision Memo and the electronic versions of the Final Decision Memo are identical in content.

Final Determination

For the reasons discussed in the Final Decision Memo, we continue to determine that the screening-process sacks are not later-developed merchandise because they were commercially available at the time of the initiation of the less-than-fair-value investigation on laminated woven sacks from the PRC. Therefore, we also continue to determine that screening-process sacks are not circumventing the *Orders* within the meaning of section 781(d) of the Act.

This final determination is published in accordance with section 781(d) of the Act and 19 CFR 351.225.

Dated: February 14, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

Comment 1: Commercial Availability in the U.S. Market Prior To Initiation of Investigations

Comment 2: The Shapiro Sacks and Complete Sack Are Commercially Comparable Merchandise

[FR Doc. 2013–04148 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–DS–P

[2] *See Orders.*

[3] *See* ''Decision Memorandum for Final Determination of Circumvention of the Antidumping and Countervailing Duty Orders: Laminated Woven Sacks from the People's Republic of China,'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, (''Final Decision Memo''), dated concurrently with this final determination for a complete description of the Scope of the Order.

[4] Additional HTSUS considerations apply. *See* Final Decision Memo.

[5] *See* Memorandum to the File from Jamie Blair-Walker regarding Anti-circumvention Inquiry of Laminated Woven Sacks from the People's Republic of China on the subject of Meeting with Counsel for the Laminated Woven Sacks Committee and its individual members, Coating Excellence International, LLC and Polytex Fibers Corporation, dated July 15, 2011.

[6] *See Laminated Woven Sacks from the People's Republic of China: Negative Preliminary Determination of Circumvention of the Antidumping and Countervailing Duty Orders,* 76 FR 72161 (November 22, 2011) (''*Negative Preliminary Determination*'').

[7] *See* Shapiro's supplemental questionnaire response entitled ''Laminated Woven Sacks from China; Printed Inks Anti-Circumvention Inquiry: Submission of AMS Third Supplemental Response'' dated January 27, 2012 (''January 27, 2012 Supplemental Response''), at 2–3 and Attachment I.

[8] *See* section 781(d)(1) of the Act.

[9] *See* Final Decision Memo for a complete description of the Scope of the Order.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–986]

Hardwood and Decorative Plywood From the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* February 25, 2013.

FOR FURTHER INFORMATION CONTACT: Katie Marksberry at (202) 482–7906, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: On October 17, 2012, the Department of Commerce (''Department'') initiated an antidumping duty investigation on hardwood and decorative plywood from

the People's Republic of China.[1] The notice of initation stated that, unless postponed, the Department would issue its preliminary determination no later than 140 days after the date of issuance of the initiation, in accordance with section 773(b)(1)(A) of the Tariff Act of 1930, as amended (''the Act''). The preliminary determination is currently due no later than March 8, 2013.[2]

On Feburary 5, 2013, the Coalition for Fair Trade of Hardwood Plywood (''Petitioners''), made a timely request, pursuant to 19 CFR 351.205(e), for postponement of the preliminary determination, in order to allow additional time for the Department to review the respondents' sections C and D questionnaire submissions, as well as other information critical to the proceeding, such as comments on the selection of a surrogate country and submissions of publicly available information to value the factors of production reported by the respondents.[3] Because there are no compelling reasons to deny the request, in accordance with section 733(c)(1)(A) of the Act, the Department is postponing the deadline for the preliminary determination by 50 days.

An extension of 50 days from the current deadline of March 8, 2013, would result in a new deadline of April 27, 2013. Because April 27, 2013, falls on a Saturday, the due date for the preliminary determination is now April 29, 2013.[4] The deadline for the final determination will continue to be 75 days after the date of the preliminary determination, unless extended.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

[1] *See Hardwood and Decorative Plywood From the People's Republic of China: Initiation of Antidumping Duty Investigation,* 77 FR 65172 (October 25, 2012).

[2] As explained in the memorandum from the Assistant Secretary for Import Administration, the Department has exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 29, through October 30, 2012. Thus, all deadlines in this segment of the proceeding have been extended by two days. The revised deadline for the preliminary determination of this investigation is now March 8, 2012. *See* Memorandum to the Record from Paul Piquado, Assistant Secretary for Import Administration, regarding ''Tolling of Administrative Deadlines As a Result of the Government Closure During Hurrican Sandy,'' dated October 31, 2012.

[3] *See* Letter to the Department, from Petitioners; Re: Hardwood and Decorative Plywood from the People's Republic of China, dated February 5, 2013.

[4] Department practice dictates that where a deadline falls on a weekend or federal holiday, the appropriate deadline is the next business day. *See Notice of Clarification: Application of ''Next Business Day'' Rule for Administrative Determination Deadlines Pursuant to the Tariff Act of 1930, As Amended,* 70 FR 24533, 24533 (May 10, 2005).

Dated: February 14, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–04154 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–932]

Certain Steel Threaded Rod From the People's Republic of China: Affirmative Final Determination of Circumvention of the Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 4, 2012, the Department of Commerce (the ''Department'') published the *Preliminary Determination* of the circumvention inquiry concerning the antidumping duty order on certain steel threaded rod (''steel threaded rod'') from the People's Republic of China (''PRC'').[1] The period of inquiry is April 1, 2010, through January 11, 2012. We gave interested parties an opportunity to comment on the *Preliminary Determination.* On December 31, 2012, Vulcan Threaded Products, Inc. (''Petitioner'') filed comments agreeing that the Department's *Preliminary Determination* is in accordance with law and supported by evidence on the record of this inquiry. No other party filed comments.

DATES: *Effective Date:* February 25, 2013.

FOR FURTHER INFORMATION CONTACT: Toni Dach, AD/CVD Operations, Office 9, Import Administration, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1655.

SUPPLEMENTARY INFORMATION:

Background

On December 4, 2012, the Department published the *Preliminary Determination* finding that imports from the PRC of steel threaded rod products with 1.25 percent or more chromium, by weight, produced by Gem-Year Industrial Co. Ltd. (''Gem-Year''), and otherwise meeting the description of in-scope merchandise, are subject to the order.[2] We invited interested parties to comment on the *Preliminary Determination.* The only party to comment was Petitioner, who agreed that the *Preliminary Determination* is in accordance with law and supported by evidence on the record of this inquiry. The Department has conducted this anticircumvention inquiry in accordance with section 781(c) of the Tariff Act of 1930, as amended (''the Act''), and 19 CFR 351.225.

Scope of the Order

The merchandise covered by the order is steel threaded rod. Steel threaded rod is certain threaded rod, bar, or studs, of carbon quality steel, having a solid, circular cross section, of any diameter, in any straight length, that have been forged, turned, cold-drawn, cold-rolled, machine straightened, or otherwise cold-finished, and into which threaded grooves have been applied. In addition, the steel threaded rod, bar, or studs subject to the order are non-headed and threaded along greater than 25 percent of their total length. A variety of finishes or coatings, such as plain oil finish as a temporary rust protectant, zinc coating (*i.e.,* galvanized, whether by electroplating or hot-dipping), paint, and other similar finishes and coatings, may be applied to the merchandise.

Included in the scope of the order are steel threaded rod, bar, or studs, in which: (1) Iron predominates, by weight, over each of the other contained elements; (2) the carbon content is two percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 1.80 percent of manganese, or
- 1.50 percent of silicon, or
- 1.00 percent of copper, or
- 0.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 1.25 percent of nickel, or
- 0.30 percent of tungsten, or
- 0.012 percent of boron, or
- 0.10 percent of molybdenum, or
- 0.10 percent of niobium, or
- 0.41 percent of titanium, or
- 0.15 percent of vanadium, or
- 0.15 percent of zirconium.

Steel threaded rod is currently classifiable under subheading 7318.15.5051, 7318.15.5056, 7318.15.5090, and 7318.15.2095 of the United States Harmonized Tariff Schedule (''HTSUS''). Although the

[1] *See Certain Steel Threaded Rod From the People's Republic of China: Affirmative Preliminary Determination of Circumvention of the Antidumping Duty Order,* 77 FR 71776 (December 4, 2012) (''*Preliminary Determination*'').

[2] *See Preliminary Determination; see also Certain Steel Threaded Rod from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 17154 (April 14, 2009).

HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Excluded from the scope of the order are: (a) Threaded rod, bar, or studs which are threaded only on one or both ends and the threading covers 25 percent or less of the total length; and (b) threaded rod, bar, or studs made to American Society for Testing and Materials (''ASTM'') A193 Grade B7, ASTM A193 Grade B7M, ASTM A193 Grade B16, or ASTM A320 Grade L7.

Scope of the Circumvention Inquiry

The merchandise subject to this circumvention inquiry consists of steel threaded rod from the PRC produced by Gem-Year containing greater than 1.25 percent chromium, by weight, and otherwise meeting the requirements of the scope of the order as listed under the ''Scope of the Order'' section above.

Final Determination

In the *Preliminary Determination,* the Department found that imports from the PRC of steel threaded rod containing greater than 1.25 percent chromium, by weight, produced by Gem-Year, and otherwise meeting the description of in-scope merchandise, are subject to the antidumping duty order on steel threaded rod from the PRC. We continue to determine that imports from the PRC of steel threaded rod containing greater than 1.25 percent chromium, by weight, produced by Gem-Year, and otherwise meeting the description of in-scope merchandise, are subject to the antidumping duty order on steel threaded rod from the PRC. The Department will issue appropriate instructions to U.S. Customs and Border Protection (''CBP'') based on our final determination.

Continuation of Suspension of Liquidation

In accordance with 19 CFR 351.225(l)(3), we are directing CBP to continue to suspend liquidation of entries of merchandise subject to this inquiry produced by Gem-Year, and entered, or withdrawn from warehouse, for consumption on or after January 5, 2012, the date of the initiation of this inquiry. We will also instruct CBP to require a cash deposit of estimated duties at the applicable rates for each unliquidated entry of the product entered, or withdrawn from warehouse, for consumption on or after January 5, 2012, the date of the initiation of this inquiry, in accordance with 19 CFR 351.225(l)(3).

Notifications

This notice serves as a reminder to parties subject to the administrative protective order (''APO'') of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

We are issuing and publishing this affirmative final determination of circumvention in accordance with sections 781(c) and 777(i) of the Act and 19 CFR 351.225.

Dated: February 13, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–04151 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

President's Export Council: Meeting of the President's Export Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an Open Meeting.

SUMMARY: The President's Export Council will hold a meeting to deliberate on recommendations related to promoting the expansion of U.S. exports. Topics may include the Administration's ''Doing Business in Africa'' campaign, the need for nominations to the U.S. Export-Import Bank Board of Directors, a rapid response mechanism for sanitary and phytosanitary issues in the Trans-Pacific Partnership Agreement, an international services agreement, bilateral investment treaties, U.S.–Canada trade facilitation, the UNIDROIT Cape Town Convention on International Interests in Mobile Equipment, and workforce readiness. The final agenda will be posted at least one week in advance of the meeting on the President's Export Council Web site at *http://trade.gov/pec*.

DATES: March 12, 2013 at 9:30 a.m. (ET).

ADDRESSES: The President's Export Council meeting will be broadcast via live webcast on the Internet at *http://whitehouse.gov/live*.

FOR FURTHER INFORMATION CONTACT: Tricia Van Orden, Executive Secretary, President's Export Council, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: 202–482–5876, email: *tricia.vanorden@trade.gov*.

SUPPLEMENTARY INFORMATION:

Background: The President's Export Council was first established by Executive Order on December 20, 1973 to advise the President on matters relating to U.S. export trade and report to the President on its activities and on its recommendations for expanding U.S. exports. The President's Export Council was renewed most recently by Executive Order 13585 of September 30, 2011, for the two-year period ending September 30, 2013. This Committee is established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

Public Submissions: The public is invited to submit written statements to the President's Export Council by C.O.B. March 8, 2013 by either of the following methods:

Electronic Submissions

Submit statements electronically to Tricia Van Orden, Executive Secretary, President's Export Council via email: *tricia.vanorden@trade.gov*.

Paper Submissions

Send paper statements to Tricia Van Orden, Executive Secretary, President's Export Council, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230. Statements will be posted on the President's Export Council Web site (*http://trade.gov/pec*) without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make publicly available.

Meeting minutes: Copies of the Council's meeting minutes will be available within ninety (90) days of the meeting.

Dated: February 21, 2013.

Tricia Van Orden,

Executive Secretary, President's Export Council.

[FR Doc. 2013–04381 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC374

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Seismic Survey in Cook Inlet, AK

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

ACTION: Notice; issuance of incidental take authorization.

SUMMARY: In accordance with the Marine Mammal Protection Act (MMPA) regulations, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to the Apache Alaska Corporation (Apache) to take marine mammals, by harassment, incidental to a proposed 3D seismic survey in Cook Inlet, Alaska, between March 2013 and March 2014.

DATES: Effective March 1, 2013, to March, 1, 2014.

ADDRESSES: An electronic copy of the IHA and application may be obtained by writing P. Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910 or by telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Brian D. Hopper, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental taking of small numbers of marine mammals shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant). The authorization must set forth the permissible methods of taking, other means of effecting the least practicable adverse impact on the species or stock and its habitat, and requirements pertaining to the mitigation, monitoring and reporting of such takings. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: ''Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].''

Summary of Request

NMFS received an application on June 15, 2012, from Apache for the taking, by harassment, of marine mammals incidental to a 3D seismic survey program in Cook Inlet, Alaska. This is the second IHA application NMFS has received from Apache for takes of marine mammals incidental to conducting a seismic survey in Cook Inlet. On April 30, 2012, NMFS issued a one-year IHA to Apache for their first season of seismic acquisition in Cook Inlet (77 FR 27720). On December 10, 2012, NMFS published a notice in the **Federal Register** (77 FR 73434) discussing the effects on marine mammals and making preliminary determinations regarding a proposed IHA. The notice initiated a 30 day public comment period, which closed on January 9, 2013. Except for the location and the size of the survey area and the potentially earlier commencement date for survey operations, the activities proposed for the second survey season are essentially the same as those conducted during the first season.

Apache's 3D seismic surveys would employ the use of two source vessels. Each source vessel would be equipped with compressors and 2400 in^3 air gun arrays, as well as additional lower-powered and higher frequency survey equipment for collecting bathymetric and shallow sub-bottom data. In addition, one source vessel would be equipped with a 440 in^3 shallow water air gun array, which it can deploy at high tide in the intertidal area in less than 1.8 m of water. The proposed survey would take place in Cook Inlet. During the 2013 survey season, Apache anticipates acquiring seismic data in an area that extends from just south of Anchor Point along the east coast extending up to Point Possession and along the west coast from the McArthur River up to south of the Beluga river, in water depths of 0–128 m (0–420 ft). Apache's planned area of seismic acquisition within this area is shown in Figure 1 below.

For the 2013 survey season, Apache intends to mobilize crews and equipment in February 2013 in order to be ready to conduct marine surveys between April and May 2013. Apache expects to complete its survey by December 15, 2013. Impacts to marine mammals may occur from noise produced from active acoustic sources (primarily air guns) used in the survey.

Description of the Specified Activity

In 2010, Apache acquired over 300,000 acres of oil and gas leases in Cook Inlet with the primary objective to explore for and develop oil fields. In the spring of 2011, Apache conducted a seismic test program to evaluate the feasibility of using new nodal (i.e., no cables) technology seismic recording equipment for operations in the Cook Inlet environment and to test various seismic acquisition parameters to finalize the design for a 3D seismic program in Cook Inlet. The test program took place in late March 2011 and results indicated that the nodal technology was feasible in the Cook Inlet environment. Apache proposes to conduct a phased 3D seismic survey program throughout Cook Inlet over the course of three to five years. The first area surveyed—and the subject of the IHA issued in April 2012—was located in mid-Cook Inlet extending along the

west coast from the Big River up to south of the Beluga River, and on the east coast from Salamantof on the Kenai peninsula to 4.4 miles north of the Swanson River. In the notice of the proposed IHA (77 FR 73434, December 10, 2012), NMFS described the second area to be surveyed—and the subject of this IHA—as covering a lower portion of Cook Inlet, but also including all of Area 1. Following the publication of the proposed IHA, Apache clarified to NMFS that Area 2 includes all of Area 1 in mid Cook Inlet and some of Area 3 to the north/northeast of Area 1; however, survey operations in 2013 are expected to occur in a smaller section of Area 2 (see Figure 1).

The survey operations are essentially the same as those that were conducted in Area 1 under the IHA for the first seismic season. The survey would again be conducted from multiple vessels. Apache employs the use of two source vessels. Each source vessel is equipped with compressors and 2400 in^3 air gun arrays. In addition, one source vessel is equipped with a 440 in^3 shallow water air gun array, which it can deploy at high tide in the intertidal area in less than 1.8 m of water. Three shallow draft vessels support cable/nodal deployment and retrieval operations, and one mitigation/chase vessel is used, which also provides berthing for the Protected Species Observers (PSOs). Finally, two smaller jet boats are used for personnel transport and node support in the extremely shallow water of the intertidal area. For additional information, such as vessel specifications, see Apache's application.

The survey will take approximately 160 days to complete over the course of 8–9 months. Apache anticipates conducting survey operations 24 hours per day. During each 24 hour period, seismic operations would be active; however air guns would only be used for approximately 2.5 hours during each of the slack tide periods. There are approximately four slack tide periods in a 24-hour day, therefore, air gun operations would be active during approximately 10–12 hours per day, if weather conditions allow.

NMFS outlined the description of the specified activities covered by this IHA in a previous notice for the proposed IHA (77 FR 73434, December 10, 2012). Except for the clarification noted above regarding the size and scope of Area 2 and the timing of the survey, the activities to be conducted have not changed between the proposed IHA notice and this final notice announcing the issuance of the IHA. For a more detailed description of the activity, including vessel and acoustic source specifications, the reader should refer to the proposed IHA notice (77 FR 73434, December 10, 2012), the IHA application, and associated documents (see **ADDRESSES**).

Comments and Responses

A notice of receipt of the Apache application and proposed IHA was published in the **Federal Register** on December 10, 2012 (77 FR 73434). During the 30-day public comment period, NMFS received comments from the Marine Mammal Commission (Commission), the Alaska Department of Natural Resources, environmental non-governmental organizations (NGOs), the International Association of Geophysical Contractors (IAGC), the Seldovia Village Tribe, the Kenaitze Indian Tribe, and one member of the public. Following are their comments and NMFS's responses:

Comment 1: The Commission recommended that NMFS refrain from taking additional action on the IHA until it has received and reviewed more specific information concerning the location and timing of Apache's proposed action.

Response: We believe that Apache's application requesting authorization to harass marine mammals incidental to seismic survey operations in Cook Inlet contained sufficient information regarding the location and timing of Apache's seismic survey to make the required findings under the MMPA.

Comment 2: The Commission recommended that NMFS require that Apache not conduct seismic activities in the inlet until after May and use aerial surveys or other means to confirm that the majority of beluga whales have moved out of the proposed survey area before initiating those activities.

Response: Beluga whales remain in Cook Inlet year-round, but demonstrate seasonal movement within the Inlet; in the summer and fall, they concentrate in upper Cook Inlet's rivers and bays, but tend to disperse offshore and move to mid-Inlet in winter (Hobbs *et al.,* 2005). The available information indicates that in the winter months belugas occur in deeper waters in mid-Inlet past Kalgin Island, with occasional forays into the upper inlet, including the upper ends of Knik and Turnagain Arms. The spatial dispersal and diversity of winter prey are likely to influence the wider beluga winter range throughout the mid-Inlet. Apache now expects to commence its seismic survey in April, which would coincide with the time of year when belugas are dispersed offshore in the mid-Inlet and away from river mouths. In the spring, beluga whales are regularly sighted in the upper Inlet beginning in late April or early May, coinciding with eulachon runs in the Susitna River and Twenty Mile River in Turnagain Arm, and outside of the area where Apache will be conducting seismic surveys at that time. Therefore, NMFS believes that the timing and location for the commencement of the seismic survey, as proposed, will largely avoid areas and seasons that overlap with important beluga whale behavioral patterns.

Comment 3: The Commission recommended that NMFS explain how we accounted for the effects of the proposed action in the context of all the other risk factors that are or may be affecting Cook Inlet beluga whales and inhibiting their recovery.

Response: Section 101(a)(5)(D) of the MMPA requires NMFS to make a determination that the harassment incidental to a specified activity will have a negligible impact on the affected species or stocks of marine mammals, and will not result in an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. Neither the MMPA nor NMFS' implementing regulations specify how to consider other activities and their impacts on the same populations. However, consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline (e.g., as reflected in the density/distribution and status of the species, population size and growth rate, and ambient noise).

In addition, cumulative effects were addressed in the Environmental Assessment and biological opinion prepared for this action, both of which NMFS indicated would be completed prior to the issuance of an IHA (77 FR 73434, December 10, 2012). These documents, as well as the Alaska Marine Stock Assessments and the most recent abundance estimate for Cook Inlet beluga whales (Shelden *et al.,* 2012), are part of NMFS' Administrative Record for this action, and provided the decision maker with information regarding other activities in the action area that affect marine mammals, an analysis of cumulative impacts, and other information relevant to the determination made under the MMPA.

Comment 4: The Commission recommended that NMFS encourage Apache to use and expand data-sharing agreements with other entities to maximize the utility of seismic data and

minimize the number of impacts of new seismic studies.

Response: We agree and have encouraged Apache to cooperate with other interested parties to minimize the impacts of new seismic surveys in the region. Currently, Apache works with other oil and gas operators in the area to enter into cooperative agreements. Sometimes these negotiations are successful, but at other times the companies cannot reach an agreement acceptable to both parties. Apache will continue its discussions with other operators in Cook Inlet to find opportunities to joint venture in oil and gas operations, including seismic data acquisition.

Comment 5: The Commission recommended that NMFS correct the estimated distance to the 190 dB threshold for the offshore surveys to 0.18 km.

Response: The maximum distance to the 190 dB threshold for the channel surveys should be 0.18 km not 1.18 km. The information in Table 2 of the proposed IHA (77 FR 73434, December 10, 2012) is correct and Table 4 should read 0.18 km not 1.18 km. NMFS regrets the unintentional error and apologizes for any confusion caused by the discrepancy.

Comment 6: The Commission recommended that NMFS require that Apache either amend its application to seek authorization for the maximum number of marine mammals that may be taken or provide sufficient and consistent justification for requiring fewer takes, particularly of beluga whales, harbor porpoises, and harbor seals.

Response: To provide some allowance for the uncertainties, Apache calculated both ''maximum estimates'' as well as ''average estimates'' of the numbers of marine mammals that could potentially be affected. For a few marine mammal species, several density estimates were available, and in those cases the mean and maximum estimates were determined from the survey data. In other cases, no applicable density estimate (or perhaps a single estimate) was available, so adjustments were used to arrive at ''average'' and ''maximum'' estimates. The species-specific estimation of these numbers is provided in Table 5 of the **Federal Register** notice for the proposed IHA (77 FR 73434, December 10, 2012). NMFS has determined that the average density data of marine mammal populations will be used to calculate estimated take numbers for species commonly reported in the vicinity of seismic survey operations—harbor seals and harbor porpoises—because using maximum density numbers for these species will result in overestimates that do not account for marine mammals avoiding the sound source before they are in the harassment zones. For killer whales and Steller sea lions, which have been documented in the past but whose occurrence is rare or whose average densities are too low to yield a take number due to extra-limital distribution in the vicinity of the proposed survey area, NMFS used the maximum densities to calculate takes of these species. For Cook Inlet beluga whales, NMFS has consulted with the beluga whale experts at NOAA's National Marine Mammal Laboratory (NMML), which directed NMFS to a recently published habitat model developed for Cook Inlet beluga whales that provides densities throughout the inlet based on the data from aerial surveys (Goetz *et al.,* 2012), and offered to conduct an analysis that would apply the model to Apache's seismic survey for the purpose of estimating beluga whale densities and takes. Additional information on the habitat-based model and the results of NMML's analysis are provided below in the Estimated Takes of Marine Mammals and Basis for Estimating ''Take by Harassment'' sections of this notice.

Comment 7: The Commission recommended that NMFS include harbor porpoises as one of the species for which implementation of delay and shutdown procedures are required when observers detect aggregations of five or more animals approaching or within the 160 dB harassment zone, based on studies reporting that harbor porpoises are particularly sensitive to air gun sounds.

Response: We agree with the proposal from the Commission regarding mitigation. These measures will be implemented if groups of five or more harbor porpoises are seen approaching or within the 160 dB zone.

Comment 8: The Commission states that the proposed monitoring measures do not appear adequate to monitor the disturbance (160 dB) zone and determine whether the requested numbers of takes have been exceeded. The Commission recommended that NMFS ensure that the monitoring measures included in the authorization are sufficient to account for all takes of marine mammals and require Apache to provide timely reports of the numbers of marine mammals taken so that, if necessary, surveys can be stopped before the authorized takes are exceeded—the measures used should account not only for the marine mammals observed, but also those marine mammals that are present but not observed.

Response: Section 101(a)(5)(D)(ii)(III) of the MMPA requires IHAs to include requirements pertaining to the monitoring and reporting of such taking by harassment. NMFS' implementing regulations at 50 CFR 216.108(c) state that a monitoring program must, if appropriate, document the effects (including acoustical) on marine mammals and document or estimate the actual level of take. As the cited regulation suggests, monitoring is not required to document all takes that may occur. The monitoring measures for Apache's seismic surveys include standard methods contained in IHAs for industry and research-related seismic survey activities to monitor takings (and they are also used to implement mitigation (i.e., the prescribed means of effecting the least practicable impact)). Given the size of the estimated Level B harassment zone, we acknowledge that some marine mammals within or entering the zone may not be immediately detected. However, the suite of required monitoring for this survey—vessel-based, shore-based, and aerial—allows for sufficient monitoring of effects and level of take (it also provides monitoring for purposes of triggering mitigation). The results of the monitoring report for the 2012 survey support this finding. Moreover, some of the required mitigation, namely the ramp-up and use of a mitigation air gun at night, is designed to prevent more serious types of take that could occur if a marine mammal were to be in the safety zone undetected. NMFS acknowledges that monitoring at night or in reduced visibility is more difficult, but observes that (1) the great majority of Apache's 2012 survey occurred when full visual monitoring was available (given the longer day during the main months of operation), which is likely to be true for the 2013 survey as well, and (2) prohibiting operations during nighttime and periods of lower visibility would reduce operational flexibility and lengthen the survey period, increasing the potential for interactions with marine mammals.

With respect to timely reporting, to better account for marine mammal takes that occur during the survey and ensure that takes do not exceed the amount authorized in the IHA, NMFS has included an additional reporting requirement in the IHA that will require the applicant to submit weekly and monthly reports to the Permits and Conservation Division. These reports will contain information regarding the species detected, in-water activity occurring at the time of the sighting,

behavioral reactions to in-water activities, and the number of marine mammals taken. NMFS believes that the inclusion of a weekly and monthly reporting requirement will allow both NMFS and Apache to regularly track the number and nature of marine mammal takes, and ensure that takes do not exceed what is authorized by the IHA. Apache must to report to NMFS immediately if 25 belugas are detected in the Level B harassment zone to allow us to consider making necessary adjustments to monitoring and mitigation. NMFS will require that seismic survey operations involving the use of air guns and pingers cease if 30 beluga whales are detected in the Level B harassment zone.

Comment 9: The Commission recommended that NMFS provide a 30-day public review and comment period that starts with the publication of the notices in the printed edition of the **Federal Register**.

Response: Although NMFS requested that the notice of the proposed IHA be available for review immediately upon filing with the **Federal Register**, due to a clerical error, the public review and comment period reflected the publication date of the notice; therefore, the public review and comment period for the proposed IHA did, in fact, start with publication in the **Federal Register**.

Comment 10: The Alaska Department of Natural Resources and Kenaitze Indian Tribe support issuance of the IHA and appreciate Apache's commitment to ensuring that activities in the Cook Inlet region result in responsible resource development.

Response: NMFS appreciates the review conducted by the State and Tribal natural resource managers and the continued collaboration and cooperation between the State of Alaska and Apache.

Comment 11: Environmental NGOs commented that NMFS failed to properly estimate take by adopting Apache's analysis that contains errors in its density calculations.

Response: The revised density and take estimates are provided in the Estimated Takes of Marine Mammals and Basis for Estimating ''Take by Harassment'' sections of this notice.

Comment 12: Environmental NGOs commented that NMFS underestimated the size of Apache's impact area by: (1) Relying on an outdated and incorrect threshold for behavioral take; (2) disregarding the best available evidence on the potential for temporary and permanent threshold shift on mid- and high-frequency cetaceans and on pinnipeds; and (3) failing to calculate take using in situ propagation analysis.

Response: The comment that NMFS uses an outdated and incorrect threshold for behavioral takes does not include any specific recommendations. NMFS uses 160 dB as the exposure level for calculating Level B harassment takes for most species in most cases. This threshold was established for underwater sound sources (except explosives and tactical active sonar) based on measured avoidance responses observed in whales in the wild. Specifically, the 160 dB threshold was derived from data for mother-calf pairs of migrating gray whales (Malme *et al.,* 1983, 1984) and bowhead whales (Richardson *et al.,* 1985, 1986) responding to seismic air guns (e.g., impulsive sound source). We acknowledge there is more recent information bearing on behavioral reactions to seismic air guns, but those data only illustrate how complex and context-dependent the relationship is between the two. See 75 FR 49710, 49716 (August 13, 2010) (IHA for Shell seismic survey in Alaska; response to comment 9). Accordingly, it is not a matter of merely replacing the existing threshold with a new one. NOAA is developing relatively sophisticated new draft guidelines for determining acoustic impacts, including information for determining Level B harassment thresholds. The draft guidelines will undergo a rigorous review that includes internal agency review, public notice and comment, and peer review before any final product is published. In the meantime, and taking into consideration the facts and available science, NMFS is using the 160 dB threshold for estimating takes of marine mammals in Cook Inlet by Level B harassment.

The comment that NMFS disregarded the best available evidence on the potential for temporary and permanent threshold shift on mid- and high-frequency marine mammals and pinnipeds does not contain any specific recommendations. We acknowledge there is more recent information available bearing on the relevant exposure levels for assessing temporary and permanent hearing impacts. Again, NMFS will be issuing new draft acoustic guidelines, but that process is not complete so we did not use it to assign new thresholds for calculate take estimates for hearing impacts. However, we did consider the information and it suggests the current 180 and 190 dB thresholds are conservative in that they likely overestimate potential for hearing impacts. See 75 FR 49710, 49715, 49724 (August 13, 2010) (IHA for Shell seismic survey in Alaska; responses to comment 8 and comment 27). Moreover, the required mitigation is designed to ensure there are no exposures to those injury thresholds.

As for in situ propagation analysis, Apache plans to conduct a Sound Source Verification (SSV) study prior to commencing seismic survey operations in Area 2. If the results from the SSV study show that the harassment zones are larger than anticipated, Apache will adjust the zones and monitor based on the new information as needed.

Comment 13: Environmental NGOs comment that the proposed IHA fails to properly evaluate the impacts of stress, the risk of stranding, potential reduction in prey, effects of increased turbidity, and cumulative impacts from other activities in Cook Inlet.

Response: NMFS provided a detailed discussion of the potential effects of this action in the notice of the proposed IHA (77 FR 73434, December 10, 2012) and believes the analyses and preliminary determinations were appropriate. The comment does not provide any specific recommendations or criticism regarding the sufficiency of those analyses. The potential effects of this action are also adequately addressed in NMFS's Environmental Assessment and Biological Opinion (which is incorporated by reference herein).

See response to Comment 3 for information on NMFS' cumulative effects analysis.

Comment 14: Environmental NGOs comment that the IHA fails to justify adequately the specific level of take it would authorize, particularly given its analysis showing average and maximum take numbers that exceed the proposed authorization.

Response: See response to Comment 6.

Comment 15: Environmental NGOs comment that NMFS provides inadequate justification for its small numbers and negligible impact determinations.

Response: This general comment contained no specific criticism or recommendations. NMFS believes the proposed and final IHA **Federal Register** notices contain sufficient justification for both the small numbers and negligible impact determinations. NMFS' conclusions regarding small numbers and negligible impact are provided in the Determinations section of this notice.

Comment 16: Environmental NGOs comment that NMFS has failed to adequately consider the current beluga population level and trends, or the fact that it is likely that subsistence use of whales will be prohibited for many years into the future in its analysis

regarding whether the proposed survey will have an ''unmitigable adverse impact'' on the subsistence harvest.

Response: Under NMFS MMPA implementing regulations at 50 CFR 216.103, unmitigable adverse impact means an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meeting subsistence needs by: (i) Causing the marine mammal to abandon or avoid hunting areas; (ii) directly displacing subsistence users; or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met. Currently there is no subsistence hunting of Cook Inlet belugas authorized (73 FR 60976, October 15, 2008). There can be no impacts on Cook Inlet beluga subsistence uses in the immediate future because they are not permitted. Moreover, any takes that occur from this IHA will not have impacts on future subsistence hunts for belugas if and when they resume because the anticipated takes are not expected to have any of the effects contemplated in NMFS' definition (above) of unmitigable adverse impact. Apache did not request and NMFS does not anticipate, nor is it authorizing, any Level A harassment takes of Cook Inlet beluga whales or takes by mortality incidental to the seismic surveys. The required mitigation and monitoring measures are designed to avoid exposing any marine mammals, including Cook Inlet beluga whales, to sound levels that may result in injury. For example, protected species observers will monitor the marine mammal exclusion zone while a sound source is active and have the authority to require power-downs or shut-downs to ensure that Level A harassment takes do not occur. In the unlikely event that marine mammals are exposed to potentially injurious levels of sound, the IHA will require Apache to cease work and report the incident to NMFS.

Comment 17: Environmental NGOs comment that the mitigation measures proposed for the Apache survey fail to meet the MMPA's ''least practicable adverse impact'' standard, and provide a list of approximately eight measures that NMFS ''failed to consider or adequately consider.''

Response: NMFS provided a detailed discussion of proposed mitigation measures and the MMPA's ''least practicable adverse impact'' standard in the notice of the proposed IHA (77 FR 73434, December 10, 2012), which are repeated in the Mitigation section of this notice. The measures that NMFS allegedly failed to consider or adequately consider are identified and discussed below:

(1) Seasonal exclusions around river mouths, including the Beluga River: Due to the location of the 2013 seismic survey, NMFS has added a 10 mile (16 km) exclusion zone around the Susitna Delta (which includes the Beluga River) to the IHA. This mitigation mirrors a measure in the Incidental Take Statement for the 2012 and 2013 Biological Opinions. Seismic surveys operations involving the use of air guns will be prohibited in this area between April and October. (In addition, the Alaska Department of Fish and Game (ADF&G) prohibits the use of air guns within 1 mile (1.6 km) of the mouth of any stream listed by the ADF&G on the Catalogue of Waters Important for the Spawning, Rearing, or Migration of Anadromous Fishes.) See additional explanation in ''Mitigation Measures Considered but not Required'' section, below.

(2) Use of advance aerial surveys to redirect activity if sufficient numbers of belugas or other species are sighted: Safety and weather permitting, aerial surveys will occur daily. Aerial surveys will be required when operating near river mouths to identify large congregations of beluga whales and harbor seal haul outs. In addition, daily aerial surveys must be conducted when there are any seismic-related activities (including, but not limited to, node laying/retrieval or air gun operations) occurring north or east of a line from Tyonek across to the eastern side of Number 3 Bay of the Captain Cook State Recreation Area, Cook Inlet (roughly the southern-most point of Corps defined Region 9). The purposes of these surveys is to mitigate impacts and reduce incidental take by identifying the presence of Cook Inlet belugas near the Susitna Delta and alert the vessels accordingly of necessary actions to avoid or minimize potential disturbance, to monitor the effects of the seismic program on Cook Inlet belugas and their primary feeding and reproduction areas, and to ensure that any displacement from the Susitna Delta region is temporary and would not be likely to cause harm to whales by reducing their ability to feed. This information allows for better planning by PSOs and assists in better understanding of the movements of large groups of beluga whales with respect to the tide. Moreover, aerial observations can be used to locate rarely seen animals (e.g., gray whales) that are difficult to track from the vessels.

(3) Field testing and use of alternative technologies, such as vibroseis and gravity gradiometry, to reduce or eliminate the need for air guns: Apache requested takes of marine mammals incidental to the seismic survey operations described in the IHA application, which identified air guns arrays as the technique Apache would employ to acquire seismic data. It would be impractical for NMFS to require Apache to make this kind of change to the underlying activity and is beyond the scope of the request for takes incidental to Apache's operation of air guns and other active acoustic sources.

(4) Independent determination and required use of the lowest practicable source level in conducting air gun activity: This general comment contained no specific recommendations. Apache determined the array sizes during the test line surveyed in March 2011 and utilizes the minimum source level necessary to image the sub-surface targets.

(5) Observance of a 10 knot speed limit for all vessels, including supply vessels, employed in the activity: NMFS does not agree with the recommendation that vessels observe a 10 knot speed limit. Stipulating vessel speeds would severely hamper Apache's seismic survey, increase the amount of time needed to complete the survey, and would not be practicable. In any event, Apache has indicated that vessels typically move at 2–4 knots during seismic surveys and NMFS requires speed and course alterations when a marine mammal is detected outside the 160 dB zone and, based on position and relative motion, is likely to enter the zone.

(6) Limitation of the mitigation air gun to the longest shot interval necessary to carry out its intended purpose: This general comment contained no specific recommendations. Apache set the mitigation gun interval to mimic the timing of the shot interval used for the full array (approximately 24 seconds). NMFS believes that the shot interval of the mitigation air gun is appropriate to carry out its intended purpose.

(7) Immediate suspension of air gun activity, pending investigation, if any beluga strandings occur within or within an appropriate distance of the Area 2 survey: There is no evidence in the literature that air gun pulses cause marine mammal strandings and the sounds produced by air guns are quite different from sound sources that have been associated with stranding events, such as military mid-frequency active sonar. Nevertheless, the IHA requires Apache to immediately cease activities

and report unauthorized takes of marine mammals, such as injury, serious injury, or mortality. Activities cannot resume until NMFS is able to review the circumstances of the unauthorized take, determine what is necessary to minimize the likelihood of further unauthorized take and ensure MMPA compliance. Apache may not resume activities until notified by NMFS.

(8) Establishment of a larger exclusion zone for beluga whales that is not predicated on the detection of cow-calf pairs: This comment does not provide any justification for why the exclusion (safety) zone for beluga whales (other than groups of five or more and cow-calf pairs) should be expanded beyond the 180 dB zone. We not that prior to commencing seismic survey activities in 2013, Apache will conduct another sound source verification study to measure the distance to the 180/190 dB safety zone and to the 160 dB harassment zone. If the sound source verification study reveals that the distance is greater than the distances measures prior to the 2012 seismic survey, the zones and monitoring will be expanded as needed. Apache is required to shut down active sound sources if groups of five or more beluga whales, killer whales, and harbor porpoises or beluga cow-calf pairs are observed within or approaching the 160 dB zone.

Comment 18: Environmental NGOs comment that monitoring measures should include passive acoustic monitoring superior to over-the-side hydrophone, require aerial-based monitoring in areas other than river mouths, and at least 2 ship-based PSOs per vessel on watch at all times during daylight hours with a maximum of 2 consecutive hours on watch and 8 hours of watch time per day per PSO.

Response: The passive acoustic monitoring plan for Apache's 2012 survey anticipated the use of a bottom-mounted telemetry buoy to broadcast acoustic measurements using a radio-system link back to a monitoring vessel. Although a buoy was deployed during the first week of surveying under the 2012 IHA, it was not successful. Upon deployment, the buoy immediately turned upside down due to the strong current in Cook Inlet. After retrieval, the buoy was not redeployed and the survey used a single omni-directional hydrophone lowered from the side of the mitigation vessel. During the entire 2012 survey season, Apache's PAM equipment yielded only six confirmed marine mammal detections, one of which was a Cook Inlet beluga whale. The single Cook Inlet beluga whale detection did not, however, result in a shutdown procedure. Given the limited capability of this particular PAM methodology for Apache's project in Cook Inlet (see Austin and Zeddies, 2012 for more information), as compared to visual monitoring methods, including expanded daily aerial surveys, the bottom-mounted telemetry buoy and omni-directional hydrophone are no longer considered practicable, and will not be a component of the 2013 seismic survey.

The IHA requires aerial surveys when operating near river mouths. In addition, NMFS has added the following monitoring measure: Safety and weather permitting, aerial surveys must be conducted when there are any seismic-related activities (including but not limited to node laying/retrieval or airgun operations) occurring north or east of a line from Tyonek across to the eastern side of Number 3 Bay of the Captain Cook State Recreation Area, Cook Inlet (roughly the southern-most point of Corps defined Region 9). Surveys are to be flown even if the air guns are not being fired.

Vessel-based observers are stationed on three vessels with two PSOs on the support vessel and one PSO on each of the two source vessels. Due to space limitations onboard the source vessels, no more than one PSO could be accommodated on each vessel. PSOs monitored for marine mammals during all daylight hours prior to and during seismic survey operations, unless precluded by weather (e.g., fog, ice, high sea states). PSOs on the vessels rotated observation shifts every 4–6 hours in order to better monitor the survey area, implement mitigation measures, and avoid fatigue. In addition, vessel crews are be instructed to assist with detecting marine mammals and implementing mitigation measures.

Comment 19: The IAGC encouraged NMFS to review a recent peer-reviewed scientific paper regarding the impacts of seismic surveys on fish. They referred NMFS to a study by Lokkeborg *et al.* (2012) that provides additional, updated information challenging the Engas *et al.* (1993) assessment that seismic surveys have adverse impacts on Norwegian fisheries.

Response: NMFS acknowledges this comment and has reviewed the study by Lokkeborg et al. (2012), which was published in the *Canadian Journal of Fisheries Aquatic Sciences* on July 10, 2012. However, this does not change the analysis provided in the notice of the proposed IHA (77 FR 73434, December 10, 2012).

Comment 20: The IAGC encouraged NMFS to consider frequency weighting in development of incidental take estimates.

Response: Frequency weighting takes into account that all marine mammal species do not have identical hearing capabilities. To reflect this, Southall *et al.* 2007 proposed that marine mammals be divided into five functional hearing groups and subsequently recommended frequency weighting functions for each of these groups. NMFS agrees that taking into account frequencies that marine mammals hear is an important consideration. For example, if a sound is entirely outside the hearing range of a species, it is not considered to have the potential to cause a significant response.

There are data to indicate that frequency weighting is an important consideration associated with noise-induced hearing loss (Finneran and Schlundt, 2009; Finneran and Schlundt, 2011). We are in the process of reviewing and considering these data within our updated marine mammal NOAA acoustic guidelines. Southall *et al.,* 2007 recommended criteria for onset of injury (i.e., permanent threshold shift) are presented using a cumulative sound exposure level, which takes into account not only the received level during exposure but also the duration of exposure, as well as incorporating frequency weighting functions. In situations where exposures of lower level but longer duration are possible (which could be possible for resident populations or population with a small range), there must be caution using the Southall *et al.,* 2007 criteria (i.e., noise-induced hearing loss my occur at a lower level than shorter exposures of higher level but with the same cumulative sound exposure level; Mooney *et al.,* 2009, Finneran *et al.,* 2010).

For behavior, the relationship between severity of response and frequency weighting is less clear and does not necessarily correspond to the severity of behavioral response expected. Behavioral effects are more challenging to predict since they often involve other variables beyond detection (e.g. perception and cognition, contextual cues, and previous experience). Despite most of the acoustic energy from seismic activities occurring outside the best hearing range of odontocetes, there are data showing that these species do behaviorally respond to these types of activities in some contexts, although not necessarily in a biologically significant way. Miller *et al.* (2005) indicates that belugas in the Beaufort Sea may have responded (avoidance) to seismic activity, although belugas may have already been in the

process of leaving the area due to their seasonal migration.

Comment 21: The IAGC commented that NMFS should provide Environmental Assessments, Biological Opinions, and other documents for review at the same time as the proposed IHA.

Response: In the notice of the proposed IHA (77 FR 73434, December 10, 2012), NMFS indicated that an Environmental Assessment (EA) was being prepared and would be completed prior to NMFS' decision to issue or deny the IHA. The Environmental Assessment and Biological Opinion prepared for the IHA NMFS issued to Apache in April 2012 have been available and posted at *http://www.nmfs.noaa.gov/pr/permits/incidental.htm.* The information in those publically available documents provided a basis for the EA we prepared for the subject IHA. All comments on the proposed IHA that were also relevant to the effects of our action on the affected environment were considered.

Based on changed in the proposed action, namely the potential survey area, we reinitiated section 7 consultation and a new biological opinion was issued. The time needed to conduct consultations does not allow for prior public review.

Comment 22: The Seldovia Village Tribe opposed the operation of seismic air guns unless NMFS required that the activities cease when marine mammals are within or approaching the Level A harassment (injury) zone.

Response: As described in detail in the notice of the proposed IHA (77 FR 73434, December 10, 2012), as well as in this document, NMFS does not believe that Apache's seismic survey will cause injury or mortality to marine mammals. NMFS requires that Apache establish, monitor, and implement mitigation measures in an area where sound has the potential to cause injury. NMFS mitigation or shutdown ''safety radii'' for limiting marine mammal exposure to impulsive sources typically correspond to the distances within which received sound levels are greater than or equal to 180 dB for cetaceans and greater than or equal to 190 dB for pinnipeds. These safety criteria are based on an assumption that SPLs received at lower levels will not result in injury or impair hearing. During Apache's survey, these ''safey zones'' will be monitored by PSOs for the presence of marine mammals and air guns will be shut down if marine mammals are observed approaching or within these zones. No injury and/or mortality of marine mammals is expected, and none was authorized.

Description of Marine Mammals in the Area of the Specified Activity

The marine mammal species under NMFS's jurisdiction that could occur near operations in Cook Inlet include three cetacean species, all odontocetes (toothed whales): Beluga whale (*Delphinapterus leucas*), killer whale (*Orcinus orca*), and harbor porpoise (*Phocoena phocoena*), and two pinniped species: Harbor seal (*Phoca vitulina richardsi*) and Steller sea lions (*Eumetopias jubatus*). The marine mammal species that is likely to be encountered most widely (in space and time) throughout the period of the planned surveys is the harbor seal.

Of the five marine mammal species likely to occur in the proposed marine survey area, only Cook Inlet beluga whales and Steller sea lions are listed as endangered under the ESA (Steller sea lions are listed as two distinct population segments (DPSs), an eastern and a western DPS; the relevant DPS in Cook Inlet is the western DPS). These species are also designated as ''depleted'' under the MMPA. Despite these designations, Cook Inlet beluga whales and the western DPS of Steller sea lions have not made significant progress towards recovery. The Cook Inlet population of beluga whales has been decreasing at a rate of 1.1 percent annually for nearly a decade (Allen and Angliss, 2011). With respect to Steller sea lions, results of aerial surveys conducted in 2008 (Fritz *et al.,* 2008) confirmed that the recent (2004–2008) overall trend in the western population of adult and juvenile Steller sea lions in Alaska is stable or possibly in decline; however, there continues to be considerable regional variability in recent trends. Pursuant to the ESA, critical habitat has been designated for Cook Inlet beluga whales and Steller sea lions. The proposed action falls within critical habitat designated in Cook Inlet for beluga whales, but is not within critical habitat designated for Steller sea lions. The portion of beluga whale critical habitat—identified as Area 2 in the critical habitat designation—where the seismic survey will occur is located south of the Area 1 critical habitat where belugas are particularly vulnerable to impacts due to their high seasonal densities and the biological importance of the area for foraging, nursery, and predator avoidance. Area 2 critical habitat is largely based on dispersed fall and winter feeding and transit areas in waters where whales typically appear in smaller densities or deeper waters (76 FR 20180, April 11, 2011).

Cetaceans

Beluga Whales—Cook Inlet beluga whales reside in Cook Inlet year-round although their distribution and density changes seasonally. Factors that are likely to influence beluga whale distribution within the inlet include prey availability, predation pressure, sea-ice cover, and other environmental factors, reproduction, sex and age class, and human activities (Rugh *et al.,* 2000; NMFS 2008). Seasonal movement and density patterns as well as site fidelity appear to be closely linked to prey availability, coinciding with seasonal salmon and eulachon concentrations (Moore *et al.,* 2000). For example, during spring and summer, beluga whales are generally concentrated near the warmer waters of river mouths where prey availability is high and predator occurrence in low (Huntington 2000; Moore *et al.,* 2000). During the winter (November to April), belugas disperse throughout the upper and mid-inlet areas, with animals found between Kalgin Island and Point Possession (Rugh *et al.,* 2000). During these months, there are generally fewer observations of beluga whales in the Anchorage and Knik Arm area (NMML 2004; Rugh *et al.,* 2004).

Beluga whales use several areas of the upper Cook Inlet for repeated summer and fall feeding. The primary hotspots for beluga feeding include the Big and Little Susitna rivers, Eagle Bay to Eklutna River, Ivan Slough, Theodore River, Lewis River, and Chickaloon River and Bay (NMFS 2008). Availability of prey species appears to be the most influential environmental variable affecting Cook Inlet beluga whale distribution and relative abundance (Moore *et al.* 2000). The patterns and timing of eulachon and salmon runs have a strong influence on beluga whale feeding behavior and their seasonal movements (Nemeth *et al.,* 2007; NMFS 2008). The presence of prey species may account for the seasonal changes in beluga group size and composition (Moore *et al.,* 2000). Aerial and vessel-based monitoring conducted by Apache during the March 2011 2D test program in Cook Inlet reported 33 beluga sightings. One of the sightings was of a large group (~25 individuals on March 27, 2011) of feeding/milling belugas near the mouth of the Drift River. Also on March 27, 2011, PSOs onboard the *M/V Dreamcatcher* reported a group of seven beluga whales approximately 0.5 nm from the vessel. Land-based PSOs were able to observe this group of beluga

whales for approximately 2.5 hrs. A single beluga whale was observed near the mouth of the Drift River by the aerial-based monitors on March 28, 2011, prior to the seismic ramp-up period. If belugas are present during the late summer/early fall, they are more likely to occur in shallow areas near river mouths in upper Cook Inlet. For example, no beluga whales were sighted in Trading Bay during the SSV conducted in September 2011 because during this time of year they are more likely to be in the upper regions of Cook Inlet. In the notice of the proposed IHA (77 FR 73434, December 10, 2012), expected densities were calculated from the annual aerial surveys conducted by NMFS between 2000 and 2012 (Rugh *et al.* 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007; Shelden *et al.* 2008, 2009, 2010, 2012; Hobbs *et al.* 2011). Those densities were presented in Table 5 of the proposed IHA. During the public comment period, in response to NMFS' request to apply a correction factor to the beluga whale aerial survey data, Apache submitted updated density estimates for beluga whales that applied a correction factor based on previously published studies. For example, in Hobbs *et al.* (2000), the correction for whales in missed groups was 1.015 (CV = 3%) for the years 1994–98 and 1.021 (CV = 1%) for the years 1999 and 2000. In all the subsequent annual survey reports (2001–2011), the authors stated that the correction factors for that particular year are within the range for 1999–2000. Therefore, a correction factor of 1.021 was applied to all of the highest number of sightings for each year and calculated the densities/takes the same as for the previous IHA. Using this correction factor, the estimated maximum take increased from 11.98 to 12.2 (12), so there was no difference from the previous uncorrected approach with respect to ''whole'' animals.

After receiving the new information from Apache, NMFS sent the updated density estimates to beluga whale experts at the National Marine Mammal Laboratory (NMML) for their review. NMML staff indicated that Apache appeared to account for both on and off effort flight hours (instead of just on-effort hours) and had not included 1,810 km of coastline. NMML attempted to correct Apache's calculations by including on-effort survey hours and 1,810 km of coastline, but determined that the resulting take calculations for beluga whales were grossly inaccurate and unreliable. NMML staff directed NMFS to a published habitat model developed for Cook Inlet beluga whales that provides densities throughout the inlet based on the data from aerial surveys (Goetz *et al.,* 2012), and agreed to conduct an analysis that would apply the habitat-based model to Apache's seismic survey for the purpose of estimating beluga whale densities and takes. Additional information on the habitat-based model and the results of NMML's analysis are provided below.

Killer Whales—In general, killer whales are rare in upper Cook Inlet, where transient killer whales are known to feed on beluga whales and resident killer whales are known to feed on anadromous fish (Shelden *et al.,* 2003). The availability of these prey species largely determines the likeliest times for killer whales to be in the area. Between 1993 and 2004, 23 sightings of killer whales were reported in the lower Cook Inlet during aerial surveys by Rugh *et al.* (2005). Surveys conducted over a span of 20 years by Shelden *et al.* (2003) reported 11 sightings in upper Cook Inlet between Turnagain Arm, Susitna Flats, and Knik Arm. No killer whales were spotted during recent surveys by Funk *et al.* (2005), Ireland *et al.* (2005), Brueggeman *et al.* (2007a, 2007b, 2008), or Prevel Ramos *et al.* (2006, 2008). Eleven killer whale strandings have been reported in Turnagain Arm, six in May 1991 and five in August 1993. Therefore, very few killer whales, if any, are expected to approach or be in the vicinity of the action area.

Harbor Porpoise—The most recent estimated density for harbor porpoises in Cook Inlet is 7.2 per 1,000 km^2 (Dahlheim *et al.,* 2000) indicating that only a small number use Cook Inlet. Harbor porpoise have been reported in lower Cook Inlet from Cape Douglas to the West Foreland, Kachemak Bay, and offshore (Rugh *et al.,* 2005). Small numbers of harbor porpoises have been consistently reported in upper Cook Inlet between April and October, except for a recent survey that recorded higher than usual numbers. Prevel Ramos *et al.* (2008) reported 17 harbor porpoises from spring to fall 2006, while other studies reported 14 in the spring of 2007 (Brueggeman *et al.* 2007) and 12 in the fall (Brueggeman *et al.* 2008). During the spring and fall of 2007, 129 harbor porpoises were reported between Granite Point and the Susitna River; however, the reason for the increase in numbers of harbor porpoise in the upper Cook Inlet remains unclear and the disparity with the result of past sightings suggests that it may be an anomaly. The spike in reported sightings occurred in July, which was followed by sightings of 79 harbor porpoises in August, 78 in September, and 59 in October, 2007. It is important to note that the number of porpoises counted more than once was unknown, which suggests that the actual numbers are likely smaller than those reported. In addition, recent passive acoustic research in Cook Inlet by the Alaska Department of Fish and Game and the National Marine Mammal Laboratory have indicated that harbor porpoises occur in the area more frequently than previously thought, particularly in the West Foreland area in the spring (NMFS, 2011); however overall numbers are still unknown at this time.

Pinnipeds

Two species of pinnipeds may be encountered in Cook Inlet: Harbor seal and Steller sea lion.

Harbor Seals—Harbor seals inhabit the coastal and estuarine waters of Cook Inlet. In general, harbor seals are more abundant in lower Cook Inlet than in upper Cook Inlet, but they do occur in the upper inlet throughout most of the year (Rugh *et al.,* 2005). Harbor seals are non-migratory; their movements are associated with tides, weather, season, food availability, and reproduction. The major haulout sites for harbor seals are located in lower Cook Inlet and their presence in the upper inlet coincides with seasonal runs of prey species. For example, harbor seals are commonly observed along the Susitna River and other tributaries along upper Cook Inlet during the eulachon and salmon migrations (NMFS, 2003). During aerial surveys of upper Cook Inlet in 2001, 2002, and 2003, harbor seals were observed 24 to 96 km south-southwest of Anchorage at the Chickaloon, Little Susitna, Susitna, Ivan, McArthur, and Beluga Rivers (Rugh *et al.,* 2005). During the 2D test program in March 2011, two harbor seals were observed by vessel-based PSOs. On March 25, 2011, one harbor seal was observed approximately 400 m from the *M/V Miss Diane.* At the time of the observation, the vessel was operating the positioning pinger and PSOs instructed the operator to implement a shut-down. The pinger was shut down for 30 minutes while PSO monitored the area and re-started the device when the animal was not sighted again during the 30 minute site clearing protocol. No unusual behaviors were reported during the time the animal was observed. The second harbor seal was observed on March 26, 2011, by vessel-based PSO onboard the *M/V Dreamcatcher* approximately 4260 m from the source vessel, which was operating the 10 in^3 air gun at the time. The animal was well outside of the 160 dB zone (330 m for the 10 in^3 air gun) and no unusual behaviors were observed. Many harbor seals were observed during the 3D seismic survey

conducted under the April 2012 IHA, especially when survey operations were conducted close to shore. NMFS and Apache do not anticipate encountering large haulouts of seals in Area 2—the closest haulout site to the action area is located on Kalgin Island, which is approximately 22 km away from the McArthur River—but we do expect to see curious individual harbor seals; especially during large fish runs in the various rivers draining into Cook Inlet.

Steller Sea Lion—Two separate stocks of Steller sea lions are recognized within U.S. waters: An eastern U.S. stock, which includes animals east of Cape Suckling, Alaska; and a western U.S. stock, which includes animals west of Cape Suckling (NMFS, 2008). Individuals in Cook Inlet are considered part of the western U.S. stock, which is listed as endangered under the ESA. Steller sea lions primarily occur in lower, rather than upper Cook Inlet and are rarely sighted north of Nikiski on the Kenai Peninsula. Haul-outs and rookeries are located near Cook Inlet at Gore Point, Elizabeth Island, Perl Island, and Chugach Island (NMFS, 2008). No Steller seal lion haul-outs or rookeries are located in the vicinity of the proposed seismic survey. Furthermore, no sightings of Steller sea lions were reported by Apache during the 2D test program in March 2011. During the 3D seismic survey in 2012, Steller sea lions were observed on three separate occasions (approximately 4 individuals). Although Apache has requested takes of Steller sea lions, Steller sea lions would be rare in the action area during seismic survey operations.

Apache's application contains additional information on the status, distribution, seasonal distribution, and abundance of each of the species under NMFS' jurisdiction mentioned in this document. Please refer to the application for that information (see ADDRESSES). Additional information can also be found in the NMFS Stock Assessment Reports (SAR). The Alaska 2011 SAR is available at: *http://www.nmfs.noaa.gov/pr/pdfs/sars/ak2011.pdf.*

Potential Effects of the Specified Activity on Marine Mammals

NMFS considered the potential effects of sound from air guns, pingers, vessels, aircraft, and land-based explosives. In addition, NMFS considered the effects of vessel operations and the potential for ship strikes.

Potential Effects of Air Gun Sounds on Marine Mammals

The effects of sounds from air gun pulses might include one or more of the following: Tolerance, masking of natural sounds, behavioral disturbance, and temporary or permanent hearing impairment or non-auditory effects (Richardson *et al.,* 1995). As outlined in previous NMFS documents, the effects of noise on marine mammals are highly variable, often depending on species and contextual factors, and can be categorized as follows (based on Richardson *et al.,* 1995):

(1) Tolerance

Numerous studies have shown that pulsed sounds from air guns are often readily detectable in the water at distances of many kilometers. Numerous studies have also shown that marine mammals at distances more than a few kilometers from operating survey vessels often show no apparent response. That is often true even in cases when the pulsed sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. In general, pinnipeds and small odotocetes (toothed whales) seem to be more tolerant of exposure to air gun pulses than baleen whales. Although various toothed whales, and (less frequently) pinnipeds have been shown to react behaviorally to air gun pulses under some conditions, at other times, mammals of both types have shown no overt reactions. For example, the available evidence also indicates that Cook Inlet beluga whales are less impacted behaviorally by anthropogenic sounds compared to marine mammals in more pristine acoustic environments (e.g., the Beaufort Sea) given the Cook Inlet population's greater experience with anthropogenic sounds.

(2) Behavioral Disturbance

Marine mammals may behaviorally react to sound when exposed to anthropogenic noise. These behavioral reactions are often shown as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (e.g., pinnipeds flushing into water from haulouts or rookeries).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification have the potential to be biologically significant if the change affects growth, survival, or reproduction. Examples of significant behavioral modifications include:

- Drastic change in diving/surfacing patterns (such as those thought to be causing beaked whale stranding due to exposure to military mid-frequency tactical sonar);
- Habitat abandonment due to loss of desirable acoustic environment; and
- Cessation of feeding or social interaction.

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall *et al.,* 2007).

Currently NMFS uses a received level of 160 dB re 1 μPa to estimate the onset threshold for marine mammal behavioral harassment for impulse noises (such as air gun pulses). As explained below, NMFS has determined that use of this threshold is appropriate for Apache's IHA considering the scientific literature pertaining to this issue and the evidence specific to the marine mammal species and populations in question.

(3) Masking

Marine mammals use acoustic signals for a variety of purposes, which differ among species, but include communication between individuals, navigation, foraging, reproduction, and learning about their environment (Erbe and Farmer, 2000; Tyack, 2000). Masking, or auditory interference, generally occurs when sounds in the environment are louder than, and of a similar frequency as, auditory signals an animal is trying to receive. Masking is a phenomenon that affects animals that are trying to receive acoustic information about their environment, including sounds from other members of their species, predators, prey, and sounds that allow them to orient in their environment. Masking these acoustic signals can disturb the biological functions of individual animals or groups of animals over long distances and times, which could potentially have population-level effects.

Masking occurs when noise and signals (that the animal utilizes) overlap at both spectral and temporal scales. For the air gun noise generated from the

proposed seismic surveys, noise will consist of low frequency (under 500 Hz) pulses with extremely short durations (less than one second). Lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. There is little concern regarding masking near the noise source due to the brief duration of these pulses and relatively longer silence between air gun shots (approximately 12 seconds). However, at long distances (over tens of kilometers away), due to multipath propagation and reverberation, the durations of air gun pulses can be ''stretched'' to seconds with long decays (Madsen *et al.,* 2006), although the intensity of the noise is greatly reduced.

This could affect communication signals used by low frequency mysticetes when they occur near the noise band and thus reduce the communication space of animals (e.g., Clark *et al.,* 2009) and cause increased stress levels (e.g., Foote *et al.,* 2004; Holt *et al.,* 2009); however, no baleen whales are expected to occur within the action area. Marine mammals are thought to be able to compensate for masking by adjusting their acoustic behavior by shifting call frequencies, and/or increasing call volume and vocalization rates. For example, blue whales are found to increase call rates when exposed to seismic survey noise in the St. Lawrence Estuary (Di Iorio and Clark, 2010). The North Atlantic right whales (*Eubalaena glacialis*) exposed to high shipping noise increase call frequency (Parks *et al.,* 2007), while some humpback whales respond to low-frequency active sonar playbacks by increasing song length (Miller *et al.,* 2000).

(4) Hearing Impairment

Marine mammals exposed to high intensity sound repeatedly or for prolonged periods can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Kastak *et al.,* 1999; Schlundt *et al.,* 2000; Finneran *et al.,* 2002; 2005). TS can be permanent (PTS), in which case the loss of hearing sensitivity is unrecoverable, or temporary (TTS), in which case the animal's hearing threshold will recover over time (Southall *et al.,* 2007). Just like masking, marine mammals that suffer from PTS or TTS could have reduced fitness in survival and reproduction, either permanently or temporarily. For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound.

Researchers have studied TTS in certain captive odontocetes and pinnipeds exposed to strong sounds (reviewed in Southall *et al.,* 2007). However, there has been no specific documentation of TTS let alone permanent hearing damage, i.e., permanent threshold shift (PTS), in free-ranging marine mammals exposed to sequences of air gun pulses during realistic field conditions.

Temporary Threshold Shift—TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter, 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. At least in terrestrial mammals, TTS can last from minutes or hours to (in cases of strong TTS) days. For sound exposures at or somewhat above the TTS threshold, hearing sensitivity in both terrestrial and marine mammals recovers rapidly after exposure to the noise ends. Few data on sound levels and durations necessary to elicit mild TTS have been obtained for marine mammals, and none of the published data concern TTS elicited by exposure to multiple pulses of sound. Available data on TTS in marine mammals are summarized in Southall *et al.* (2007).

To avoid the potential for injury, NMFS (1995, 2000) concluded that cetaceans and pinnipeds should not be exposed to pulsed underwater noise at received levels exceeding 180 and 190 dB re 1 µPa (rms), respectively. The 180 and 190 dB (rms) criteria are not considered to be the levels above which TTS might occur. Rather, they are the received levels above which, in the view of a panel of bioacoustics specialists convened by NMFS before TTS measurements for marine mammals started to become available, one could not be certain that there would be no injurious effects, auditory or otherwise, to marine mammals. NMFS also assumes that cetaceans and pinnipeds exposed to levels exceeding 160 dB re 1 µPa (rms) may experience Level B harassment.

For toothed whales, researchers have derived TTS information for odontocetes from studies on the bottlenose dolphin and beluga. The experiments show that exposure to a single impulse at a received level of 207 kPa (or 30 psi, p-p), which is equivalent to 228 dB re 1 Pa (p-p), resulted in a 7 and 6 dB TTS in the beluga whale at 0.4 and 30 kHz, respectively. Thresholds returned to within 2 dB of the pre-exposure level within 4 minutes of the exposure (Finneran *et al.,* 2002). For the one harbor porpoise tested, the received level of air gun sound that elicited onset of TTS was lower (Lucke *et al.,* 2009). If these results from a single animal are representative, it is inappropriate to assume that onset of TTS occurs at similar received levels in all odontocetes (*cf.* Southall *et al.,* 2007). Some cetaceans apparently can incur TTS at considerably lower sound exposures than are necessary to elicit TTS in the beluga or bottlenose dolphin.

In pinnipeds, researchers have not measured TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound. Initial evidence from more prolonged (non-pulse) exposures suggested that some pinnipeds (harbor seals in particular) incur TTS at somewhat lower received levels than do small odontocetes exposed for similar durations (Kastak *et al.,* 1999, 2005; Ketten *et al.,* 2001). The TTS threshold for pulsed sounds has been indirectly estimated as being an SEL of approximately 171 dB re 1 $\mu Pa^2 \cdot s$ (Southall *et al.,* 2007) which would be equivalent to a single pulse with a received level of approximately 181 to 186 dB re 1 µPa (rms), or a series of pulses for which the highest rms values are a few dB lower. Corresponding values for California sea lions and northern elephant seals are likely to be higher (Kastak *et al.,* 2005).

No cases of TTS are expected as a result of Apache's proposed activities given the strong likelihood that marine mammals would avoid the approaching air guns (or vessel) before being exposed to levels high enough for there to be any possibility of TTS, and the mitigation measures proposed to be implemented during the survey described later in this document.

Permanent Threshold Shift—When PTS occurs, there is physical damage to the sound receptors in the ear. In severe cases, there can be total or partial deafness, whereas in other cases, the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter, 1985). There is no specific evidence that exposure to pulses of air gun sound can cause PTS in any marine mammal, even with large arrays of air guns. However, given the possibility that mammals close to an air gun array might incur at least mild TTS, there has been further speculation about the possibility that some individuals occurring very close to air guns might incur PTS (e.g., Richardson *et al.,* 1995; Gedamke *et al.,* 2008). Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage, but repeated or (in some cases) single exposures to a level well above that causing TTS onset might elicit PTS.

Relationships between TTS and PTS thresholds have not been studied in

marine mammals, but are assumed to be similar to those in humans and other terrestrial mammals (Southall *et al.,* 2007). PTS might occur at a received sound level at least several dBs above that inducing mild TTS if the animal were exposed to strong sound pulses with rapid rise times. Based on data from terrestrial mammals, a precautionary assumption is that the PTS threshold for impulse sounds (such as air gun pulses as received close to the source) is at least 6 dB higher than the TTS threshold on a peak-pressure basis, and probably greater than 6 dB (Southall *et al.,* 2007).

Given the higher level of sound necessary to cause PTS as compared with TTS, it is considerably less likely that PTS would occur during the proposed seismic survey in Cook Inlet. Cetaceans generally avoid the immediate area around operating seismic vessels, as do some other marine mammals. Some pinnipeds show avoidance reactions to air guns, but their avoidance reactions are generally not as strong or consistent as those of cetaceans, and occasionally they seem to be attracted to operating seismic vessels (NMFS, 2010).

(5) Non-auditory Physical Effects

Non-auditory physical effects might occur in marine mammals exposed to strong underwater pulsed sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, and other types of organ or tissue damage. Some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds. However, there is no definitive evidence that any of these effects occur even for marine mammals in close proximity to large arrays of air guns, and beaked whales do not occur in the proposed project area. In addition, marine mammals that show behavioral avoidance of seismic vessels, including most baleen whales, some odontocetes (including belugas), and some pinnipeds, are especially unlikely to incur non-auditory impairment or other physical effects. The distances to the 180 and 190 dB thresholds for the air gun arrays proposed to be used by Apache are provided in Table 1.

Therefore, it is unlikely that such effects would occur during Apache's proposed surveys given the brief duration of exposure and the planned monitoring and mitigation measures described later in this document.

(6) Stranding and Mortality

Marine mammals close to underwater detonations of high explosive can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.,* 1993; Ketten, 1995). Air gun pulses are less energetic and their peak amplitudes have slower rise times. To date, there is no evidence that serious injury, death, or stranding by marine mammals can occur from exposure to air gun pulses, even in the case of large air gun arrays.

However, in numerous past IHA notices for seismic surveys, commenters have referenced two stranding events allegedly associated with seismic activities, one off Baja California and a second off Brazil. NMFS has addressed this concern several times, including in the **Federal Register** notice announcing the IHA for Apache's first seismic survey in 2012, and, without new information, does not believe that this issue warrants further discussion. For information relevant to strandings of marine mammals, readers are encouraged to review NMFS' response to comments on this matter found in 69 FR 74905 (December 14, 2004), 71 FR 43112 (July 31, 2006), 71 FR 50027 (August 24, 2006), 71 FR 49418 (August 23, 2006), and 77 FR 27720 (May 11, 2012).

It should be noted that strandings related to sound exposure have not been recorded for marine mammal species in Cook Inlet. Beluga whale strandings in Cook Inlet are not uncommon; however, these events often coincide with extreme tidal fluctuations (''spring tides'') or killer whale sightings (Shelden *et al.,* 2003). For example, in August 2012, a group of Cook Inlet beluga whales stranded in the mud flats of Turnagain Arm during low tide and were able to swim free with the flood tide. No strandings or marine mammals in distress were observed during the 2D test survey conducted by Apache in March 2011 and none were reported by Cook Inlet inhabitants. Furthermore, no strandings were reported during seismic survey operations conducted under the April 2012 IHA. As a result, NMFS does not expect any marine mammals will incur serious injury or mortality in Cook Inlet or strand as a result of the proposed seismic survey.

Potential Effects From Pingers on Marine Mammals

Active acoustic sources other than the air guns have been proposed for Apache's 2013 seismic survey in Cook Inlet. The specifications for the pingers (source levels and frequency ranges) were provided in the notice of the proposed IHA (77 FR 73434, December 10, 2012). In general, the potential effects of this equipment on marine mammals are similar to those from the air guns, except the magnitude of the impacts is expected to be much less due to the lower intensity of the source (i.e., an animal would need to be within 25 m of the boat to be exposed to received levels of sound above 160 dB, which is unlikely to occur without triggering mitigation).

Potential Effects From Vessels and Vessel Noise on Marine Mammals

Vessel activity and noise associated with vessel activity will temporarily increase in the action area during Apache's seismic survey as a result of the operation of eight vessels. To minimize the effects of vessels and noise associated with vessel activity, Apache will follow NMFS' Marine Mammal Viewing Guidelines and Regulations and will alter heading or speed if a marine mammal gets too close to a vessel. In addition, vessels will be operating at slow speed (2–4 knots) when conducting surveys and in a purposeful manner to and from work sites in as direct a route as possible. Marine mammal monitoring observers and passive acoustic devices will alert vessel captains as animals are detected to ensure safe and effective measures are applied to avoid coming into direct contact with marine mammals. Therefore, NMFS neither anticipates nor authorizes takes of marine mammals from ship strikes.

Odontocetes, such as beluga whales, killer whales, and harbor porpoises, often show tolerance to vessel activity; however, they may react at long distances if they are confined by ice, shallow water, or were previously harassed by vessels (Richardson, 1995). Beluga whale response to vessel noise varies greatly from tolerance to extreme sensitivity depending on the activity of the whale and previous experience with vessels (Richardson, 1995). Reactions to vessels depends on whale activities and experience, habitat, boat type, and boat behavior (Richardson, 1995) and may include behavioral responses, such as altered headings or avoidance (Blane and Jaakson, 1994; Erbe and Farmer, 2000); fast swimming; changes in vocalizations (Lesage *et al.,* 1999; Scheifele *et al.,* 2005); and changes in dive, surfacing, and respiration patterns.

There are few data published on pinniped responses to vessel activity, and most of the information is anecdotal (Richardson, 1995). Generally, sea lions in water show tolerance to close and frequently approaching vessels and sometimes show interest in fishing

vessels. They are less tolerant when hauled out on land; however, they rarely react unless the vessel approaches within 100–200 m (330–660 ft; reviewed in Richardson, 1995).

The addition of eight vessels and noise due to vessel operations associated with the seismic survey would not be outside the present experience of marine mammals in Cook Inlet, although levels may increase locally. Given the large number of vessels in Cook Inlet and the apparent habituation to vessels by Cook Inlet beluga whales and the other marine mammals that may occur in the area, vessel activity and noise is not expected to have effects that could cause significant or long-term consequences for individual marine mammals or their populations.

Potential Effects From Aircraft Noise on Marine Mammals

Apache plans to utilize the crew helicopter or small fixed-wing aircraft to conduct aerial surveys in order to identify locations or congregations of beluga whales and other marine mammals prior to the commencement of operations. The aircraft should be used every day, but must be used for surveys near river mouths. In addition, weather and safety permitting, daily aerial surveys must be conducted when there are any seismic-related activities (including but not limited to node laying/retrieval or air gun operations) occurring north or east of a line from Tyonek across to the eastern side of Number 3 Bay of the Captain Cook State Recreation Area, Cook Inlet (roughly the southern-most point of Corps defined Region 9). Surveys are to be flown even if the air guns are not being fired. Aerial surveys will fly at an altitude of 305 m (1,000 ft) when practicable and weather conditions permit. In the event of a marine mammal sighting, aircraft will try to maintain a radial distance of 457 m (1,500 ft) from the marine mammal(s). Aircraft will avoid approaching marine mammals from head-on, flying over or passing the shadow of the aircraft over the marine mammals.

Studies on the reactions of cetaceans to aircraft show little negative response (Richardson *et al.,* 1995). In general, reactions range from sudden dives and turns and are typically found to decrease if the animals are engaged in feeding or social behavior. Whales with calves or in confined waters may show more of a response. Generally there has been little or no evidence of marine mammals responding to aircraft overflights when altitudes are at or above 1,000 ft, based on three decades of flying experience in the Arctic (NMFS, unpublished data). Based on long-term studies that have been conducted on beluga whales in Cook Inlet since 1993, NMFS expect that there will be no effects of this activity on beluga whales or other cetaceans. No change in beluga swim directions or other noticeable reactions have been observed during the Cook Inlet aerial surveys flown from 600 to 800 ft. (e.g., Rugh *et al.,* 2000). By applying the operational requirements discussed above, sound levels underwater are not expected to reach NMFS' harassment thresholds.

The majority of observations of pinnipeds reacting to aircraft noise are associated with animals hauled out on land or ice. There are very little data describing the reactions of pinnipeds in water to aircraft (Richardson *et al.,* 1995). In the presence of aircraft, pinnipeds hauled out for pupping or molting generally became alert and then rushed or slipped (when on ice) into the water. Stampedes often result from this response and may increase pup mortality due to crushing or an increase rate of pup abandonment. The greatest reactions from hauled out pinnipeds were observed when low flying aircrafts passed directly above the animal(s) (Richardson *et al.,* 1995). Although noise associated with aircraft activity could cause hauled out pinnipeds to rush into the water, there are no known haul out sites in the vicinity of the survey site.

Therefore, the operation of aircraft during the seismic survey is not expected to have effects that could cause significant or long-term consequences for individual marine mammals or their populations. To minimize the noise generated by aircraft, Apache will follow NMFS' Marine Mammal Viewing Guidelines and Regulations found at *http://www.alaskafisheries.noaa.gov/protectedresources/mmv/guide.htm.*

Land-Based Explosives

The onshore component of the seismic survey involves the underground detonation of explosive devices to acquire seismic data on land. Because underwater sound levels associated with the land-based explosives were previously unknown, in September 2011, Apache conducted a SSV study, which found that marine mammals would not be exposed to underwater sound levels that exceed the NMFS injury or harassment thresholds.

Anticipated Effects on Marine Mammal Habitat

NMFS included a detailed discussion of the potential effects of this action on marine mammal habitat, including physiological and behavioral effects on marine fish and invertebrates, in the notice of the proposed IHA (77 FR 73434, December 10, 2012). While NMFS anticipates that the specified activity may result in marine mammals avoiding certain areas due to temporary ensonification, this impact to habitat is temporary and site-specific. The main impact associated with the activity would be temporarily elevated noise levels and the associated direct effects on marine mammals.

Mitigation

In order to issue an incidental take authorization under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

To reduce the potential for disturbance from acoustic stimuli associated with the activities, Apache and/or its designees will implement the following mitigation measures for marine mammals:

(1) Operation of Mitigation Air Gun at Night

Apache proposes to conduct both daytime and nighttime operations. Nighttime operations would only be initiated if a mitigation air gun (typically the 10 in^3) has been continuously operational from the time that PSO monitoring has ceased for the day. The mitigation air gun would operate on a longer duty cycle than the full air gun arrays, firing every 30–45 seconds. Seismic activity would not ramp up from an extended shut-down (i.e., when the air gun has been down with no activity for at least 10 minutes) during nighttime operations and survey activities would be suspended until the following day because dedicated PSOs would not be on duty. At night, the vessel captain and crew would maintain lookout for marine mammals and would order the air gun(s) to be shut down if marine mammals are observed in or about to enter the established safety radii. After a shut down during night operations, seismic survey activities will be suspended until the following day when the full safety zone is visible.

(2) Safety and Disturbance Zones

NMFS mitigation or shutdown ''safety radii'' for limiting marine mammal exposure to impulse sources typically

correspond to the distances within which received sound levels are ≥180 dB_{rms} re 1 μPa for cetaceans and ≥190 dB_{rms} re 1 μPa for pinnipeds. These safety criteria are based on an assumption that SPLs received at levels lower than these will not injure these animals or impair their hearing abilities. Disturbance or behavioral effects to marine mammals from underwater sound may occur from exposure to sound at lower SPLs, at distances greater than the safety radii (Richardson *et al.,* 1995). The disturbance zone is defined as the area between the 180/190 dB threshold and the 160 dB threshold where NMFS has determined that harassment in the form of behavioral disturbance may occur.

The proposed survey would use air gun sources composed of two 2400 in^3 air guns, a single 440 in^3 air gun, and a single 10 in^3 air gun. Safety and disturbance radii for the sound levels produced by the planned air gun configurations and pinger were estimated for the 2012 IHA issued for Area 1; however, distances to the 190, 180, and 160 dB thresholds were measured in late April 2012 (see Table 1) and would be used for mitigation purposes during the seismic survey activities until the results from the 2013 SSV study are available.

TABLE 1—DISTANCES TO SOUND THRESHOLDS FOR MONITORING AND MITIGATION

Source	190 dB	180 dB	160 dB
Pinger	1 m	3 m	25 m
10 cui air gun	10 m	33 m	330 m
440 cui air gun	NA	NA	NA
2,400 cui air gun (nearshore)	380 m	1400 m	9500 m
2,400 cui air gun (offshore)	290 m	910 m	8700 m

In addition to the marine mammal monitoring radii described above, pursuant to Alaska Department of Fish and Game restrictions, there would be a 1.6 km setback of sound source points from the mouths of any anadromous streams.

Apache also plans to use dedicated vessels to deploy and retrieve the nodal recording system. Sounds produced by those vessels are not expected to exceed 180 dB (rms). Therefore, mitigation related to acoustic impacts from these activities is not required.

(3) Speed and Course Alterations

If a marine mammal is detected outside the applicable safety radius and, based on its position and the relative motion, is likely to enter the safety radius, changes of the vessel's speed and/or direct course will be considered if this does not compromise operational safety. For marine seismic surveys using large arrays, course alterations are not typically possible. However, for the smaller air gun arrays planned during the proposed site surveys, such changes may be possible. After any such speed and/or course alteration is begun, the marine mammal activities and movements relative to the survey vessel will be closely monitored to ensure that the marine mammal does not approach within the safety radius. If the mammal appears likely to enter the safety radius, further mitigative actions will be taken, including a power down or shut down of the air gun(s).

(4) Power-Downs

A power-down for mitigation purposes is the immediate reduction in the number of operating air guns such that the radii of the 190 dB rms and 180 dB rms zones are decreased to the extent that an observed marine mammal(s) are not in the applicable safety zone of the full array. During a power-down, one ''mitigation'' air gun, typically the 10 in^3, continues firing. Operation of the 10 in^3 air gun decreases the safety radii to 10 m, 33 m, and 330 m for the 190 dB, 180 dB, and 160 dB, respectively. The continued operation of one air gun is intended to (a) alert marine mammals to the presence of the survey vessel in the area, and (b) retain the option of initiating a ramp up to full operations under poor visibility conditions.

The array will be immediately powered down whenever a marine mammal is sighted approaching close to or within the applicable safety zone of the full array, but is outside the applicable safety zone of the single mitigation air gun. Likewise, if a mammal is already within the safety zone when first detected, the air guns will be powered down immediately. If a marine mammal is sighted within or about to enter the applicable safety zone of the single mitigation air gun, it too will be shut down (see following section).

Following a power-down, operation of the full air gun array would not resume until the marine mammal has cleared the safety zone. The animal would be considered to have cleared the safety zone if it:

- Is visually observed to have left the safety zone of the full array, or
- Has not been seen within the zone for 15 min in the case of pinnipeds or small odontocetes, or
- Has not been seen within the zone for 30 min in the case of large odontocetes.

(5) Shut-Downs

The operating air gun(s) will be shut down completely if a marine mammal approaches or enters the safety radius and a power-down is not practical or adequate to reduce exposure to less than 190 or 180 dB rms, as appropriate. In most cases, this means the mitigation air gun will be shut down completely if a marine mammal approaches or enters the estimated safety radius around the single 10 in^3 air gun while it is operating during a power down. Air gun activity will not resume until the marine mammal has cleared the safety radius. The animal would be considered to have cleared the safety radius as described above under power down procedures.

(6) Ramp-Ups

A ramp-up of an air gun array provides a gradual increase in sound levels, and involves a step-wise increase in the number and total volume of air guns firing until the full volume is achieved. The purpose of a ramp-up (or ''soft start'') is to ''warn'' cetaceans and pinnipeds in the vicinity of the air guns and to provide the time for them to leave the area and thus avoid any potential injury or impairment of their hearing abilities.

During the proposed seismic survey, the seismic operator will ramp up the air gun array slowly. NMFS requires the rate of ramp-up to be no more than 6 dB per 5-minute period. Ramp-up is used at the start of air gun operations, after a power- or shut-down, and after any period of greater than 10 minutes in duration without air gun operations (i.e., extended shutdown).

A full ramp-up after a shut down will not begin until there has been a

minimum of 30 minutes of observation of the safety zone by PSOs to assure that no marine mammals are present. The entire safety zone must be visible during the 30-minute lead-in to a full ramp up. If the entire safety zone is not visible, then ramp-up from a cold start cannot begin. If a marine mammal(s) is sighted within the safety zone during the 30-minute watch prior to ramp-up, ramp-up will be delayed until the marine mammal(s) is sighted outside of the safety zone or the animal(s) is not sighted for at least 15–30 minutes: 15 minutes for small odontocetes and pinnipeds (e.g. harbor porpoises, harbor seals, and Steller sea lions), or 30 minutes for large odontocetes (e.g., killer whales and beluga whales).

(7) Shut-downs for Aggregations of Whales, Harbor Porpoises, and Beluga Cow-Calf Pairs

The following additional protective measures beluga whale cow-calf pairs and aggregations of whales and harbor porpoises are required. Specifically, a 160-dB vessel monitoring zone would be established and monitored in Cook Inlet during all seismic surveys. Whenever an aggregation of beluga whales, killer whales, or harbor porpoises (five or more animals of any age/sex class), or any beluga whale cow-calf pairs are observed approaching the 160-dB safety zone around the survey operations, the survey activity would not commence or would shut down, until they are no longer present within the 160-dB safety zone of seismic surveying operations.

Additional Mitigation Measures Proposed by NMFS

In addition to the mitigation measures discussed above, NMFS requires the following protective measures:

(1) All vessels should reduce speed when within 300 yards (274 m) of whales, and those vessels capable of steering around such groups should do so. Vessels may not be operated in such a way as to separate members of a group of whales from other members of the group;

(2) Avoid multiple changes in direction and speed when within 300 yards (274 m) of whales; and

(3) When weather conditions require, such as when visibility drops, support vessels must adjust speed (increase or decrease) and direction accordingly to avoid the likelihood of injury to whales.

(4) When aggregations of five or more harbor porpoises are observed approaching the 160 dB zone around survey operations, the survey activity will not commence or will shut down, until they are no longer present within the 160 dB zone. (This was recommended in a comment from the Commission).

(5) Apache must immediately report to NMFS if 25 beluga whales are detected in the disturbance zone. If the number of detected takes is meets or exceeds the amount authorized for any marine mammal species, Apache must immediately cease survey operations involving the use of active sound sources (e.g., air guns and pingers) and notify NMFS.

(6) Apache must not operate air guns within 10 miles (16 km) of the mean higher high water (MHHW) line of the Susitna Delta (Beluga River to the Little Susitna River) between mid-April and mid-October (to avoid any effects to belugas in an important feeding and potential breeding area).

(7) Safety and weather permitting, aerial surveys shall be conducted on a daily basis when there are any seismic-related activities (including but not limited to node laying/retrieval or airgun operations) occurring north or east of a line from Tyonek across to the eastern side of Number 3 Bay of the Captain Cook State Recreation Area, Cook Inlet (roughly the southern-most point of Corps defined Region 9). Surveys are to be flown even if the air guns are not being fired.

Mitigation Measures Considered but Not Required

NMFS considered whether time/area restrictions were warranted. Mirroring a requirement in the Incidental Take Statement for the related Biological Opinion, NMFS has included an exclusion zone that extends 10 miles (16 km) from the mean higher high water (MHHW) line of the Susitna Delta (Beluga River to the Little Susitna River) to avoid impacts to beluga in an important feeding and potential breeding area. Between mid-April and mid-October, air guns may not be operated within the exclusion zone. NMFS determined that such restrictions are not necessary or practicable elsewhere in the 2013 survey area. Beluga whales remain in Cook Inlet year-round, but demonstrate seasonal movement within the Inlet; in the summer and fall, they concentrate in upper Cook Inlet's rivers and bays, but tend to disperse offshore and move to mid-Inlet in winter (Hobbs *et al.,* 2005). The available information indicates that in the winter months belugas are dispersed in deeper waters in mid-Inlet past Kalgin Island, with occasional forays into the upper inlet, including the upper ends of Knik and Turnagain Arms. Their winter distribution does not appear to be associated with river mouths, as it is during the warmer months. The spatial dispersal and diversity of winter prey are likely to influence the wider beluga winter range throughout the mid-Inlet. Apache now expects to mobilize crews and equipment for its seismic survey in February 2013, which would coincide with the time of year when belugas are dispersed offshore in the mid-Inlet and away from river mouths. In the spring, when survey operations are expected to start, beluga whales are regularly sighted in the upper Inlet beginning in late April or early May, coinciding with eulachon runs in the Susitna River and Twenty Mile River in Turnagain Arm. Therefore, NMFS believes that the timing and location of the seismic survey, with the exclusion zone around the Susitna Delta, will avoid areas and seasons that overlap with important beluga whale behavioral patterns.

NMFS also considered whether to require time area restrictions for areas identified as home ranges during August through March for 14 satellite-tracked beluga whales in Hobbs *et al.,* 2005. NMFS has determined not to require time/area restrictions for these areas within the phase 2 survey area. The areas in question within phase 2 are relatively large areas in which belugas are dispersed. In addition, data for 14 tracked belugas does not establish that belugas will not appear in other areas—particularly during the periods of the year when belugas are more dispersed in Cook Inlet. Time/area restrictions for these areas thus would not yield a material benefit for the species. Such restrictions also are not practicable given the applicant's need to survey the areas in question and the need for operational flexibility given weather conditions, real-time adjustment of operations to avoid marine mammals and other factors. The suite of other mitigation and monitoring measures will still apply.

Mitigation Conclusions

NMFS has carefully evaluated the applicant's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals;

• The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and

• The practicability of the measure for applicant implementation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered, NMFS has determined that the mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104 (a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

Summary of 2012 Monitoring and Mitigation

Marine mammal monitoring was conducted in central Cook Inlet between May 6 and September 30, 2012, which resulted in a total of 6,912 hours of observations. Monitoring was conducted from the two seismic survey vessels, a mitigation vessel, four land platforms, and an aerial platform (either a helicopter or small fixed wing aircraft). PSOs monitored from the seismic vessels, mitigation vessel, and land platforms during all daytime seismic operations. Aerial overflights were conducted 1–2 times daily over the survey area and surrounding coastline, including the major river mouths, to monitor for larger concentrations of marine mammals in and around the survey site. Passive acoustic monitoring (PAM) took place from the mitigation vessel during all night time seismic survey operations and most daytime seismic survey operations. During the entire 2012 survey season, Apache's PAM equipment yielded only six confirmed marine mammal detections, one of which was a Cook Inlet beluga whale. The single Cook Inlet beluga whale detection did not, however, result in a shutdown procedure.

Six identified species and three unidentified species of marine mammals were observed from the vessel, land, and aerial platforms between May 6 and September 30, 2012. The species observed included Cook Inlet beluga whales, harbor seals, harbor porpoises, Steller sea lion, gray whale, and California sea lions. PSOs also observed unidentified species including a large cetacean, pinniped, and marine mammal. The gray whale and California sea lion were not included in the 2012 IHA, so mitigation measures were implemented for these species to prevent unauthorized takes. There were a total of 882 sightings and an estimated 5,232 individuals (the number or individuals is typically higher than the number of sightings because a single sighting may consist of multiple individuals). Harbor seals were the most frequently observed marine mammal at 563 sightings (~3,471 individuals), followed by beluga whales with 151 sightings (~1,463 individuals), harbor porpoises with 137 (~190 individuals), and gray whales with 9 sightings (9 individuals). Steller sea lions were observed on three separate occasions (~4 individuals) and California sea lions were observed once (~2 individuals). No killer whales were observed during seismic survey operations conducted under the 2012 IHA.

A total of 88 safety zone clearing delays, 154 shut downs, 7 power downs, 23 shut downs followed by a power down, and 1 speed and course alteration occurred under the 2012 IHA. Safety zone clearing delays, shut downs, and shut downs followed by a power down occurred most frequently during harbor seal sightings (n=61, n=110, n=14, respectively), followed by harbor porpoise sightings (n=18, n=28, n=6, respectively), and then beluga whale sightings (n=5, n=6, n=3, respectively). Power downs occurred most frequently with harbor seal (n=3) and harbor porpoise (n=3) sightings. One speed and course alteration occurred in response to a beluga whale sighting. A total of 17 Level B harassment takes were detected from May 6 to September 30, 2012, including harbor porpoise (n=4) and harbor seals (n=13). No other marine mammal species were detected in the Level B harassment zone. There were no detected Level A harassment takes of either cetaceans or pinnipeds during the 2012 seismic survey.

Monitoring Measures

Apache will provide marine mammal monitoring to implement the mitigation measures that require real-time monitoring.

(1) Visual Vessel-Based Monitoring

Vessel-based monitoring for marine mammals will be done by experienced PSOs throughout the period of marine survey activities. PSOs will monitor the occurrence and behavior of marine mammals near the survey vessel during all daylight periods during operation and during most daylight periods when air gun operations are not occurring. PSO duties will include watching for and identifying marine mammals, recording their numbers, distances, and reactions to the survey operations, and documenting take.

A sufficient number of PSOs will be required onboard the survey vessel to meet the following criteria: (1) 100 percent monitoring coverage during all periods of survey operations in daylight; (2) maximum of 4 consecutive hours on watch per PSO; and (3) maximum of 12 hours of watch time per day per PSO.

PSO teams will consist of experienced field biologists. An experienced field crew leader will supervise the PSO team onboard the survey vessel. Apache currently plans to have PSOs aboard the three vessels: the two source vessels (*M/V Peregrine Falcon* and *M/V Arctic Wolf*) and one support vessel (*M/V Dreamcatcher*). Two PSOs will be on the source vessels and two PSOs will be on the support vessel to observe the safety, power down, and shut down areas. The vessel-based observers will watch for marine mammals during all periods when sound sources are in operation and for a minimum of 30 minutes prior to the start of air gun or pinger operations after an extended shut down.

Crew leaders and most other biologists serving as observers will be individuals with experience as observers during seismic surveys in Alaska or other areas in recent years.

The observer(s) will watch for marine mammals from the best available vantage point on the source and support vessels, typically the flying bridge. The observer(s) will scan systematically with the unaided eye and 7×50 reticle binoculars. Laser range finders will be available to assist with estimating distance. Personnel on the bridge would assist the observer(s) in watching for marine mammals.

All observations will be recorded in a standardized format. Data would be entered into a custom database using a notebook computer. The accuracy of the data will be verified by computerized validity data checks as the data are entered and by subsequent manual checks of the database. These procedures will allow for initial summaries of the data to be prepared during and shortly after the completion of the field program, and will facilitate transfer of the data to statistical, geographical, or other programs for

future processing and achieving. When a mammal sighting is made, the following information about the sighting will be recorded:

(A) Species, group size, age/size/sex categories (if determinable), behavior when first sighted and after initial sighting, heading (if consistent), bearing and distance from the PSO, apparent reaction to activities (e.g., none, avoidance, approach, paralleling, etc.), closest point of approach, and behavioral pace;

(B) Time, location, speed, activity of the vessel, sea state, ice cover, visibility, and sun glare; and

(C) The positions of other vessel(s) in the vicinity of the PSO location.

The ship's position, speed of support vessels, and water temperature, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables.

(2) Visual Shore-Based Monitoring

In addition to the vessel-based PSOs, Apache will utilize a shore-based station to visually monitor for marine mammals. The shore-based station will follow all safety procedures, including bear safety. The location of the shore-based station will need to be sufficiently high to observe marine mammals; the PSOs will be equipped with pedestal mounted ''big eye'' (20x110) binoculars. The shore-based PSOs will scan the area prior to, during, and after the air gun operations, and will be in contact with the vessel-based PSOs via radio to communicate sightings of marine mammals approaching or within the project area.

(3) Aerial-Based Monitoring

When survey operations occur near a river mouth, Apache will utilize the crew helicopter or a small fixed-wing aircraft to conduct aerial surveys near river mouths prior to the commencement of air gun operations in order to identify locations where beluga whales congregate. In addition, aerial surveys shall be conducted on a daily basis (weather and safety permitting) when there are any seismic-related activities (including but not limited to node laying/retrieval or air gun operations) occurring north or east of a line from Tyonek across to the eastern side of Number 3 Bay of the Captain Cook State Recreation Area, Cook Inlet (roughly the southern-most point of Corps defined Region 9). Surveys are to be flown even if the air guns are not being fired. The types of helicopters currently planned for use by Apache include a Bell 407, Bell UH1B, and ASB3. A twin-engine Islander, or similar fixed-wing aircraft, may also be used to conduct aerial surveys in lieu of helicopter. Weather and safety permitting, aerial surveys will fly at an altitude of 305 m (1,000 ft). In the event of a marine mammal sighting, aircraft will attempt to maintain a radial distance of 457 m (1,500 ft) from the marine mammal(s). Aircraft will avoid approaching marine mammals from head-on, flying over or passing the shadow of the aircraft over the marine mammal(s). By following these operational requirements, sound levels underwater are not expected to meet or exceed NMFS harassment thresholds (Richardson *et al.,* 1995; Blackwell *et al.,* 2002).

Based on data collected from Apache during its survey operations conducted under the April 2012 IHA, NMFS believes that the foregoing monitoring measures will allow Apache to identify animals nearing or entering the 160 dB zone with a reasonably high degree of effectiveness.

Reporting Measures

(1) Weekly Field Reports

During the proposed survey, the PSOs will prepare a report each day summarizing the recent results of the monitoring program. The field reports will summarize the species and numbers of marine mammals sighted. These reports will be provided to NMFS and to the survey operators on a weekly basis. At the end of each month, a summary of the weekly reports will be submitted to NMFS.

(2) Technical Report

The results of Apache's 2013 monitoring program, including estimates of ''take'' by harassment (based on presence in the 160 dB harassment zone), will be presented in the ''90-day'' and Final Technical reports. The Technical Report will include:

(a) Summaries of monitoring effort (e.g., total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(b) Analyses of the effects of various factors influencing detectability of marine mammals (e.g., sea state, number of observers, and fog/glare);

(c) Species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(d) Analyses of the effects of survey operations;

- Sighting rates of marine mammals during periods with and without seismic survey activities (and other variables that could affect detectability), such as:
- Initial sighting distances versus survey activity state;
- Closest point of approach versus survey activity state;
- Observed behaviors and types of movements versus survey activity state;
- Numbers of sightings/individuals seen versus survey activity state;
- Distribution around the source vessels versus survey activity state; and
- Estimates of take by harassment based on presence in the 160 dB disturbance zone.

(3) Comprehensive Report

Following the survey season, a comprehensive report describing the vessel-based, shore-based, and aerial-based monitoring programs will be prepared. The comprehensive report will describe the methods, results, conclusions and limitations of each of the individual data sets in detail. The report will also integrate (to the extent possible) the studies into a broad based assessment of industry activities, and other activities that occur in Cook Inlet, and their impacts on marine mammals. The report will help to establish long-term data sets that can assist with the evaluation of changes in the Cook Inlet ecosystem. The report will attempt to provide a regional synthesis of available data on industry activity in this part of Alaska that may influence marine mammal density, distribution and behavior.

(4) Notification of Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as an injury (Level A harassment), serious injury or mortality (e.g., ship-strike, gear interaction, and/or entanglement), Apache will immediately cease the specified activities and immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinators. The report will include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;

- Water depth;
- Environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities will not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with Apache to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Apache will not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Apache discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (i.e., in less than a moderate state of decomposition as described in the next paragraph), Apache will immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators. The report will include the same information identified in the paragraph above. Activities will be able to continue while NMFS reviews the circumstances of the incident. NMFS will work with Apache to determine whether modifications in the activities are appropriate.

In the event that Apache discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Apache will report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinators, within 24 hours of the discovery. Apache would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Estimated Take of Marine Mammals

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed marine survey. Anticipated impacts to marine mammals are associated with noise propagation from the sound sources (e.g., air guns and pingers) used in the seismic survey; no take is expected to result from the detonation of explosives onshore, as supported by the SSV study, or from vessel strikes.

Apache requests authorization to take five marine mammal species by Level B harassment. These five marine mammal species are: Cook Inlet beluga whale (*Delphinapterus leucas*); killer whale (*Orcinus orca*); harbor porpoise (*Phocoena phocoena*); harbor seal (*Phoca vitulina richardsi*), and Steller sea lion (*Eumetopias jubatus*).

The full suite of potential impacts to marine mammals was described in detail in the Potential Effects of the Specified Activity on Marine Mammals section found earlier in this document and in the notice of the proposed IHA (77 FR 73434, December 10, 2012). The potential effects of sound from the proposed seismic survey might include one or more of the following: tolerance; masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.* 1995). The most common and likely impact would be from behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of the animal. Hearing impairment (TTS and PTS) are highly unlikely to occur based on the required mitigation and monitoring measures that would preclude marine mammals being exposed to noise levels high enough to cause hearing impairment.

For impulse sounds, such as those produced by air gun(s) and pingers used in the seismic survey, NMFS uses a received level of 160 dB_{rms} re 1 µPa to indicate the onset of Level B harassment. However, not all animals react to sounds at this level, and many will not show strong reactions (and in some cases any reaction) until sounds are stronger. Southall *et al.* (2007) provide a severity scale for ranking observed behavioral responses of both free-ranging marine mammals and laboratory subjects to various types of anthropogenic sound (see Table 4 in Southall *et al.* (2007)). Tables 7, 9, and 11 in Southall *et al.* (2007) outline the numbers of low-frequency cetaceans, mid-frequency cetaceans, and pinnipeds in water, respectively, reported as having behavioral responses to multi-pulses in 10-dB received level increments. These tables illustrate that although some studies have found moderate responses at these levels, some show that more severe reactions did not occur until sounds were much higher than 160 dB_{rms} re 1µPa, while some also show reactions to sounds lower than 160 dB_{rms} re 1 µPa. However, Tables 9 and 11 for mid-frequency cetaceans and pinnipeds, respectively, do not report significant reactions to multiple pulse sounds below 160 dB, except one study involving whales in the Beaufort Sea—a less industrialized and sparsely populated area compared to Cook Inlet. Beluga whales in that area are not as experienced with the types and variety of sound sources as the belugas in Cook Inlet.

To estimate take by Level B harassment, Apache provided calculations for the 160-dB isopleths and then overlaid those isopleths with the density of marine mammals in the total area ensonified within those isopleths over the time of the surveys. Apache provided a full description of the methodology used to estimate takes by harassment in its IHA application (see **ADDRESSES**), which is also provided in the following sections. Following the publication of the **Federal Register** notice of the proposed IHA for Area 2, NMFS asked Apache to apply a correction factor to take estimates for beluga whales in its analysis (Hobbs *et al.,* 2000). After receiving the new information from Apache, NMFS sent the updated density estimates to beluga whale experts at NOAA's National Marine Mammal Laboratory (NMML) for their review. NMML directed NMFS to a published habitat model developed for Cook Inlet beluga whales that was not considered by Apache and provides densities throughout the inlet based on the data from aerial surveys (Goetz *et al.,* 2012). NMML agreed to conduct an analysis that would apply the habitat-based model to Apache's seismic survey for the purpose of estimating beluga whale densities and takes. The results of NMML's analysis using the habitat-based model are provided below.

Basis for Estimating ''Take by Harassment''

As stated previously, it is current NMFS policy to estimate take by Level B harassment for impulse sounds at a received level of 160 dB_{rms} re 1µPa. As

described earlier in this notice, impulsive sounds would be generated by air gun arrays that would be used to obtain geological data during the surveys. To estimate potential takes by Level B harassment in this application, as well as for mitigation radii to be implemented by PSOs, ranges to the 160 dB_{rms} re 1 μPa isopleths were estimated at three different water depths (5 m, 25 m, and 45 m) for nearshore surveys and at 80 m for channel surveys (Tables 2 and 3).

TABLE 2—DISTANCES TO SOUND THRESHOLDS FOR NEARSHORE SURVEYS

Threshold (dB re 1 μPa)	Water depth at source location (m)	Distance in the onshore direction (km)	Distance in the offshore direction (km)	Distance in the parallel to shore direction (km)
160	5	0.85	3.91	1.48
	25	4.70	6.41	6.34
	45	5.57	4.91	6.10
180	5	0.46	0.60	0.54
	25	1.06	1.07	1.42
	45	0.70	0.83	0.89
190	5	0.28	0.33	0.33
	25	0.35	0.36	0.44
	45	0.10	0.10	0.51

TABLE 3—DISTANCES TO SOUND THRESHOLDS FOR THE CHANNEL SURVEYS

Threshold (dB re 1 μPa)	Water depth at source location (m)	Distance in the broadside direction (km)	Distance in the endfire direction (km)
160	80	4.24	4.89
180	80	0.91	0.98
190	80	0.15	0.18

TABLE 4—AREAS ENSONIFIED TO 160 dB FOR NEARSHORE SURVEYS

Nearshore survey depth classification	Depth range (m)	Area ensonifed to 160 dB (km^2)
Shallow	5–21	346
Mid-Depth	21–38	458
Deep	38–54	455

The areas ensonified to the 160 dB isopleth for the nearshore survey are provided in Table 4. The area ensonifed to the 160 dB isopleth for the channel survey is 389 km^2.

The notice of the proposed IHA (77 FR 73434, December 10, 2012) describes Apache's estimated densities of marine mammals that may occur in the areas where activities are planned, and areas of water that may be ensonified by pulsed sounds to ≥160 dB. The following paragraphs provide information regarding Apache's approach to correcting the density estimates for Cook Inlet beluga whales, NMML's review of the corrected densities and recommendations, and NMFS revised estimates of beluga whale densities and take estimates based on NMML's habitat-based model.

Marine mammal densities near the planned activities in Cook Inlet were estimated from the annual aerial surveys conducted by NMFS between 2000 and 2011 for Cook Inlet beluga whales (Rugh *et al.,* 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007; Shelden *et al.,* 2008, 2009, 2010; Hobbs *et al.,* 2011). These surveys are flown in June to collect abundance data for beluga whales, but sightings of other marine mammals are also reported. Although these data are only collected in one month each year, these surveys provide the best available relatively long-term data set for sighting information in the proposed action area, but do not correct for missed whales or account for seasonal variations in distribution or habitat use of each species. To correct for missed whales, Apache applied the correction factor of 1.015 (CV= 3%) for the years 1994 to 1998 and 1.021 (CV=1%) for the years 1999 and 2000, which was applied in Hobbs *et al.* (2000). In the subsequent annual aerial survey reports (2001 to 2011), the authors state that the correction factors are within the range for 1999 and 2000. Therefore, Apache applied the correction factor of 1.021 to all of the highest number of sightings for each year and calculated the densities and takes the same as the previous IHA.

After receiving the new information from Apache, NMFS sent the updated density estimates to beluga whale experts at NMML for their review. NMML staff indicated that Apache's calculations appeared to account for both on and off effort flight hours (instead of just on-effort hours) and had not included 1,810 km of coastline. NMML attempted to correct Apache's calculations by including on-effort survey hours and 1,810 km of coastline, but the resulting take calculations for beluga whales were grossly inaccurate and unreliable. NMML staff directed NMFS to a published habitat model developed for Cook Inlet beluga whales that provides densities throughout the inlet based on the data from aerial surveys (Goetz *et al.,* 2012). Moreover, NMML staff agreed to conduct an

independent analysis that would apply the habitat-based model to Apache's seismic survey for the purpose of estimating beluga whale densities and takes. Additional information on the habitat-based model is provided in Goetz *et al.,* (2012). A summary of the habitat-based model and the results of NMML's analysis are provided below.

NMML developed a predictive habitat model from the distribution and group size of beluga whales observed between 1994 and 2008. A 2-part ''hurdle'' model (a hurdle model is a modified count model in which there are two processes, one generating the zeros and one generating the positive values) was applied to describe the physical and anthropogenic factors that influence (1) beluga presence (mixed model logistic regression) and (2) beluga count data (mixed model Poisson regression). Beluga presence was negatively associated with sources of anthropogenic disturbance and positively associated with fish availability and access to tidal flats and sandy substrates. Beluga group size was positively associated with tidal flats and proxies for seasonally available fish. Using this analysis, Goetz *et al.* (2012) produced habitat maps for beluga presence, group size, and the expected number of belugas in each 1 km^2 cell of Cook Inlet.

The habitat-based model developed by NMML uses a Geographic Information System (GIS). A GIS is a computer system capable of capturing, storing, analyzing, and displaying geographically referenced information; that is, data identified according to location. NMML created a digital representations of Apache's actual anticipated 2013 marine survey area (called a shapefile), which included a 9.5 km ''buffer'' to represent the approximate distance from the sound source to the 160 dB isopleth. This is a smaller portion of Area 2, where Apache plans on conducting operations during the 2013 survey. When NMML staff applied their model of beluga density estimates to the 2013 survey area, they estimated that at a total of 21.5 belugas could taken by Level B harassment (Figure 1). This estimate assumed a ''snap shot'' survey (i.e., that the entire survey area would be ensonified at once rather than the sum of multiple track lines). In reality, the entire area will not be completely ensonfied at once, and most of the survey will occur where beluga density is extremely low or zero based on the NMML habitat model. Calculating a take or exposure level for each transect line separately and adding those up over the survey period will likely be lower (or not significantly different) than if one assumes the entire area is ensonfied at one time, particularly since the operation will only be at the ''edges'' for a short time where the beluga densities are highest and almost all of the estimate take occurs based on NMML's calculation. For this and other reasons explained in the notice, we believe 21.5 (22) takes is a reasonable estimate for the survey.

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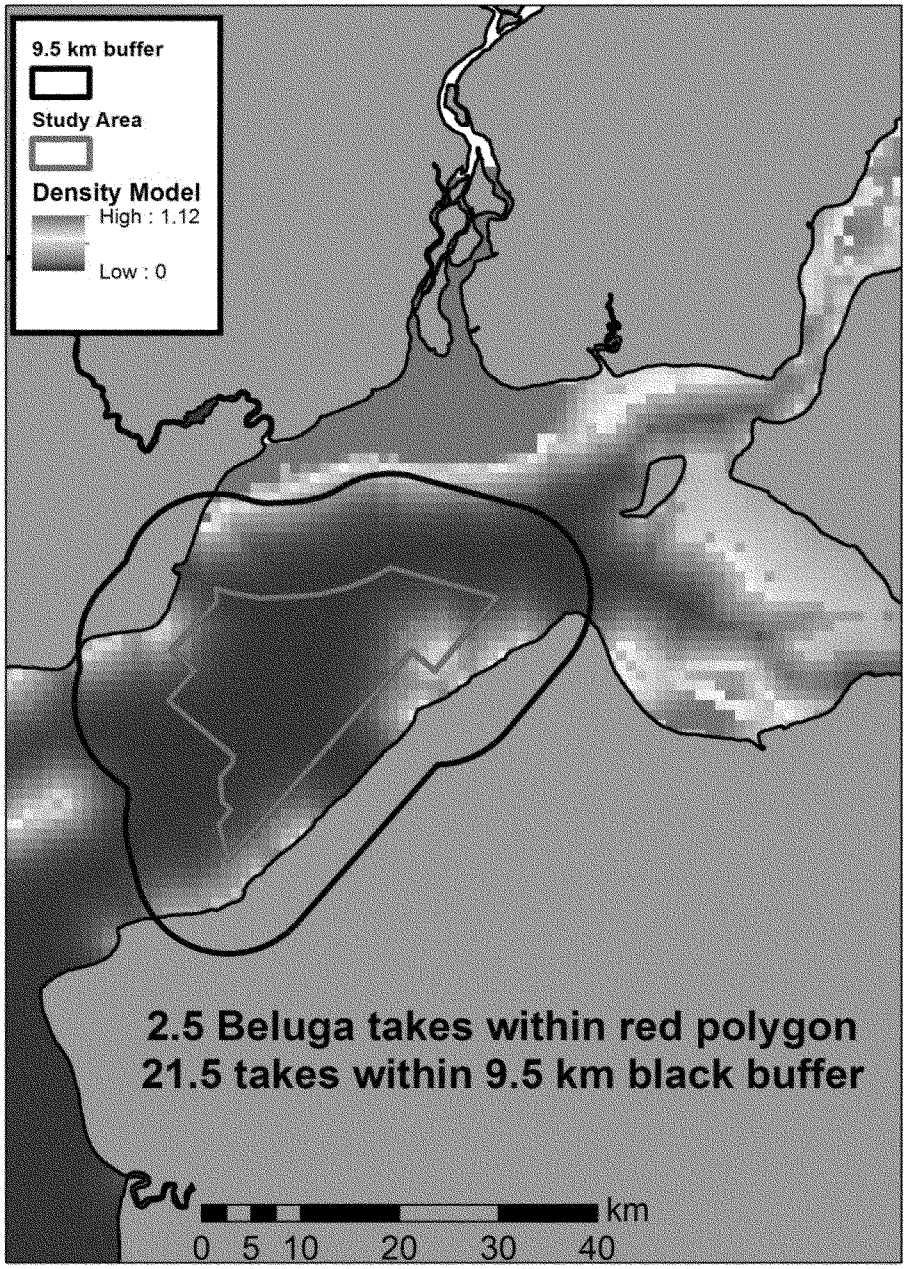

Figure 1. NMML Estimate of Beluga Density and Takes in the 2013 Survey Area

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TABLE 5—SUMMARY OF APACHE'S MARINE MAMMAL DENSITIES

Species	Density (number/km^2)	
	Maximum	Average
Harbor seal (total number observed)	0.00644	0.00317
Harbor porpoise (total number observed)	0.00179	0.00006
Killer whale (total number observed)	0.00011	0.00001
Steller sea lion (total number observed)	0.00035	0.00011

Fifteen species of marine mammals are known to occur in Cook Inlet, but Apache only request takes by Level B harassment of five (Cook Inlet beluga whales, killer whales, harbor porpoises, harbor seals, and Steller sea lions) that are most likely to be encountered during the proposed survey. Two of the five species (Cook Inlet beluga whales and western population of Steller sea lions) are listed as endangered under the ESA.

Potential Number of Takes by Harassment

This subsection provides estimates of the number of individuals potentially exposed to sound levels ≥ 160 dB_{rms} re 1 μPa during seismic survey operations. Except for Cook Inlet beluga whales, the estimates were calculated by multiplying the expected densities by the anticipated area ensonified by levels ≥ 160 dB_{rms} re 1 μPa by the number of expected days that will be subject to seismic survey activities in the action area. As discussed above, NMML's analysis multiplied beluga whale densities from their habitat-based model by the entire 2013 survey area within Area 2. According to section 2 in Apache's IHA application, a survey crew will collect seismic data 10–12 hours per day over approximately 160 days over the course of 8 to 9 months. Apache assumes that over the course of these 160 days, 100 days would be working in the offshore region and 60 days would be working in the shallow, intermediate, and deep nearshore region. Of those 60 days in the nearshore region, 20 days would be spent working in each of the three depths. It is important to note that environmental conditions (such as ice, wind, and fog) will play a significant role in the actual number of operating days; therefore, these are considered over estimates.

Except for Cook Inlet beluga whales, the number of estimated takes by Level B harassment was calculated using the following assumptions:

- The number of nearshore and shallow water survey days is 20 and daily acoustic footprint is 356 km^2.
- The number of nearshore and intermediate water depth survey days is 20 and daily acoustic footprint is 468 km^2.
- The number of nearshore and deep water depth survey days is 20 days and daily acoustic footprint is 455 km^2.
- The number of offshore survey days is 100 and daily acoustic footprint is 389 km^2.

The probability of sightings for harbor seals and Steller sea lions is higher than what is anticipated because there are no haul-out sites within the action area. These density estimates are skewed by the numbers observed in large haul outs during aerial surveys. Seals in the water usually travel in small groups or as single individuals; therefore, although Table 3 indicates an average of 204 and maximum of 414 seals to be observed, it is highly unlikely that those number of seals will actually be taken by harassment during the proposed seismic survey.

Similarly, the number of actual takes by Level B harassment of Steller sea lions is expected to be much lower than the average of seven and maximum of 22. During the NMFS aerial surveys, no Steller sea lions were observed in upper Cook Inlet. Less than five Steller sea lions have been observed by the Port of Anchorage monitoring program, and those observed have been juvenile animals (likely male). According to Apache's final report submitted under the 2012 IHA, only four Steller sea lions were observed during seismic survey operations conducted between May 6 and September 30, 2012. Therefore, Apache anticipates that there will be less than five Steller sea lions in the proposed action area during the effective period of the IHA.

The average and maximum observations for harbor porpoise and killer whales shown in Table 6 appear to be reasonable based on the NMFS aerial surveys, although the actual number of animals is expected to be low.

The NMML analysis found that a total of 21.5 Cook Inlet beluga whales in the 2013 survey area within Area 2 could be taken by Level B harassment over the course of the seismic survey. NMFS recognizes that the NMML analysis has limitations, including calculating take based on the expected project area rather than on a transect-by-transect basis, relying on data from the June beluga surveys, and not accounting for the fact that operations shut down if animals are observed within or approaching the 180 dB safety zone. However, estimating the number of belugas that actually will be exposed to 160 dB is difficult and imprecise by nature and NMFS believes that the NMML estimate is reasonably accurate. In addition, it is important to note that a combination of factors—including extensive visual and acoustic monitoring used throughout this project, particularly for sighting beluga whales approaching the area—are expected to result in the actual number of takes being no higher than (and likely, much lower than) the NMML estimates. Furthermore, based on the time it took to complete the previous year's survey, the total number of days surveying that will actually occur is likely to be much lower than the 160 days used to estimate total takes over the duration of the survey; therefore, this take estimate is likely to be conservative. Finally, NMFS will require that seismic survey operations involving the use of air guns and pingers cease if 30 beluga whales are detected in the Level B harassment zone and Apache must immediately report to NMFS if 25 belugas are detected in that zone to allow us to consider making any necessary adjustments to monitoring and mitigation. As a result, due to the actual number of days and hours Apache is likely to be operating air guns near river mouths and taking into account the monitoring and mitigation measures applicable when operating seismic survey equipment near rivers, Apache expects the actual number of takes by Level B harassment estimated for Cook Inlet beluga whales to be no higher than (and likely much lower than) the numbers provided in the NMML analysis. This conclusion is also supported by (1) the survey's avoidance of areas of high beluga density in late spring and summer when most of Apache's surveying effort is expected to occur; (2) the availability of alternative, suitable beluga habitat outside of the areas ensonified to 160 dB; (3) the beluga's tendency to avoid local noise sources when alternative, suitable habitat is available and they lack motivation to remain; and (4) the experience of Apache's survey operations in 2012, in which no observed takes of belugas occurred.

TABLE 6—PROBABILITY OF SIGHTINGS PER SPECIES FOR YEAR 2

Species	Shallow (356 km²)		Intermediate (458 km²)		Deep (455 km²)		Offshore (389 km²)		Total	
	20 days		20 days		20 days		100 days		160 days	
	max	avg	max	avg	max	avg	max	avg	max	avg
Harbor seals	45.9	22.6	59.0	29.0	58.6	28.9	250.5	123.4	414	203.8
Harbor porpoises	12.8	0.4	16.4	0.6	16.3	0.6	69.7	2.4	115.2	4.0
Killer whales	0.8	0.1	1.0	0.1	1.0	0.1	4.3	0.6	7.2	1.0
Steller sea lions	2.5	0.8	3.2	1.1	3.2	1.0	13.6	4.5	22.5	7.4

Estimated Take Conclusions

Cetaceans—Effects on cetaceans are generally expected to be restricted to avoidance of an area around the seismic survey and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment.''

The requested take numbers of individual cetaceans represent varying proportions of the populations of each species in Cook Inlet (Table 7). For Cook Inlet beluga whales, Apache requested 30 takes by Level B harassment. The authorized number of 30 beluga whale takes is based on NMML's estimate of 22 whales, which was adjusted by the average group size of approximately 8 whales reported during the 2012 seismic survey to account for the fact that these whales often travel in groups. This number is approximately 10 percent of the population of approximately 312 animals (Shelden *et al.,* 2012). NMFS will require Apache to immediately contact the Office of Protected Resources if 25 belugas are detected in either the disturbance zone or the safety zone to discuss the need to make modifications to the monitoring and mitigation. If 30 belugas are detected in the disturbance zone, seismic survey operations involving the use of air guns and pingers must cease. For other cetaceans that might occur in the vicinity of the seismic survey in Cook Inlet, the requested takes represent an even smaller percentage of their respective populations. The requested takes of 10 killer whales and 20 harbor porpoises represent 0.89 percent and 0.06 percent of their respective populations in the proposed action area.

Pinnipeds—Two pinniped species may be encountered in the proposed action area, but the harbor seal is likely to be the more abundant species in this area. The number of takes requested for individuals exposed to sounds at received levels ≥160 dB_{rms} re 1 μPa during the proposed seismic survey are as follows: harbor seals (200) and Steller sea lions (20). These numbers represent 0.69 percent and 0.12 percent of their respective populations in the proposed action area.

TABLE 7—AUTHORIZED NUMBER OF TAKES

Species	Number of authorized takes	Population abundance	Percent of population
Beluga whales	30	312	9.6
Harbor seals	200	29,175	0.69
Harbor porpoises	20	31,406	0.06
Killer whales	10	1,437	0.89
Steller sea lions	20	41,197	0.12

Determinations

Negligible Impact

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''* * * an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the takes occur.

Given the required mitigation and related monitoring, no injuries or mortalities are anticipated to occur as a result of Apache's proposed seismic survey in Cook Inlet, and none are proposed to be authorized. Additionally, animals in the area are not expected to incur hearing impairment (i.e., TTS or PTS) or non-auditory physiological effects. The small number of takes that are anticipated are expected to be limited to short-term Level B behavioral harassment. Although it is possible that some marine mammal individuals may be exposed to sounds from seismic survey activities more than once, the duration of these multi-exposures is expected to be low since both the animals and the survey vessels will be moving constantly in and out of the survey area and the seismic air guns do not operate continuously all day, but for a few hours at a time totaling about 12 hours a day.

Odontocete (including Cook Inlet beluga whales, killer whales, and harbor porpoises) reactions to seismic energy pulses are usually assumed to be limited to shorter distances from the air gun(s) than are those of mysticetes, in part because odontocete low-frequency hearing is assumed to be less sensitive than that of mysticetes. When in the Canadian Beaufort Sea in summer, belugas appear to be fairly responsive to seismic energy, with few being sighted within 6–12 mi (10–20 km) of seismic vessels during aerial surveys (Miller *et al.* 2005). However, as noted above, Cook Inlet belugas are more accustomed to anthropogenic sound than beluga whales in the Beaufort Sea. Accordingly, NMFS does not find this data determinative here. Also, due to the dispersed distribution of beluga whales in Cook Inlet during winter and the concentration of beluga whales in upper Cook Inlet from late April through early fall, belugas would likely

occur in small numbers in the phase two survey area during the survey period and few will likely be affected by the survey activity in a manner that would be considered behavioral harassment. In addition, due to the constant moving of the survey vessel, the duration of the noise exposure by cetaceans to seismic impulse would be brief. For the same reason, it is unlikely that any individual animal would be exposed to high received levels multiple times.

Taking into account the mitigation measures that are planned, effects on cetaceans are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment''. Animals are not expected to permanently abandon any area that is surveyed, and any behaviors that are interrupted during the activity are expected to resume once the activity moves away from the area. Only a very small portion of marine mammal habitat will be affected at any time, and other areas within Cook Inlet will be available for necessary biological functions. In addition, the area where the survey will take place is not known to be an important location where beluga whales congregate for feeding, calving, or nursing.

Furthermore, while the estimated amount of take is not the principal factor in NMFS' negligible impact analysis, the estimated numbers of animals potentially exposed to sound levels sufficient to cause Level B harassment are low percentages of the population sizes in Cook Inlet, as shown in Table 7.

Mitigation measures such as controlled vessel speed, dedicated marine mammal observers, non-pursuit, and shut downs or power downs when marine mammals are seen within defined ranges will further reduce short-term reactions and minimize any effects on hearing sensitivity. In all cases, the effects of the seismic survey are expected to be short-term, with no lasting biological consequence. Therefore, the exposure of cetaceans to sounds produced by the phase two seismic survey is not anticipated to have an effect on annual rates or recruitment or survival.

Some individual pinnipeds may be exposed to sound from the proposed marine surveys more than once during the time frame of the project. However, as discussed previously, due to the constant moving of the survey vessel, the probability of an individual pinniped being exposed to sound multiple times is much lower than if the source is stationary. Taking into account the mitigation measures that are planned, effects on pinnipeds are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment''. Animals are not expected to permanently abandon any area that is surveyed, and any behaviors that are interrupted during the activity are expected to resume once the activity moves out of the area. Only a very small portion of marine mammal habitat will be affected at any time, and other areas within Cook Inlet will be available for necessary biological functions. In addition, the area where the survey will take place is not known to be an important location where pinnipeds haulout. The closest known haulout site is located on Kalgin Island, which is about 22 km from the McArthur River. Therefore, NMFS has determined that the exposure of pinnipeds to sounds produced by the proposed seismic survey in Cook Inlet is not expected to result in more than Level B harassment and will not have an adverse effect on annual rates of recruitment or survival. Therefore, it is anticipated to have no more than a negligible impact on the animals.

Potential impacts to marine mammal habitat were discussed previously in this document (see the ''Anticipated Effects on Habitat'' section). Although some disturbance is possible to food sources of marine mammals, the impacts are anticipated to be minor enough as to not affect rates of recruitment or survival of marine mammals in the area. Based on the size of Cook Inlet where feeding by marine mammals occurs versus the localized area of the marine survey activities, any missed feeding opportunities in the direct project area would be minor based on the fact that other feeding areas exist elsewhere.

Small Numbers

The requested takes authorized under the MMPA represent 9.6 percent of the Cook Inlet beluga whale population of approximately 312 animals (Shelden *et al.,* 2012), 0.89 percent of the combined Alaska resident stock and Gulf of Alaska, Aleutian Island and Bering Sea stock of killer whales (1,123 residents and 314 transients), and 0.06 percent of the Gulf of Alaska stock of approximately 31,046 harbor porpoises. The take requests presented for harbor seals represent 0.69 percent of the Gulf of Alaska stock of approximately 29,175 animals. The requested takes proposed for Steller sea lions represent 0.12 percent of the western stock of approximately 41,197 animals. These take estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment if each animal is taken only once. The number of marine mammals taken is small relative to the affected species or stocks. In addition, while NMFS' small numbers determination is based on the authorized amount of take, the mitigation and monitoring measures (described previously in this document) in the IHA are expected to prevent take from exceeding the amounts authorized and likely to reduce even further any potential disturbance to marine mammals.

Conclusion

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS finds that the total taking from Apache's proposed seismic survey in Cook Inlet will have a negligible impact on the affected species or stocks. NMFS also finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

Section 101(a)(5)(D) also requires NMFS to determine that the authorization will not have an unmitigable adverse effect on the availability of marine mammal species or stocks for subsistence use. NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as: an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The subsistence harvest of marine mammals transcends the nutritional and economic values attributed to the animal and is an integral part of the cultural identity of the region's Alaska Native communities. Inedible parts of the whale provide Native artisans with materials for cultural handicrafts, and the hunting itself perpetuates Native

traditions by transmitting traditional skills and knowledge to younger generations (NOAA 2007). However, due to dramatic declines in the Cook Inlet beluga whale population, on May 21, 1999, legislation was passed to temporarily prohibit (until October 1, 2000) the taking of Cook Inlet belugas under the subsistence harvest exemption in section 101(b) of the MMPA without a cooperative agreement between NMFS and the affected Alaska Native Organizations (ANOs) (Public Law No. 106–31, section 3022, 113 Stat. 57,100). That prohibition was extended indefinitely on December 21, 2000 (Public Law No. 106–553, section 1(a)(2), 114 Stat. 2762). NMFS subsequently entered into six annual co-management agreements (2000–2003, 2005–2006) with the Cook Inlet Marine Mammal Council, an ANO representing Cook Inlet beluga hunters, which allowed for the harvest of 1–2 belugas. On October 15, 2008, NMFS published a final rule that established long-term harvest limits on the Cook Inlet beluga whales that may be taken by Alaska Natives for subsistence purposes (73 FR 60976). That rule prohibits harvest for a 5-year period (2008–2012), if the average abundance for the Cook Inlet beluga whales from the prior five years (2003–2007) is below 350 whales. The next 5-year period that could allow for a harvest (2013–2017), would require the previous five-year average (2008–2012) to be above 350 whales.

There is a low level of subsistence hunting for harbor seals in Cook Inlet. Seal hunting occurs opportunistically among Alaska Natives who may be fishing or travelling in the upper Inlet near the mouths of the Susitna River, Beluga River, and Little Susitna River. Consistent with NMFS' implementing regulations, Apache met with the Cook Inlet Marine Mammal Council (CIMMC)—a now dissolved ANO that represented Cook Inlet tribes—on March 29, 2011, to discuss the proposed activities and discuss any subsistence concerns. Apache also met with the Tyonek Native Corporation on November 9, 2010 and the Salamatof Native Corporation on November 22, 2010. Additional meetings were held with the Native Village of Tyonek, the Kenaitze Indian Tribe, and Knik Tribal Council, and the Ninilchik Traditional Council. According to Apache, during these meetings, no concerns were raised regarding potential conflict with subsistence harvest of marine mammals. Apache has identified the following features that are intended to reduce impacts to subsistence users:

- In-water seismic activities will follow mitigation procedures to minimize effects on the behavior of marine mammals and, therefore, opportunities for harvest by Alaska Native communities; and
- Regional subsistence representatives may support recording marine mammal observations along with marine mammal biologists during the monitoring programs and will be provided with annual reports.

Since the issuance of the April 2012 IHA, Apache has maintained regular and consistent communication with federally recognized Alaska Natives. The Alaska Natives, Native Corporations, and ANOs that Apache has communicated with include: the Native Village of Tyonek; Tyonek Native Corporation; Ninilchik Native Association; Ninilchik Traditional Council; Salamatof Native Association; Knikatnu; Knik Native Council; Alexander Creek; Cook Inlet Region, Inc.; the Native Village of Eklutna; Kenaitze Indian Tribe; and Seldovia Native Assocaition. Apache has shared information gathered during the seismic survey conducted under the April 2012 IHA, and plans on hosting an information exchange with Alaska Native Villages, Native Corporations, and other Non-Governmental Organizations in the spring of 2013 where data from the past year's monitoring operations would be presented.

Apache concluded, and NMFS agrees, that the size of the affected area, mitigation measures, and input from the consultations Alaska Natives should result in the proposed action having no effect on the availability of marine mammals for subsistence uses. Apache and NMFS recognize the importance of ensuring that ANOs and federally recognized tribes are informed, engaged, and involved during the permitting process and will continue to work with the ANOs and tribes to discuss operations and activities.

On February 6, 2012, in response to requests for government-to-government consultations by the CIMMC and Native Village of Eklutna, NMFS met with representatives of these two groups and a representative from the Ninilchik. We engaged in a discussion about the proposed IHA for Area 1, the MMPA process for issuing an IHA, concerns regarding Cook Inlet beluga whales, and how to achieve greater coordination with NMFS on issues that impact tribal concerns. Following the publication of the proposed IHA, NMFS contacted the local Native Villages to inform them of the availability of the **Federal Register** notice and the opening of the public comment period. During the public comment period, NMFS received letters from two tribes—the Kenaitze Indian Tribe and the Seldovia Village Tribe—which were addressed in the Comment and Responses section of this notice.

NMFS anticipates that any effects from Apache's proposed seismic survey on marine mammals, especially harbor seals and Cook Inlet beluga whales, which are or have been taken for subsistence uses, would be short-term, site specific, and limited to inconsequential changes in behavior and mild stress responses. NMFS does not anticipate that the authorized taking of affected species or stocks will reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (1) Causing the marine mammals to abandon or avoid hunting areas; (2) directly displacing subsistence users; or (3) placing physical barriers between the marine mammals and the subsistence hunters; and that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met. Therefore, NMFS has determined that the proposed regulations will not have an unmitigable adverse impact on the availability of marine mammal stocks for subsistence uses.

Endangered Species Act (ESA)

There are two marine mammal species listed as endangered under the ESA with confirmed or possible occurrence in the proposed project area: the Cook Inlet beluga whale and Steller sea lion. In addition, the proposed action would occur within designated critical habitat for the Cook Inlet beluga whales. NMFS' Permits and Conservation Division consulted with NMFS' Alaska Region Protected Resources Division under section 7 of the ESA on the issuance of the first IHA to Apache under section 101(a)(5)(D) of the MMPA, which analyzed the impacts in the other areas where Apache's has proposed to conduct seismic surveys, including Area 2. On May 21, 2012, NMFS' Alaska Region issued a revised biological opinion, which concluded that the IHA is not likely to jeopardize the continued existence of the marine mammal species (such as Cook Inlet beluga whales and Steller sea lions) affected by the seismic survey or destroy or adversely modify designated critical habitat for Cook Inlet beluga whales. Although the biological opinion considered the effects of multiple years of seismic surveying in the entire project area as a whole, see figure 6 of the biological opinion, to be cautious in light of the change in scope, NMFS' Permits and Conservation Division requested reinitiation of consultation

under Section 7 of the ESA to address these changes in the proposed action. A new Biological Opinion was issued on February 14, 2012. The Biological Opinion determined that the issuance of IHA is not likely to jeopardize the continued existence of the Cook Inlet beluga whales or the western DPS of Steller sea lions, or destroy or adversely modify Cook Inlet beluga whale critical habitat. Finally, the Biological Opinion includes an Incidental Take Statement (ITS) for Cook Inlet beluga whales and Steller sea lions. The ITS contains reasonable and prudent measures implemented by terms and conditions to minimize the effects of this take.

National Environmental Policy Act (NEPA)

NMFS prepared an Environmental Assessment to determine whether this proposed activity will have a significant effect on the human environment. This analysis was completed prior to the issuance the IHA with NMFS' issuance of a Finding of No Significant Impact (FONSI).

Authorization

NMFS has issued an incidental harassment authorization for the take of marine mammals incidental to Apache's seismic survey in Cook Inlet, Alaska, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: February 20, 2013.

Helen M. Golde,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–04202 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Submission for OMB Review; Comment Request

The United States Patent and Trademark Office (USPTO) will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: United States Patent and Trademark Office (USPTO).

Title: Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

Form Number(s): PTO/SB/93.

Agency Approval Number: 0651–0024.

Type of Request: Revision of a currently approved collection.

Burden: 138,225 hours annually.

Number of Respondents: 25,250 responses per year.

Avg. Hours per Response: The USPTO estimates that it will take the public approximately six minutes (0.10 hours) to six hours to gather the necessary information, prepare the form or sequence listing, and submit it to the USPTO.

Needs and Uses: Patent applications that contain nucleotide and/or amino acid sequence disclosures must include a copy of the sequence listing in accordance with the requirements in 37 CFR 1.821–1.825. Applicants may submit sequence listings for both U.S. and international patent applications. The USPTO uses the sequence listings during the examination process to determine the patentability of the associated patent application. Sequence listings are also disclosed as part of the published patent application or issued patent. Applicants use sequence data when preparing biotechnology patent applications and may also search sequence listings after publication.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Nicholas A. Fraser, email:

Nicholas_A._Fraser@omb.eop.gov.

Once submitted, the request will be publicly available in electronic format through the Information Collection Review page at *www.reginfo.gov.*

Paper copies can be obtained by:

• *Email:*

InformationCollection@uspto.gov. Include ''0651–0024 copy request'' in the subject line of the message.

• *Mail:* Susan K. Fawcett, Records Officer, Office of the Chief Information Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Written comments and recommendations for the proposed information collection should be sent on or before March 27, 2013 to Nicholas A. Fraser, OMB Desk Officer, via email to *Nicholas_A._Fraser@omb.eop.gov,* or by fax to 202–395–5167, marked to the attention of Nicholas A. Fraser.

Dated: February 20, 2013.

Susan K. Fawcett,

Records Officer, USPTO, Office of the Chief Information Officer.

[FR Doc. 2013–04200 Filed 2–22–13; 8:45 am]

BILLING CODE 3510–16–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled National Service Trust Enrollment Form and National Service Trust Exit Form for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Bruce Kellogg, at (202) 606–6954 or email to *bkellogg@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register**:

(1) *By fax to:* (202) 395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) *By email to: smar@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

• Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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;

• Propose ways to enhance the quality, utility, and clarity of the information to be collected; and

• Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

Comments

A 60-day public comment Notice was published in the **Federal Register** on Wednesday, October 31, 2012. This comment period ended December 30, 2012. No public comments were received from this Notice.

Description: CNCS is seeking approval of the Enrollment Form, which is used by AmeriCorps members and program staff to enroll in the National Service Trust. The Exit Form is used by AmeriCorps members and program staff to document the completion of their term of service. This information is also collected electronically.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: National Service Trust Enrollment Form and National Service Trust Exit Form.

OMB Number: 3045–0006 (Enrollment) and 3045–0015 (Exit).

Agency Number: None.

Affected Public: AmeriCorps members and program staff.

Total Respondents: 81,000 (Enrollments) and 79,000 (Exits).

Frequency: Once per form per term of service.

Average Time per Response: 10 minutes per form.

Estimated Total Burden Hours: 13,500 hours (Enrollment) and 13,166.67 (Exit).

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: February 19, 2013.

Maggie Taylor-Coates,

Chief, Trust Operations.

[FR Doc. 2013–04146 Filed 2–22–13; 8:45 am]

BILLING CODE 6050–$$–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2013–OS–0029]

Submission for OMB Review; Comment Request

AGENCY: Department of Defense (DoD), DoD Chief Information Officer (DoD CIO).

ACTION: Notice.

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 (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by March 27, 2013.

Title, Associated Form and OMB Number: Information Assurance Scholarship Program; OMB Control Number 0704–0486.

Type of Request: Extension.

Number of Respondents: 337.

Responses per Respondent: 1.

Annual Responses: 337.

Average Burden per Response: 5.852 hours.

Annual Burden Hours: 1,972 hours.

Needs and Uses: The National Security Agency (NSA) is the Executive Administrator of the DoD Information Assurance Scholarship Program (IASP), serving on behalf of DoD Chief Information Officer. Those who wish to participate in the DoD IASP Recruitment program must complete and submit an application package through their college or university to NSA. Centers of Academic Excellence in Information Assurance Education and Research (CAEs) interested in applying for capacity-building grants must complete and submit a written proposal, and all colleges and universities subsequently receiving grants must provide documentation on how the grant funding was utilized and the resulting accomplishments. Without this written documentation detailing scholarship applicants' credentials, grant proposals, and grant execution accomplishments, the DoD has no means of judging the quality of applicants to the program or collecting information regarding program performance.

Affected Public: ''Individuals or households,'' specifically college students at institutions designated as CAEs who are interested in, and qualify to apply for a scholarship; CAEs interested in submitting proposals for capacity-building grants, and faculty advisors (Principal Investigators).

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. John Kraemer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Kraemer at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket 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 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: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD Information Management Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: February 20, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–04199 Filed 2–22–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

Accelerated Payments to Small Business Subcontractors

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice.

SUMMARY: DoD has discontinued its temporary practice of providing accelerated payments to all contractors.

DATES: *Effective date:* February 25, 2013.

FOR FURTHER INFORMATION CONTACT: Ms. Lee Renna, telephone 571–372–6095.

SUPPLEMENTARY INFORMATION:

A. Background

DoD provided notice in the **Federal Register** at 77 FR 63298, on October 16, 2012, that it had taken steps to accelerate payments to all DoD prime contractors, in order to implement the temporary policy established in OMB Memorandum M–12–16, *Providing Prompt Payment to Small Business* Subcontractors (July 11, 2012).

DoD has now discontinued the temporary practice of accelerating payments to all prime contractors. This action does not affect DoD's policy to assist small business prime contractors by paying them as quickly as possible after receipt of an invoice and all proper documentation, while also maintaining necessary DoD internal controls. The Department plans to continue phased implementation of the policy at Defense Federal Acquisition Regulation Supplement 232.903 and 232.906.

Authority: 41 U.S.C. 1303.

Manuel Quinones,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2013–04394 Filed 2–22–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

Intrepid Robotics, Inc.

AGENCY: Office of the General Counsel, Department of Energy.

ACTION: Notice of intent to grant exclusive patent license.

SUMMARY: Notice is hereby given to an intent to grant to Intrepid Robotics, Inc., of Houston, Texas, an exclusive license to practice the inventions described in U.S. Patent No. 8,122,780, entitled ''Explosion Proof Vehicle for Tank Inspection''. The invention is owned by the United States of America, as represented by the U.S. Department of Energy (DOE).

DATES: Written comments or nonexclusive license applications are to be received at the address listed below no later than March 27, 2013.

ADDRESSES: Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: John T. Lucas, Office of the Assistant General Counsel for Technology Transfer and Intellectual Property, U.S. Department of Energy, Forrestal Building, Room 6F–067, 1000 Independence Ave. SW., Washington, DC 20585; Telephone (202) 586–2939.

SUPPLEMENTARY INFORMATION: 35 U.S.C. 209 provides federal agencies with authority to grant exclusive licenses in federally-owned inventions, if, among other things, the agency finds that the public will be served by the granting of the license. The statute requires that no exclusive license may be granted unless public notice of the intent to grant the license has been provided, and the agency has considered all comments received in response to that public notice, before the end of the comment period.

Intrepid Robotics, Inc., of Houston, Texas has applied for an exclusive license to practice the inventions embodied in U.S. Patent No. 8,122,780 and has plans for commercialization of the inventions.

The exclusive license will be subject to a license and other rights retained by the U.S. Government, and other terms and conditions to be negotiated. DOE intends to negotiate to grant the license, unless, within 30 days of this notice, the Assistant General Counsel for Technology Transfer and Intellectual Property, Department of Energy, Washington, DC 20585, receives in writing any of the following, together with supporting documents:

(i) A statement from any person setting forth reason why it would not be in the best interests of the United States to grant the proposed license; or

(ii) An application for a nonexclusive license to the invention in which applicant states that it already has brought the invention to practical application or is likely to bring the invention to practical application expeditiously.

The Department will review all timely written responses to this notice, and will proceed with negotiating the license if, after consideration of written responses to this notice, a finding is made that the license is in the public interest.

Issued in Washington, DC, on February 15, 2013.

John T. Lucas,

Assistant General Counsel for Technology Transfer and Intellectual Property.

[FR Doc. 2013–04299 Filed 2–22–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge Reservation. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register.**

DATES: Wednesday, March 13, 2013, 6:00 p.m.

ADDRESSES: Department of Energy Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37830.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Federal Coordinator, Department of Energy Oak Ridge Operations Office, P.O. Box 2001, EM–90, Oak Ridge, TN 37831. Phone (865) 241–3315; Fax (865) 576–0956 or email: *noemp@oro.doe.gov* or check the Web site at *www.oakridge.doe.gov/em/ssab.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer
- Comments from the DOE, Tennessee Department of Environment and Conservation, and Environmental Protection Agency Liaisons
- Public Comment Period
- Presentation on EM's Approach to Contracting and Transfer and Development of Properties at East Tennessee Technology Park
- Additions/Approval of Agenda
- Motions/Approval of February 13, 2013 Meeting Minutes
- Status of Recommendations with DOE
- Committee Reports
- Federal Coordinator Report
- Adjourn

Public Participation: The EM SSAB, Oak Ridge, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Melyssa P. Noe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to the agenda item should contact Melyssa P. Noe at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Melyssa P. Noe at the address and phone number listed above. Minutes will also be available at the following Web site: *http://www.oakridge.doe.gov/em/ssab/minutes.htm.*

Issued at Washington, DC, on February 15, 2013.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2013–04238 Filed 2–22–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho National Laboratory

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho National Laboratory. The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register.**

DATES: Wednesday, March 13, 2013, 8:00 a.m.–5:00 p.m. The opportunities for public comment will be at 10:00 a.m. and 3:00 p.m. These times are subject to change; please contact the Federal Coordinator (below) for confirmation of times prior to the meeting.

ADDRESSES: Hilton Garden Inn, 700 Lindsay Boulevard, Idaho Falls, Idaho 83402.

FOR FURTHER INFORMATION CONTACT: Robert L. Pence, Federal Coordinator, Department of Energy, Idaho Operations Office, 1955 Fremont Avenue, MS–1203, Idaho Falls, Idaho 83415. Phone (208) 526–6518; Fax (208) 526–8789 or email: *pencerl@id.doe.gov* or visit the Board's Internet home page at: *http://inlcab.energy.gov/.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Topics (agenda topics may change up to the day of the meeting; please contact Robert L. Pence for the most current agenda):

- Recent Public Involvement
- Idaho Cleanup Project Progress to Date
- Sodium Bearing Waste Treatment Plant Update
- DOE-Idaho Review of Blue Ribbon Commission Recommendations
- Overview of RCRA Process—Public Involvement Opportunity
- Rad 101—Personal Protection Equipment
- Overview of Integrated Safety Management System

Public Participation: The EM SSAB, Idaho National Laboratory, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Robert L. Pence at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral presentations pertaining to agenda items should contact Robert L. Pence at the address or telephone number listed above. The request must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Robert L. Pence, Federal Coordinator, at the address and phone number listed above. Minutes will also be available at the following Web site: *http://inlcab.energy.gov/pages/meetings.php.*

Issued at Washington, DC, on February 19, 2013.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2013–04235 Filed 2–22–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC13–11–000]

Commission Information Collection Activities (FERC–539); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–539, Gas Pipeline Certificates: Import/Export Related.

DATES: Comments on the collection of information are due April 26, 2013.

ADDRESSES: You may submit comments (identified by Docket No. IC13–11–000) by either of the following methods:

- *eFiling at Commission's Web Site: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Hand Delivery/Courier:* Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: Gas Pipeline Certificates: Import/Export Related.

OMB Control No.: 1902–0062.

Type of Request: Three-year extension of the FERC–539 information collection requirements with no changes to the current reporting requirements.

Abstract: Section 3 of the Natural Gas Act (NGA)[1] provides, in part, that ''* * * no person shall export any natural gas from the United States to a foreign country or import any natural gas from a foreign country without first having secured an order from the Commission authorizing it to do so.'' The 1992 amendments to Section 3 of the NGA concern importation or exportation from/to a nation which has a free trade agreement with the United States and requires that such importation or exportation: (1) Shall be deemed to be a ''first sale'' (i.e. not a sale for a resale) and (2) shall be deemed to be consistent with the public interest. Applications for such importation or exportation should be granted without modification or delay.

Type of Respondents: Facilities proposing to import or export natural gas.

Estimate of Annual Burden:[2] The Commission estimates the total Public

[1] 15 U.S.C. 717–717w.

[2] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

Reporting Burden for this information collection as:

FERC–539: GAS PIPELINE CERTIFICATES: IMPORT/EXPORT RELATED

Number of respondents	Number of responses per respondent	Total number of responses	Average burden hours per response	Estimated total annual burden
(A)	(B)	(A) × (B) = (C)	(D)	(C) × (D)
7	1	7	12	84

The total estimated annual cost burden to respondents is $5,880[84 hours * $70/hour [3] = $5,880].

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: February 19, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–04272 Filed 2–22–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 9202–179]

Upper Yampa Water Conservancy District; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Types of Application:* Non-project use of project lands and waters.

b. *Project No.:* 9202–179.

c. *Date Filed:* January 22, 2013, and supplemented February 7, 2013.

d. *Applicant:* Upper Yampa Water Conservancy District.

e. *Name of Project:* Stagecoach Hydropower Project.

f. *Location:* Yampa River, in Routt County, Colorado.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Kevin McBride, District Manager, Upper Yampa Water Conservancy District, 3310 Clear Water Trail, P.O. Box 775529, Steamboat Springs, CO 80477, (970) 871–1035.

i. *FERC Contact:* Mr. Mark Carter, (678) 245–3083, *mark.carter@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* 30 days from the issuance date of this notice by the Commission.

All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* or toll free at 1–866–208–3676, or for TTY, (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may be paper-filed. To paper-file, mail an original and seven copies to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P–9202–179) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Application:* The licensee proposes to allow commercial development of the site with a marina and restaurant operation that would have elements located both inside and outside the project boundary. The following facilities would be located within the project boundary: (1) Boat docks; (2) a sand beach area for swimming; (3) miscellaneous landscaping improvements, including an event lawn; and (4) four walkways to the proposed docks, swimming area, and event lawn. The proposed dock facilities would consist of two floating docks accommodating a maximum of 40 watercraft per dock, and each dock would be constructed in separate phases.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field (P–9202) to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, and .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's

[3] Average salary (per hour) plus benefits per full-time equivalent employee.

Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by a proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: February 19, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–04274 Filed 2–22–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 9202–178]

Upper Yampa Water Conservancy District; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Types of Application:* Request to amend the project boundary, relocate portions of a recreational trail, and relocate a flowage area.

b. *Project No.:* 9202–178.

c. *Date Filed:* January 22, 2013, and supplemented February 7, 2013.

d. *Applicant:* Upper Yampa Water Conservancy District.

e. *Name of Project:* Stagecoach Hydropower Project.

f. *Location:* Yampa River, in Routt County, Colorado.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Kevin McBride, District Manager, Upper Yampa Water Conservancy District, 3310 Clear Water Trail, P.O. Box 775529, Steamboat Springs, CO 80477, (970) 871–1035.

i. *FERC Contact:* Mr. Jeremy Jessup, (202) 502–6779, *Jeremy.Jessup@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests, is 30 days from the issuance date of this notice by the Commission. All documents may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov/docs-filing/efiling.asp.* If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and seven copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments.

Please include the project number (P–9202–178) on any comments, motions, or recommendations filed.

k. *Description of Request:* The applicant proposes to relocate a recreation trail, modify the flowage area by adding approximately 3,500 cubic yards of fill in the project boundary, and amend the project boundary to exclude portions of the filled-in area and include the relocated recreation trail. The applicant is requesting to remove approximately 3.4 acres from within the project boundary, relocate approximately 1,550 linear feet of the recreation trail, and impact approximately 0.04 acres of the reservoir's 100-year flood plain area. The lands that the applicant proposes to remove from inside the project boundary will no longer be necessary for project purposes after the relocation of the recreation trail and modification of the flowage area. The applicant intends to convey the lands to a local developer for commercial site development once they are removed from the project boundary.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title ''COMMENTS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All motions to intervene, protests, or comments should relate to project works which are the subject of the application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in

accordance with 18 CFR 4.34(b) and 385.2010.

Dated: February 19, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–04273 Filed 2–22–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL13–47–000]

FirstEnergy Solutions Corp., Allegheny Energy Supply Company, LLC v. PJM Interconnection, L.L.C.; Notice of Complaint

Take notice that on February 15, 2013, pursuant to section 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824(e) and 825(e), FirstEnergy Solutions Corp. and Allegheny Energy Supply Company, LLC (Complainants) filed a formal complaint against PJM Interconnection, L.L.C. (Respondent) alleging that, the provisions of the Respondent's Open Access Transmission Tariff and Operating Agreement as related to the rules governing the funding of Financial Transmission Rights are unjust, unreasonable, unduly discriminatory and preferential.

Complainants certify that copies of the complaint were served on the contact of the Respondent as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 7, 2013.

Dated: February 19, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–04275 Filed 2–22–13; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RC13–4–000]

South Louisiana Electric Cooperative Association; Notice of Filing

Take notice that on January 29, 2013, South Louisiana Electric Cooperative Association (SLECA) filed an appeal of the January 16, 2013 Decision of North American Electric Reliability Corporation (NERC) Board of Trustees Compliance Committee denying SLECA's request to be removed from the Compliance Registry. In addition, on February 14, 2013 SLECA filed a supplement in support of its January 29, 2013 appeal.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 18, 2013.

Dated: February 19, 2013.

Kimberly D. Bose,

Secretary.

[FR Doc. 2013–04271 Filed 2–22–13; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information burden

for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before April 26, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Judith B. Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0986.

Title: Competitive Carrier Line Count Report and Self-Certification as a Rural Carrier.

Form Numbers: FCC Form 525 and new FCC Form 481.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 8,690 respondents; 8,804 responses.

Estimated Time per Response: .5 hours to 100 hours.

Frequency of Response: On occasion, quarterly and annual reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 154(i) and (j), 205, 221(c), 254, 303(r), 403, 410, and 1302 of the Communications Act of 1934, as amended.

Total Annual Burden: 272,017 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: We note that USAC must preserve the confidentiality of all data obtained from respondents and contributors to the universal service support program mechanism; must not use the data except for purposes of administering the universal service support program; and must not disclose data in company-specific form unless directed to do so by the Commission.

Needs and Uses: The Commission will submit this information collection after this comment period to obtain the full, three year clearance from the Office of Management and Budget (OMB). The Commission is requesting approval for a revision.

There are no changes to the existing FCC Form 525. However, the Commission is requesting OMB approval for a new FCC Form 481, Annual Reporting Form for High-Cost Recipients and other new and modified information collection requirements.

In November 2011, the Commission adopted an order reforming its high-cost universal service support mechanisms. Connect America Fund; A National Broadband Plan for Our Future; Establish Just and Reasonable Rates for Local Exchange Carriers; High-Cost Universal Service Support; Developing a Unified Intercarrier Compensation Regime; Federal-State Joint Board on Universal Service; Lifeline and Link-Up; Universal Service Reform—Mobility Fund, WC Docket Nos. 10–90, 07–135, 05–337, 03–109; GN Docket No. 09–51; CC Docket Nos. 01–92, 96–45; WT Docket No. 10–208, FCC 11–161, Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011) (USF/ICC Transformation Order); see also Connect America Fund et al., WC Docket No. 10–90 et al., Third Order on Reconsideration, 27 FCC Rcd 5622 (2012); Connect America Fund et al., WC Docket No. 10–90 et al., Order, 27 FCC Rcd 605 (Wireline Comp. Bur. 2012); Connect America Fund et al., WC Docket No. 10–90 et al., Fifth Order on Reconsideration, 27 FCC Rcd 14549 (2012).

In its March 2012 supporting statement which was submitted and approved by OMB, the Commission implemented some of the information collections required by this order, but also noted that at a later date it planned to submit additional revisions or new collections for OMB review to address other reforms adopted in the order. This revision addresses those additional requirements.

The Order provides: (1) Requires that any carrier receiving Connect America support to file a five-year service quality improvement plan by July 1, 2013, and to file annually thereafter a progress report on its plan; (2) Seeks to ensure parity between urban and rural areas for broadband and voice rates. To accomplish this, the order adopts a rule requiring carriers to report pricing information for both voice and broadband offerings; (3) Requires that a support recipient report the holding company, operating companies, affiliates, and any branding (a ''dba'' or ''doing-business-as company'' or brand designation), for each such entity by Study Area Codes; (4) ETCs are required to submit a self-certification that the pricing of their voice services is no more than two standard deviations above the national average urban rate for voice services; (5) ETCs are required to submit information and data required by 47 CFR section 54.313(a)(1)–(7) separately broken out for both voice and broadband service; (6) recipients of high-cost support that serve Tribal lands must report on their Tribal engagement; (7) Recipients of frozen high-cost support must annually certify that increasing levels of support have been used to achieve the goal of universal availability of voice and broadband; (8) All price cap carriers that receive support pursuant to 47 CFR section 54.304, to offset reductions in access charges, must use such support to build and operate broadband-capable networks used to offer the provider's own retail service in areas substantially unserved by an unsubsidized competitor; (9) Within three years of the implementation of Phase II, funding recipients must certify that the company is providing broadband service to 85% of its supported locations at actual speeds of at least 4 Mbps downstream and 1 Mbps upstream, with latency suitable for real-time applications, including Voice over Internet Protocol, and usage capacity that is reasonably comparable to comparable offerings in urban areas. Within five years of the implementation of Phase II, recipients must certify that the company is providing broadband service to 100% of its supported locations at actual speeds of at least 4 Mbps downstream and 1 Mbps upstream, and a percentage of supported locations, as specified by the Wireline Competition Bureau, at actual speeds of at least 6 Mbps downstream and 1.5 Mbps upstream, with latency suitable for real-time applications, including Voice over Internet Protocol, and usage capacity that is reasonably comparable to comparable offerings in urban areas; (10) Requires a progress report on the company's five-year service quality plan; (11) Rate-of-return carriers are required to provide broadband service upon reasonable request; (12) Privately held rate-of-return carriers that receive high-cost support must submit a various forms of financial statements. Those companies that borrow funds from the Rural Utilities Service (RUS) must submit a

copy of their RUS Operating Report for Telecommunications Borrowers; (13) Recognizes that satellite backhaul may limit the performance of broadband networks as compared to terrestrial backhaul, thus carriers compelled to rely exclusively on satellite backhaul in their study area must certify that no terrestrial backhaul options exist; (14) All incumbent local exchange carrier recipients of high-cost support must already report all of their rates for residential local service for all portions of their service area, as well as state fees (state subscriber line charges, state universal service fees and mandatory extended area service charges), to the extent the sum of those rates and fees are below the rate floor, and the number of lines for each rate specified.

OMB Control Number: 3060–1030.

Title: Service Rules for Advance Wireless Services (AWS) in the 1.7 GHz and 2.1 GHz.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, Federal Government, and state, local or tribal government.

Number of Respondents: 979 respondents; 1,625 responses.

Estimated Time per Response: .25 hours to 5 hours.

Frequency of Response: On occasion, annual and every 10 year reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 151, 152, 154(i), 201, 301, 302, 303(f), 303(g), 303(r), 307, 308, 309, 310, 316, 319, 324, 332, and 333 of the Communications Act of 1934, as amended; and the Commercial Spectrum Enhancement Act (CSEA), Public Law 108–494, 118 Stat. 3896, 3992 (2004).

Total Annual Burden: 32,384 hours.

Total Annual Cost: $581,800.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: There is no need for confidentiality except as follows: some relocators that seek reimbursement through the FCC cost-sharing plan administered by the clearinghouses will be required to retain records for more than three years, as will the clearinghouses themselves.

Needs and Uses: The Commission will submit this information collection after this comment period to obtain the full, three year clearance from the Office of Management and Budget (OMB). The Commission is requesting OMB approval for a revision.

The Commission in the revisions proposed in the AWS–4 *NPRM,* FCC 12–32, which was submitted for OMB approval, proposed terrestrial service, technical, assignment and licensing rules for the 2000–2020 MHz and 2180–2200 MHz spectrum bands. These proposed rules were designed to provide for flexible use of this spectrum, to encourage innovation and investment in mobile broadband, and to provide a stable regulatory environment in which broadband deployment could develop. The AWS–4 *NPRM* proposed terrestrial service rules for these spectrum bands that would generally follow the Commission's Part 27 rules, which apply to flexible use services (such as AWS–1), modified as necessary to account for issues unique to the 2000–2020 MHz and 2180–2200 MHz bands. The proposals in the AWS–4 *NPRM* included band-specific buildout, renewal, and discontinuance of service criteria. Given the proximity of these spectrum bands to spectrum bands previously identified as Advanced Wireless Services (AWS), the *NPRM* referred to these spectrum bands as ''AWS–4'' or ''AWS–4 spectrum''. The AWS–4 *NPRM* proposed to expand spectrum available for AWS, which the Commission first adopted in theAWS–1 *Report and Order.*

For this revision, subject to OMB approval, the Commission in the AWS–4 *Report and Order,* FCC 12–151, adopts flexible use rules for 40 megahertz of spectrum in the 2 GHz band (2000–2020 MHz and 2180–2200 MHz) that would increase the nation's supply of spectrum for mobile broadband. We adopt AWS–4 terrestrial service, technical, and licensing rules that generally follow the Commission's Part 27 flexible use rules, modified as necessary to account for issues unique to the AWS–4 bands.

Recordkeeping, reporting and third party disclosure requirements associated with the items listed in paragraph one of the supporting statement that is submitted to OMB for approval, will be used by incumbent licensees and new entrants to negotiate relocation agreements and to coordinate operations to avoid interference. The information will also be used by the clearinghouses to maintain a national database, determine reimbursement obligations of entrants pursuant to the Commission's rules, and notify such entrants of their reimbursement obligations. Additionally, the information will be used to facilitate dispute resolution and for FCC oversight of the clearinghouses and the cost-sharing plan.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–04167 Filed 2–22–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: The Federal Communications Commission (FCC), as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act (PRA) of 1995. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid control number. Comments are requested concerning whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written comments should be submitted on or before March 27, 2013. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should

advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via fax 202–395–5167, or via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email PRA@fcc.gov and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0748.

Title: Section 64.104, 64.1509, 64.1510 Pay-Per-Call and Other Information Services.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 5,125 respondents; 5,175 responses.

Estimated Time per Response: 2 to 260 hours.

Frequency of Response: Annual and on occasion reporting requirements; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority(s) for the information collection are found at 47 U.S.C. 228(c)(7)-(10); Public Law 192–556, 106 stat. 4181 (1992), codified at 47 U.S.C. 228 (The Telephone Disclosure and Dispute Resolution Act of 1992).

Total Annual Burden: 47,750 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: 47 CFR 64.1504 of the Commission's rules incorporates the requirements of Sections 228(c)(7)-(10) of the Communications Act restricting the manner in which toll-free numbers may be used to charge telephone subscribers for information services. Common carriers may not charge a calling party for information conveyed on a toll-free number call, unless the calling party: (1) Has executed a written agreement that specifies the material terms and conditions under which the information is provided, or (2) pays for the information by means of a prepaid account, credit, debit, charge, or calling card and the information service provider gives the calling party an introductory message disclosing the cost and other terms and conditions for the service. The disclosure requirements are intended to ensure that consumers know when charges will be levied for calls to toll-free numbers and are able to obtain information necessary to make informed choices about whether to purchase toll-free information services.

47 CFR 64.1509 of the Commission rules incorporates the requirements of 47 U.S.C. (c)(2) and 228 (d)(2)-(3) of the Communications Act. Common carriers that assign telephone numbers to pay-per-call services must disclose to all interested parties, upon request, a list of all assigned pay-per-call numbers. For each assigned number, carriers must also make available: (1) A description of the pay-per-call services; (2) the total cost per minute or other fees associated with the service; and (3) the service provider's name, business address, and telephone number. In addition, carriers handling pay-per-call services must establish a toll-free number that consumers may call to receive information about pay-per-call services. Finally, the Commission requires carriers to provide statements of pay-per-call rights and responsibilities to new telephone subscribers at the time service is established and, although not required by statute, to all subscribers annually.

Under 47 CFR 64.1510 of the Commission's rules, telephone bills containing charges for interstate pay-per-call and other information services must include information detailing consumers' rights and responsibilities with respect to these charges. Specifically, telephone bills carrying pay-per-call charges must include a consumer notification stating that: (1) The charges are for non-communication services; (2) local and long distance telephone services may not be disconnected for failure to pay per-call charges; (3) pay-per-call (900 number) blocking is available upon request; and (4) access to pay-per-call services may be involuntarily blocked for failure to pay per-call charges. In addition, each call billed must show the type of services, the amount of the charge, and the date, time, and duration of the call. Finally, the bill must display a toll-free number which subscribers may call to obtain information about pay-per-call services. Similar billing disclosure requirements apply to charges for information services either billed to subscribers on a collect basis or accessed by subscribers through a toll-free number. The billing disclosure requirements are intended to ensure that telephone subscribers billed for pay-per-call or other information services can understand the charges levied and are informed of their rights and responsibilities with respect to payment of such charges.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–04165 Filed 2–22–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice; request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of

information technology; and ways to further reduce the information burden for small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before April 26, 2013. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Submit your PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via Internet at *Nicholas_A._Fraser@omb.eop.gov* and to Judith B.Herman, Federal Communications Commission, via the Internet at *Judith-b.herman@fcc.gov.* To submit your PRA comments by email send them to: *PRA@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1127.

Title: First Responder Emergency Contact Information in the Universal Licensing System (ULS).

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 13,310 respondents; 13,310 responses.

Estimated Time per Response: .25 hours.

Frequency of Response: On occasion reporting requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. section 4(i) and 154(i).

Total Annual Burden: 3,327 hours.

Total Annual Cost: N/A.

Privacy Impact Assessment: N/A.

Nature and Extent of Confidentiality: To protect the identities and locations of key first responder communications personnel, the Commission will treat emergency contact information submitted into the Universal Licensing System (ULS), pursuant to the Public Notice the Bureau released in 2009, as confidential and will not make such information publicly available. The contact information submitted into ULS by public safety licensees and non-public safety licensees designated as emergency first responders will be available only to Commission staff. Interested licensees should file their operational point of contact information in ULS in the form of a confidential pleading.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) for approval of an extension request (no change in the public reporting requirement). The Commission is reporting a 33,274 hour reduction in burden which is due to fewer respondents and responses. The Commission's Public Safety and Homeland Security Bureau (Bureau) enhanced the existing ULS to collect operational point of contact information from public safety licensees designated as emergency first responders responsible for coordinating with state, county and local authorities during times of emergency. The process of procuring and maintaining spectrum using the ULS remains intact and requires no additional training for licensees to participate in this voluntary collection. This enhancement to ULS to collect emergency point of contact information enables Commission staff to more effectively provide immediate assistance and outreach to licensees during times of emergency. Using this information, the Bureau is able to coordinate among licensees in given geographic areas to make more wireless service available to emergency first responders and emergency operations.

Public safety licensees and non-public safety licensees designated as emergency first responders operating pursuant to Part 90 of the Commission's rules should identify the following information regarding the operational point of contact for the licensee directly responsible for coordinating with the state, county, and/or local emergency authorities:

(1) Name and title;

(2) Office telephone number;

(3) Mobile telephone number; and

(4) Email address.

The Bureau issued a Public Notice with step-by-step instructions on how to use the enhanced features made available to licensees to provide this information.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–04166 Filed 2–22–13; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Update to Notice of Financial Institutions for Which the Federal Deposit Insurance Corporation Has Been Appointed Either Receiver, Liquidator, or Manager

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Update Listing of Financial Institutions in Liquidation.

SUMMARY: Notice is hereby given that the Federal Deposit Insurance Corporation (Corporation) has been appointed the sole receiver for the following financial institutions effective as of the Date Closed as indicated in the listing. This list (as updated from time to time in the **Federal Register**) may be relied upon as ''of record'' notice that the Corporation has been appointed receiver for purposes of the statement of policy published in the July 2, 1992 issue of the **Federal Register** (57 FR 29491). For further information concerning the identification of any institutions which have been placed in liquidation, please visit the Corporation Web site at *www.fdic.gov/bank/individual/failed/banklist.html* or contact the Manager of Receivership Oversight in the appropriate service center.

Dated: February 19, 2013.

Federal Deposit Insurance Corporation.

Pamela Johnson,

Regulatory Editing Specialist.

INSTITUTIONS IN LIQUIDATION

[In alphabetical order]

FDIC ref. No.	Bank name	City	State	Date closed
10470	Covenant Bank	Chicago	IL	2/15/2013.

[FR Doc. 2013–04236 Filed 2–22–13; 8:45 am]
BILLING CODE 6714–01–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0058; Docket 2012–0076; Sequence 55]

Federal Acquisition Regulation; Submission for OMB Review; Schedules for Construction Contracts

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension regarding an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning schedules for construction contracts. A notice was published in the **Federal Register** at 77 FR 73659, on December 11, 2012. One respondent submitted comments.

DATES: Submit comments on or before March 27, 2013.

ADDRESSES: Submit comments identified by Information Collection 9000–0058, Schedules for Construction Contracts 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 9000–0058, Schedules for Construction Contracts''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0058, Schedules for Construction Contracts'' on your attached document.
- *Fax:* 202–501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417. ATTN: Hada Flowers/IC 9000–0058, Schedules for Construction Contracts.

Instructions: Please submit comments only and cite Information Collection 9000–0058, Schedules for Construction Contracts, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis E. Glover, Sr., Procurement Analyst, Office of Acquisition Policy, (202) 501–1448 or email *curtis.glover@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal construction contractors may be required to submit schedules, in the form of a progress chart, showing the order in which the Contractor proposes to perform the work. In accordance with FAR 52.236–15, Schedules for Construction Contracts, the Contractor shall, within five days after work commences on the contract or another period of time determined by the contracting officer, prepare and submit to the contracting officer for approval three copies of a practicable schedule showing the order in which the Contractor proposes to perform the work, and the dates on which the Contractor contemplates starting and completing the several salient features of the work (including acquiring materials, plants, and equipment). This information is used to monitor progress under a Federal construction contract when other management approaches for ensuring adequate progress are not used. If the Contractor fails to submit a schedule within the time prescribes, the Contracting Officer may withhold approval of progress payments until the Contractor submits the required schedule.

B. Discussion and Analysis

One respondent submitted public comments on the extension of the previously approved information collection. The analysis of the public comments is summarized as follows:

Comment: The respondent commented that the extension of the information collection would violate the fundamental purpose of the Paperwork Reduction Act because of the burden it puts on the entity submitting the information and the agency collecting the information.

Response: In accordance with the Paperwork Reduction Act (PRA), agencies can request an OMB approval of an existing information collection. The PRA requires that agencies use the **Federal Register** Notice and comment process, to extend the OMB's approval, at least every three years. This extension, to a previously approved information collection, pertains to FAR 36.515, Schedules for Construction Contracts. The purpose of this subpart is to monitor progress under a federal construction contract when other management approaches for ensuring adequate progress are not used. This subpart provides the contracting officer with a construction schedule, in the form of a progress chart. Actual progress is entered on the chart as directed by the contracting officer. Not granting this extension would eliminate the Government's ability to track the contractor's progress when other management approaches for ensuring adequate progress are not used.

Comment: The respondent commented that the agency does not accurately estimate the public burden an extension of the information collection requirement would create. The respondent requested an explanation how the estimated number of respondents and responses was derived. The respondent also indicated that the estimate of one hour per response is unrealistically low and respectfully submitted that a more reasonable estimate would likely be in the range of 15 to 30 hours per response.

Response: Based on Federal procurement Data System (FPDS) data, 4,450 fixed-price construction contracts were awarded to 2,679 unique vendors in Fiscal Year 2011. Contracting officers only use clause 52.236–15, Schedules for Construction Contracts, when other management approaches for ensuring that a Contractor makes adequate progress are not available. Despite this criterion, the estimated total burden is calculated using total number of awards for FY11 as the baseline. An addition number of respondents are included in the estimate to account for existing contracts that may have incorporated FAR clause 52.236–15. The Government estimates that approximately fifty percent of the contracts cross-over to the following fiscal year, so another 1340 respondents are added to the 2,679 for an estimated total of 4,019 respondents.

Based on the FY11 data, each unique vendor responded 1.67 times to Government requests for information. The number of responses is rounded up to two, the nearest whole number. As a result, the estimated annual responses are 8,038.

The Contractor is required, within five days after the work commences on the contract or another period of time determined by the contracting officer, to prepare and submit for approval three copies of a practicable schedule showing the order in which the Contractor proposes to perform the

work, and the dates on which the Contractor contemplates starting and completing the several salient features of the work (including acquiring materials, plant, and equipment). The schedule shall be in the form of a progress chart of suitable scale to indicate appropriately the percentage of work scheduled for completion by any given date during the period. Subject matter experts in construction state that when contractors submit their proposals for construction projects, they usually include a schedule to complete the project. Based on this information being readily available to the Contractor once an award is made, it is not expected that a significant amount of time would be required to update the information at the request of the Government. However, in consideration of the public comment an upward adjustment is made to estimates hours per response.

Comment: The respondent commented the collective burden of compliance with the information collection requirement greatly exceeds the agency's estimate and outweighs any potential utility of the extension.

Response: The Paperwork Reduction Act (PRA) was designed to improve the quality and use of Federal information to strengthen decision-making, accountability, and openness in government and society. Central to this process is the solicitation of comments from the public. This process incorporates an enumerated specification of targeted information and provides interested parties a meaningful opportunity for comment on the relevant compliance cost. This process has led to decreases in the overall collective burden of compliance for the information collection requirement in regards to the public. Based on OMB estimates, in FY 2010, the public spent 8.8 billion hours responding to information collections. This was a decrease of one billion hours, or ten percent from the previous fiscal year. In effect, the collective burden of compliance for the public is going down as the Government publishes rules that make the process less complex, more transparent, and reduces the cost of federal regulations to both the Contractor community and Government.

Comment: The respondent commented that the Government's response to the Paperwork Reduction Act waiver for Far Case 2007–006 is instructive on the total burden for respondents.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provide by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to sixty. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business. Careful consideration went into assessing the estimated burden hours for this collection, and it is determined that an upward adjustment is warranted at this time.

C. Annual Reporting Burden

Respondents: 4,019.

Responses per Respondent: 2.

Annual Responses: 8,038.

Hours per Response: 4.

Total Burden Hours: 32,152.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0058, Schedules for Construction Contracts, in all correspondence.

Dated: February 19, 2013.

William Clark,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–04194 Filed 2–22–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–13–13JI]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404–639–7570 or send comments to Ron Otten, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; 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. Written comments should be received within 60 days of this notice.

Proposed Project

Virtual Reality to Train and Assess Emergency Responders—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NIOSH, under Public Law 91–173 as amended by Public Law 95–164 (Federal Mine Safety and Health Act of 1977), and Public Law 109–236 (Mine Improvement and New Emergency Response Act of 2006) has the responsibility to conduct research to improve working conditions and to prevent accidents and occupational diseases in underground coal and metal/nonmetal mines in the U.S.

The turn of the 21st century started with much promise for the coal mining industry. Because there was only one underground disaster in the 1990s, it seemed that emergency response in the

United States no longer needed to be a top research priority. However, major coal mine disasters between 2001 and 2010 have resulted in 65 fatalities. These events highlighted the critical need to balance investments to reduce low probability/high severity events with those that focus on frequent, but less severe injuries and illnesses.

The present research project seeks to determine optimal use of virtual reality (VR) technologies for training and assessing mine emergency responders using the Mine Rescue and Escape Training Laboratory (MRET Lab). Responders include specially trained individuals, such as mine rescue or fire brigade team members, and also managers and miners who may either be called upon to respond to an emergency situation or engage in self-protective actions in response to an emergency. This project is a step toward determining how new immersive virtual reality technologies should be used for miner training and testing in the U.S.

The project objective will be achieved through specific aims in the two related areas of training assessment and training development. Training assessment includes evaluating four training modules, evaluating participant reactions, and developing guidelines. Training development involves the use of 3D technologies to develop a prototype for a mine rescue closed-circuit breathing apparatus (Dräger BG4).

To accomplish these goals over the life of the project, researchers will utilize a variety of data collection strategies, including self-report pre-and post-test instruments for assessing trainee reaction and measuring learning. Data collection will take place with approximately 150 underground coal miners over three years. The respondents targeted for this study include rank-and-file miners, mine rescue team members, and mine safety and health professionals. A sample of 150 individuals will be selected from various mining operations and mine rescue teams which have agreed to participate. All participants will be between the ages of 18 and 65, currently employed, and living in the United States. Findings will be used to improve the safety and health of underground coal miners by assessing the efficacy of immersive VR environments for teaching critical mine safety and health skills.

To assess learning as a result of training, each participant will complete a pre-training questionnaire, a post-simulation questionnaire, and a post-training questionnaire. Participants evaluating the closed-circuit breathing apparatus training will only complete a version of the pre-training questionnaire. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Dräger BG4 participants (i.e., closed circuit breathing apparatus training participants).	Pre-Training Questionnaire.	30	1	3/60	2
Mine Rescue participants	Pre-Training Questionnaire.	60	1	3/60	3
	Post-Simulation Questionnaire.	60	1	3/60	3
	Post-Training Questionnaire.	60	1	3/60	3
Mine Escape participants	Pre-Training Questionnaire.	60	1	3/60	3
	Post-Simulation Questionnaire.	60	1	3/60	3
	Post-Training Questionnaire.	60	1	3/60	3
Mine Escape/Longwall Mining participants	Pre/Post-Training Knowledge Test.	30	1	6/60	3
Mine Escape/Continuous Mining participants	Pre/Post-Training Knowledge Test.	30	1	6/60	3
Mine Rescue/Longwall Mining participants	Pre/Post-Training Knowledge Test.	30	1	6/60	3
Mine Rescue/Continuous Mining participants	Pre/Post-Training Knowledge Test.	30	1	6/60	3
Total					32

Date: February 19, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–04233 Filed 2–22–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10445]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* New collection; *Title:* Medicare Advantage Quality Bonus Payment Demonstration; *Use:* In response to the provision of the Affordable Care Act, beginning in 2012, quality bonus payments (QBPs) are given to all plans earning four or five stars in Medicare's Star Rating program. As an extension of this legislation, CMS launched the Medicare Advantage Quality Bonus Payment Demonstration, which accelerates the phase-in of QBPs by extending bonus payments to three-star plans and eliminating the cap on blended county benchmarks that would otherwise limit QBPs. Through this demonstration, CMS seeks to understand how incentive payments impact plan quality across a broader spectrum of plans.

The data collection effort will be conducted in the form of a survey of Medicare Advantage Organizations (MAOs) and up to 10 case studies with MAOs in order to supplement what can be learned from the analyses of administrative and financial data for MAOs, and from an environmental and literature scan. The data collected is needed to evaluate the QBP demonstration to better understand what impact the demonstration has had on MAO operations and their efforts to improve quality. The data collection instrument is a survey questionnaire designed to capture information on how MAOs perceive the demonstration and are planning for or implementing changes in quality initiatives and to identify factors that help or hinder the capacity to achieve quality improvement and that influence the decision calculus to make changes. Specifically, the information is expected to provide a detailed picture to CMS of the kinds of quality initiatives utilized by MAOs and some preliminary information on how they assess the effectiveness of these programs. The survey is designed to provide an overall picture of the QBP that can be used for national comparisons across plans as part of the larger evaluation of the QBP demonstration.

The case studies will be conducted as a series of open-ended discussions with MAO staff that will be guided by a discussion protocol. The case studies will supplement the information gathered from the survey and data analysis, providing valuable context and details about successful quality improvement activities. The case studies are particularly well suited to exploring the detailed characteristics of the plans' quality improvement activities, emphasizing the decision-making and thought processes underlying the structure and direction of their efforts and capturing the contextual factors that impact the nature, structure, and scope of the programs. The 60-day **Federal Register** notice published on September 17, 2012, (77 FR 57090). Subsequently, there were revisions to the MAO survey. *Form Number:* CMS–10445 (OCN: 0938-New); *Frequency:* Annual; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 730; *Total Annual Responses:* 1,280; *Total Annual Hours:* 683. (For policy questions regarding this collection contact Gerald Riley at 410–786–6699. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *March 27, 2013.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974, Email: *OIRA_submission@omb.eop.gov.*

Dated: February 19, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–04152 Filed 2–22–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Annual Survey of Refugees (Form ORR–9).

OMB No.: 0970–0033.

Description: The Annual Survey of Refugees collects information on the social and economic characteristics of a random sample of refugees, Amerasians, and entrants who arrived in the United States in the five years prior to the date of the survey. The survey focuses on employment and other training, labor force participation, and welfare utilization rates. From the responses, the Office of Refugee Resettlement reports on the economic adjustment of refugees to the American economy. These data are used by Congress in its annual deliberations on refugee admissions and funding and by program managers in formulating policies for the future direction of the Refugee Resettlement Program.

Respondents: Refugees, Amerasians, and entrants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–9 Annual Survey of Refugees	2,000	1	0.62	1,240
Request for Participation Letter	2,000	1	0.05	100

Estimated Total Annual Burden Hours: 1,340

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the

information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–04176 Filed 2–22–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Self-Assessment Review and Report.

OMB No.: 0970–0223.

Description: Section 454(15)(A) of the Social Security Act, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, requires each State to annually assess the performance of its child support enforcement program in accordance with standards specified by the Secretary of the Department of Health and Human Services, and to provide a report of the findings to the Secretary. This information is required to determine if States are complying with Federal child support mandates and providing the best services possible. The report is also intended to be used as a management tool to help States evaluate their programs and assess performance.

Respondents: State Child Support Enforcement Agencies or the Department/Agency/Bureau responsible for Child Support Enforcement in each State.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Self-assessment report	54	1	4	216

Estimated Total Annual Burden Hours: 216.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–04278 Filed 2–22–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0282; formerly 2005D–0183]

Draft Guidance for Industry on Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting Hepatitis C Virus Resistance Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HCV Resistance Data.'' The purpose of this attachment is to assist sponsors in submitting hepatitis C virus (HCV) clinical virology data, which are important for supporting clinical trials of products in development for the treatment of HCV. HCV resistance data submitted in appropriately formatted datasets is a critical component in the review of investigational antiviral products for the treatment of HCV. The information in this attachment will facilitate the development and regulatory review of anti-HCV products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 26, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa K. Naeger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6366, Silver Spring, MD 20993–0002, 301–796–0771.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Attachment to Guidance on Antiviral Product Development—Conducting and Submitting Virology Studies to the Agency: Guidance for Submitting HCV Resistance Data.'' The purpose of this attachment is to assist sponsors in submitting HCV clinical virology data, which are important for supporting clinical trials of products in development for the treatment of HCV. This attachment revises and replaces the attachment on submitting HCV resistance data published in June 2006 and represents FDA's current thinking regarding how sponsors should submit HCV resistance data. The revised attachment provides the format, recommended definitions, standardization of column headings and variables, and recommended data for submission of HCV resistance datasets.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on submitting HCV clinical virology data. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04196 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–D–0153; formerly 2005D–0011]

Guidance for Industry on Labeling for Human Prescription Drug and Biological Products—Implementing the Physician Labeling Rule Content and Format Requirements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements.'' This guidance is intended to assist applicants in complying with the content and format requirements of labeling for human prescription drug and biological products. The recommendations in this guidance will help ensure that the labeling is clear; useful; informative; and to the extent possible, consistent in content and format. It will assist applicants in developing labeling for new products, revising existing labeling, and implementing the requirements on content and format of labeling for human prescription drug and biological products (71 FR 3922), which appeared in the **Federal Register** of January 24, 2006. The rule is commonly referred to as the ''Physician Labeling Rule'' (PLR) because it addresses prescription drug labeling that is used by prescribers and other health care practitioners.

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

ADDRESSES: 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, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. 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.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Bickel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6353, Silver Spring, MD 20993–0002, 301–796–0210; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the PLR Content and Format Requirements.'' The guidance provides recommendations on how to create professional labeling consistent with the requirements on content and format of labeling for human prescription drug and biological products under §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) (71 FR 3922). The guidance also provides recommendations on how to organize labeling sections and what information should be included in each.

This guidance is one of a series of guidances FDA is developing, or has

developed, to assist applicants with the content and format of the labeling for human prescription drug and biological products. In the **Federal Register** of January 24, 2006 (71 FR 3998), FDA announced the availability of final guidances on the content and format of the ''Adverse Reactions'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075057.pdf*) and ''Clinical Studies'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075059.pdf*) sections of labeling. In the **Federal Register** of October 19, 2009 (74 FR 53507), FDA announced the availability of final guidance on determining established pharmacologic class for use in the Highlights of Prescribing Information (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM186607.pdf*). In the **Federal Register** of March 23, 2010 (75 FR 13766), FDA announced the availability of final guidance on the content and format of the ''Dosage and Administration'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075066.pdf*). In the **Federal Register** of October 12, 2011 (76 FR 63303), FDA announced the availability of final guidance on the content and format of the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM075096.pdf*) and in the **Federal Register** of March 3, 2009 (74 FR 9250), FDA announced the availability of draft guidance on the content and format of the ''Clinical Pharmacology'' section of labeling (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM109739.pdf*). The labeling requirements and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

On January 24, 2006, FDA announced the availability of draft guidance entitled ''Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format Requirements'' to obtain public comment (71 FR 3998). FDA received a number of comments, most of which sought clarifications and illustrations of the issues discussed in individual sections of the guidance. FDA reviewed all received comments carefully during the finalization of the guidance and made clarifying changes based on input from these comments and comments from FDA reviewers with labeling expertise.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on implementing the PLR content and format requirements for labeling for human prescription drug and biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in §§ 201.56 and 201.57 have been approved under OMB control number 0910–0572.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.*

Dated: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04195 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2006–D–0409] (formerly 2006D–0169)

Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the withdrawal of a guidance entitled ''Guidance for Industry: Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act,'' dated April 2006, that was announced in the **Federal Register** on May 2, 2006. The guidance explained FDA's then current thinking on the labeling of certain uses of lecithin derived from soy under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and was part of FDA's implementation of the Food Allergen Labeling and Consumer Protection Act (FALCPA). We are taking this action because the policy stated in the guidance regarding FDA's consideration of the exercise of enforcement discretion no longer reflects our current thinking.

DATES: The withdrawal is effective February 25, 2013.

FOR FURTHER INFORMATION CONTACT: Steven M. Gendel, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1056.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 2, 2006 (71 FR 25844), we announced the availability of a guidance entitled ''Guidance on the Labeling of Certain Uses of Lecithin Derived From Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act.'' The guidance explained that, consistent with the need to establish enforcement priorities, we would consider the exercise of enforcement discretion for a food labeled on or after January 1, 2006, in which lecithin derived from soy is used solely as a component of a release agent and the label for such food does not declare the presence of soy consistent with the requirements of section 403(w) of the FD&C Act (21 U.S.C. 343(w)). In that guidance, the

term ''release agent'' referred to an agent used to facilitate the release of foods from food contact surfaces, where the agent has been applied directly to the food contact surface, rather than incorporated into the food. In that guidance, we also stated our intention to reconsider our enforcement priorities with regard to the labeling of lecithin derived from soy used as a component of a release agent approximately 18 months after the issuance of the guidance. Further, we stated our expectation that, during the period in which we considered the exercise of our enforcement discretion, manufacturers of foods that use lecithin derived from soy as a component of a release agent would revise as necessary the labels of their relevant food products to comply with FALCPA and begin to label their products using the FALCPA-compliant labels by the end of the enforcement discretion period.

We believe that there has been sufficient time for all manufacturers of foods that use lecithin derived from soy as a component of a release agent to revise the labels for such foods to be consistent with the requirements of section 403(w) of the FD&C Act. Therefore, we no longer believe it is appropriate to consider the exercise of our enforcement discretion with regard to foods that use lecithin derived from soy as a component of a release agent. For these reasons, we are withdrawing the April 2006 guidance entitled ''Guidance on the Labeling of Certain Uses of Lecithin Derived from Soy Under Section 403(w) of the Federal Food, Drug, and Cosmetic Act.''

Dated: February 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04251 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Joint Meeting of the Medical Imaging Drugs Advisory Committee and the Oncologic Drugs Advisory Committee; Notice of Meeting.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Medical Imaging Drugs Advisory Committee and the Oncologic Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 3, 2013, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (rm. 1503), 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Diane Goyette, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *MIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On May 3, 3013, the committees will discuss the safety and efficacy of currently approved leukocyte growth factors (LGFs) as potential treatments for radiation-induced myelosuppression associated with a radiological/nuclear incident. (Myelosuppression is a reduction of blood cell production, which can be caused by radiation exposure.) Currently approved LGFs are licensed under biological license applications (BLAs): 103353, NEUPOGEN (filgrastim, Amgen, Inc.), 125031, NEULASTA (pegfilgrastim, Amgen, Inc.), 103362, LEUKINE, (sargramostim, Genzyme, Inc.), and 125294, TBO–FILGRASTIM (tbo-filgrastim, Sicor Biotech, UAB). The National Institute of Allergy and Infectious Diseases (NIAID) has submitted efficacy data for filgrastim, based on treatment in an animal model of radiation-induced myelosuppression. Safety and other supportive information are currently described in the labeling for LGFs.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 19, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 11, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 12, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Diane Goyette at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/Advisory*

Committees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–04141 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on Thursday, March 14, 2013 from 8 a.m. to 5:30 p.m.

Location: Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910, 301–589–0800 or visit the hotel's Web site at *http://www.sheratonsilverspring.com/*.

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5154, Silver Spring, MD 20993, 301–796–0885, email *walter.ellenberg@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On Thursday, March 14, 2013, the Pediatric Advisory Committee will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Public Law 107–109) and the for Pediatric Research Equity Act (Public Law 108–155) for: ACTEMRA (tocilizumab), ALIMTA (Pemetrexed disodium), CREON (pancrelipase), GADAVIST (gadobutrol), HIZENTRA [Immune Globulin Subcutaneous (Human), 20% Liquid], INOMAX (nitric oxide), INVEGA (paliperidone), KEDBUMIN (albumin human), KYTRIL Injection (granisetron hydrochloride), LAMICTAL XR (lamotrigine), MENACTRA [Meningococcal (Groups A, C, Y and W–135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine], MOXEZA (moxifloxacin ophthalmic solution 0.5%), NATROBA (spinosad), NEXIUM (esomeprazole magnesium), NEXIUM IV (esomeprazole sodium), UROXATRAL (alfuzosin hydrochloride), and ZENPEP (pancrelipase). Also, there will be an Informational Update on Codeine.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 7, 2013. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 27, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 28, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Walter Ellenberg at 301–796–0885, email *walter.ellenberg@fda.hhs.gov,* at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 19, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–04256 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Fecal Microbiota for Transplantation; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), and the National Institutes of Health, National Institute of Allergy and Infectious Diseases (NIAID), are announcing a public workshop entitled ''Fecal Microbiota for Transplantation.'' The purpose of the public workshop is to exchange information with the medical and scientific community about the regulatory and scientific issues associated with fecal microbiota for transplantation (FMT).

Date and Time: The public workshop will be held on May 2 and 3, 2013, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at Lister Hill Center Auditorium, National Institutes of Health, Bldg. 38A, 8600 Rockville Pike, Bethesda, MD 20894. Preregistered participants will receive additional information on security procedures, parking, and public transportation with their email registration confirmation.

Contact Person: Chris Nguyen, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, email: *CBERPublicEvents@fda.hhs.gov* (subject line: FMT Workshop).

Registration: Mail or fax your registration information (including name, title, firm name, address, telephone, and fax numbers) to Chris Nguyen (see *Contact Person*) or email to *CBERPublicEvents@fda.hhs.gov* (subject line: FMT Workshop Registration) by April 18, 2013. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Chris Nguyen (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Fecal microbiota samples that have been isolated from healthy individuals are being investigated for use in the treatment of *Clostridium difficile* colitis. Published data from case studies and metaanalyses suggest that the use of fecal microbiota to restore gut flora may be an effective therapy in the management of refractory *C. difficile* infection. However, the efficacy of this intervention has not yet been demonstrated in controlled clinical trials. Such controlled trials are needed to demonstrate the safety and effectiveness of FMT products for *C. difficile* infection refractory to conventional therapy. FMT is also being considered as a treatment for inflammatory bowel disease, obesity, and other disorders, and controlled trials are needed in these settings as well.

Clinical studies to evaluate the safety and efficacy of FMT are regulated by FDA. FDA's primary objectives in reviewing an investigational new drug application are, in all phases of the investigation, to assure the safety and rights of subjects, and, in Phases 2 and 3, to help insure that the quality of the scientific evaluation of the product is adequate to permit an evaluation of safety and effectiveness. In addition, the complex nature of FMT products presents specific scientific and regulatory challenges.

To facilitate clinical development of FMT, CBER and NIAID are holding this workshop to provide a forum for the exchange of information, knowledge, and experience between CBER, NIAID, and the scientific-medical community.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible at: *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.* Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857.

Dated: February 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04232 Filed 2–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Office of Health Assessment and Translation Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments—February 2013; Request for Comments; Notice of a Meeting

SUMMARY: The National Toxicology Program (NTP) requests public comments on the Draft Office of Health Assessment and Translation (OHAT) Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments—February 2013 (available at *http://ntp.niehs.nih.gov/go/38138*). The NTP also plans to release two protocols to illustrate the application of this framework. These documents were prepared by the OHAT, Division of NTP, National Institute of Environmental Health Sciences (NIEHS). The NTP will hold a public web-based, informational meeting during the public-comment period to provide an overview of the framework, describe the contents in the case-study protocols, and respond to questions from the public on any of the documents.

DATES: *Public Comment Submissions:* Deadline is June 11, 2013.

Document Availability: Draft OHAT Approach—February 2013 will be available by February 26, 2013, and case-study protocols should be available on April 2, 2013, at *http://ntp.niehs.nih.gov/go/38673.*

Registration for public, web-based, informational meeting: Deadline is April 16, 2013.

Meeting: April 23, 2013, 12:00–4:00 p.m. Eastern Daylight Time (EDT). The meeting may end earlier depending on the number of registered participants and will be cancelled if there are no registered participants by close of business on April 16, 2013. Registrants will receive information by email to access the web-based meeting on or before April 19, 2013.

ADDRESSES: *Agency Web site:* The Draft OHAT Approach—February 2013, protocols, registration for web-based meeting, and public comments are at *http://ntp.niehs.nih.gov/go/38673.*

Public Comment Submissions: Email: *andrew.rooney@nih.gov* or submit online at *http://ntp.niehs.nih.gov/go/38673.*

TTY users should contact the Federal TTY Relay Service at (800) 877–8330. Requests must be made at least 5 business days in advance of the web-based meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Andrew Rooney, Deputy Director, OHAT, Division of NTP, NIEHS, P.O. Box 12233, K2–04, Research Triangle Park, NC 27709. Phone: 919–541–2999, Fax: 301–480–3299, Email: *Andrew.Rooney@nih.gov.* Hand Deliver/Courier address: 530 Davis Drive, Room K2154, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The OHAT, Division of NTP, NIEHS, has led an effort for the NTP to develop an approach for carrying out literature-based health assessments that incorporates systematic review methodology. Systematic review and plans for developing the approach were introduced at the NTP Board of Scientific Counselors (BSC) meeting on June 21—22, 2012. A BSC working group reviewed an earlier draft of the approach (then called the draft NTP Approach) at a meeting on August 28—29, 2012, and provided a draft report with recommendations to the BSC at its meeting on December 11, 2012; the report was unanimously accepted by the BSC. Information, presentations, and minutes (when available) from the June and December meetings are available at *http://ntp.niehs.nih.gov/go/9741.*

The NTP prepared the ''Draft OHAT Approach for Systematic Review and Evidence Integration for Literature-based Health Assessments—February 2013,'' (Draft OHAT Approach—February 2013) taking into consideration input from the BSC working group, the BSC, and the public (available at *http://ntp.niehs.nih.gov/go/38673*). The approach includes seven steps that provide a framework for incorporating systematic review and evidence integration into NTP literature-based health assessments. To assist with determining if additional refinement or revision to the Draft OHAT Approach—February 2013 might be needed, OHAT plans to apply it to two case-study evaluations. One case study will evaluate the association of bisphenol A (BPA) exposure with obesity and the other will examine the association of perflurooctanoic acid (PFOA) or perfluorooctane sulfonate (PFOS) exposure with immunotoxicity. Prior to initiating these evaluations, OHAT is developing protocols that include specific elements for how the seven steps in the Draft OHAT Approach—February 2013 would be carried out. The protocols on BPA exposure and obesity and PFOA or PFOS exposure and immunotoxicity should be available on April 2, 2013, at *http://ntp.niehs.nih.gov/go/38673.* Persons interested in the Draft OHAT Approach—February 2013 and the protocols are encouraged to access this Web site to stay abreast of the most current information.

The NTP will carefully consider the public comments on the Draft OHAT Approach—February 2013 and consider what changes, if any, might be needed. The NTP plans to present the Draft OHAT Approach—February 2013 to the NTP BSC at the meeting on June 25–26, 2013 and discuss plans to update the document based on comments. Details about this meeting will be published in the **Federal Register** and posted on the NTP Web site (*http://ntp.niehs.nih.gov/go/165*).

Request for Comments

The NTP invites public comments on the Draft OHAT Approach—February 2013. Two protocols are being released to illustrate application of this framework: BPA exposure and obesity and PFOA or PFOS exposure and immunotoxicity. The deadline for submission of public comments is June 11, 2013. Comments will be posted on the NTP Web site *http://ntp.niehs.nih.gov/go/38668* and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Public comments can be submitted on-line or by email (see **ADDRESSES**, Public Comment Submissions). Persons submitting written comments should include their name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document.

Web-based Informational Meeting

The NTP will hold a public, web-based, informational meeting on April 23, 2013, 12:00–4:00 p.m. EDT to provide an overview of the Draft OHAT Approach—February 2013, describe the contents in the two case-study protocols, and respond to questions from the public on any of the documents. The meeting will be interactive and opportunities will be provided for members of the public to ask NTP staff specific questions that may assist in their review or understanding of the Draft OHAT Approach—February 2013. The deadline for registration for the webinar is April 16 at *http://ntp.niehs.nih.gov/go/38673,* and the event will be cancelled if there are no registered participants by close of business that day. Registrants will receive information by email to access the web-based meeting on or before April 19, 2013.

Background Information on OHAT

OHAT was established to serve as an environmental health resource to the public and regulatory and health agencies (*http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3094430*). This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as ''substances'') cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences. OHAT assessments are published as NTP Monographs. Information about OHAT is found at *http://ntp.niehs.nih.gov/go/ohat.*

Dated: February 19, 2013.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2013–04254 Filed 2–22–13; 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 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 Initial Review Group; Pediatrics Subcommittee.

Date: March 14, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel Bethesda (Formerly Holiday Inn Select) 8120 Wisconsin Avenue Bethesda, MD 20814.

Contact Person: Rita Anand, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of, Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–496–1487, *anandr@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: February 15, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04207 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (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: National Cancer Institute Special Emphasis Panel; National Cancer Institute Provocative Questions B.

Date: March 21–22, 2013.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center 5701 Marinelli Road Bethesda, MD 20852.

Contact Person: Michael B. Small, Ph.D. Scientific Review Officer Division of Extramural Activities National Cancer Institute National Institutes of Health 6116 Executive Blvd., Room 8127 Bethesda, MD 20892–8328 301–402–0996 *smallm@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Training and Education.

Date: March 26, 2013.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health 6116 Executive Boulevard Room 707 Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Timothy C. Meeker, MD, Ph.D. Scientific Review Officer Resources and Training Review Branch Division of Extramural Activities National Cancer Institute, NIH 6116 Executive Boulevard, Room 8103 Bethesda, MD 20892 301–594–1279 *meekert@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 19, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04203 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Special Emphasis Panel; Innovative Radiation Sources for Advanced Radiotherapy Equipment.

Date: March 14, 2013.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: NIH—National Cancer Institute, 6116 Executive Blvd., Room 611, Bethesda, MD 20852 (Telephone Conference Call).

Contact Person: Kirt Vener, Ph.D., Branch Chief, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 8061, Bethesda, MD 20892–8329, 301–496–7174, *venerk@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 19, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04209 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; SBIR Topic 80: Developing Fluorescent Nanodiamonds for Biological Imaging.

Date: March 1, 2013.

Time: 2:15 p.m. to 6:15 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Improving Safety and Efficiency of Red Blood Cell Products in Transfusions.

Date: March 4, 2013.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7204, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: David A Wilson, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7204, Bethesda, MD 20892–7924, 301–435–0299, *wilsonda2@nhlbi.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Thrombotic and Hemostatic Disorders.

Date: March 5, 2013.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Michael P Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–496–9659, *reillymp@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Resource Related Research Project in National Biological Sample Data Repository.

Date: March 6, 2013.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Kristen Page, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7185, Bethesda, MD 20892, 301–435–0725, *kristen.page@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 15, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04205 Filed 2–22–13; 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 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Peer Review Meeting.

Date: March 14, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Yong Gao, Ph.D., Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, 6700B Rockledge Drive, Room 3127, Bethesda, MD 20892, 301–443–8115, *gaol2@niaid.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: February 19, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04211 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; 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: National Heart, Lung, and Blood Institute Special Emphasis Panel; Translational Programs in Lung Diseases.

Date: March 13, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Washington DC/Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, *sunnarborgsw@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Evaluating Obstructive Sleep Apnea Dental Device Treatment.

Date: March 15, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924, 301–435–0725, *creazzotl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 15, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04206 Filed 2–22–13; 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 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 Initial Review Group; Population Sciences Subcommittee.

Date: March 14–15, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Carla T. Walls, Ph.D., Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute, of Child Health And Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–7510, 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: February 15, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04208 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, NIDDK Central Repositories Sample Access (X01): Hepatitis E and Advanced Chronic Hepatitis C.

Date: March 27, 2013

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 19, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04213 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; AKI Outcomes.

Date: March 28, 2013.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Peritoneal Dialysis.

Date: April 1, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 19, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04212 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, NIDDK Career Awards Review.

Date: March 19, 2013.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Novel Interventions to Reduce Morbidity and Mortality of Hemodialysis Patients (U01).

Date: April 8, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–2242, *jerkinsa@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 19, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04215 Filed 2–22–13; 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: AIDS and Related Research Integrated Review Group; AIDS Immunology and Pathogenesis Study Section.

Date: March 18, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Mayflower Park Hotel, 405 Olive Way, Seattle, WA 98101.

Contact Person: Shiv A Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Predictors of Substance Use in Young Adulthood.

Date: March 18, 2013.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Anna L Riley, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7759, Bethesda, MD 20892, 301–435–2889, *rileyann@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: CounterACT U54 Centers of Excellence.

Date: March 19, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Jonathan K Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncological Sciences.

Date: March 19–20, 2013.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Inese Z Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: CounterAct U01 Cooperative Agreements.

Date: March 19, 2013.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Jonathan K Ivins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040A, MSC 7806, Bethesda, MD 20892, (301) 594–1245, *ivinsj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA DA14–001: U.S.-RUSSIA Bilateral Collaborative Research Partnerships (CRP) on the Prevention and Treatment of HIV/AIDS and Co-Morbidities (R21).

Date: March 19–20, 2013.

Time: 7:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: 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: February 15, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04204 Filed 2–22–13; 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 a meeting of the Vaccine Research Center Board of Scientific Counselors, NIAID.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Allergy and Infectious Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Name of Committee: Vaccine Research Center Board of Scientific Counselors, NIAID.

Date: April 29–30, 2013.

Closed: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 40, Room 1201/1203, 40 Center Drive, Bethesda, MD 20892.

Contact Person: John R Mascola, MD, Deputy Director, Vaccine Research Center, NIAID, NIH, 40 Convent Drive, Bethesda, MD 20892, (301) 496–1852, *jmascola@nih.gov.*

Name of Committee: Vaccine Research Center Board of Scientific Counselors, NIAID.

Date: April 29, 2013.

Closed: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate personal qualifications and performances, and competence of individual investigators.

Place: National Institutes of Health, Building 40, Room 1201/1203, 40 Center Drive, Bethesda, MD 20892.

Contact Person: John R. Mascola, MD, Deputy Director, Vaccine Research Center, NIAID, NIH, 40 Convent Drive, Bethesda, MD 20892, (301) 496–1852, *jmascola@nih.gov.*

Name of Committee: Vaccine Research Center Board of Scientific Counselors, NIAID.

Date: April 30, 2013.

Closed: 8:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate personal qualifications and performances, and competence of individual investigators.

Place: National Institutes of Health, Building 40, Room 1201/1203, 40 Center Drive, Bethesda, MD 20892, (301) 496–1852.

Contact Person: John R. Mascola, MD, Deputy Director, Vaccine Research Center, NIAID, NIH, 40 Convent Drive, Bethesda, MD 20892, (301) 496–1852, *jmascola@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: February 19, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–04210 Filed 2–22–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: National Outcome Measures (NOMs) for Substance Abuse Prevention—(OMB No. 0930–0230)—Revision

This is a revision to the previously OMB approved instrument for the Center for Substance Abuse Prevention's (CSAP) National Outcome Measures for Substance Abuse Prevention (NOMs). Data are collected from SAMHSA/CSAP grants and contracts where community and participant outcomes are assessed. The analysis of these data helps determine whether progress is being made in achieving SAMHSA/CSAP's mission. The primary purpose of this system is to promote the use among SAMHSA/CSAP grantees and contractors of common National Outcome Measures recommended by SAMHSA/CSAP with significant input from panels of experts and state representatives.

Approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRAMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance, and address goals and objectives outlined in the Office of National Drug Control Policy's Performance Measures of Effectiveness.

Note that the only changes is the deletion of one question per instrument, the deletion of prior Fiscal Years, and the PPC program which was not funded. The question being deleted is *Has the Service Member experienced any of the following (select all that apply)*

(a) Deployed in support of combat operations (e.g. Iraq or Afghanistan)

(b) Was physically injured during combat operations

(c) Developed combat stress symptoms/difficulties adjusting following deployment, including PTSD, depression, or suicidal thoughts

(d) Died or was killed

The total annual burden estimate is shown below:

SAMHSA/CSAP program	Number of grantees	Number of respondents	Number of responses	Responses per respondent	Hours/ response	Total hours
FY 13						
Science/Services:						
Fetal Alcohol	23	4,800	14,400	3	0.4	5,760
Capacity:						
HIV	122	31,964	95,892	3	0.4	38,357
SPF SIG	35	.....	.....	0	.....	.....
SPF SIG/Community Level *	.....	29,925	29,925	1	0.4	11,970
SPF SIG/Program Level *	.....	9,100	27,300	3	0.4	10,920
PFS	37	.....	.....	0	.....	.....
PFS/Community Level *	.....	37,000	37,000	1	0.4	14,800
Annual Average	217	112,889	204,517	.....	.....	81,807

* The Strategic Prevention Framework State Incentive Grant (SPF SIG) and Partnerships for Success (PFS) have a three level evaluation: The Grantee, Community and Program Level. The Grantee level data will be pre-populated by SAMHSA. The use of the Community Level instrument is optional as they relate to targeted interventions implemented during the reporting period. At the program level, items will be selected in line with direct services implemented.

Written comments and recommendations concerning the proposed information collection should be sent by March 27, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2013–04270 Filed 2–22–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the combined meeting on March 15, 2013, from 1:30 p.m. to 3:00 p.m. EST via teleconference, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) four National Advisory Councils (the SAMHSA National Advisory Council (NAC), the Center for Mental Health Services NAC, the Center for Substance Abuse Prevention NAC, the Center for Substance Abuse Treatment NAC), and the two SAMHSA Advisory Committees (Advisory Committee for Women's Services, and the Tribal Technical Advisory Committee).

The Councils were established to advise the Secretary, Department of Health and Human Services (HHS), the Administrator, SAMHSA, and Center Directors, concerning matters relating to the activities carried out by and through the Centers and the policies respecting such activities.

Under Section 501 of the Public Health Service Act, the Advisory Committee for Women's Services (ACWS) is statutorily mandated to advise the SAMHSA Administrator and the Associate Administrator for Women's Services on appropriate activities to be undertaken by SAMHSA and its Centers with respect to women's substance abuse and mental health services.

Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of September 23, 2004, SAMHSA established the Tribal Technical Advisory Committee (TTAC) for working with Federally-recognized Tribes to enhance the government-to-government relationship, honor Federal trust responsibilities and obligations to Tribes and American Indian and Alaska Natives. The SAMHSA TTAC serves as an advisory body to SAMHSA.

The meeting is open and will include discussion of the President's plan to increase access to mental health services.

The public is invited to listen to the teleconference meeting. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions should be forwarded to the contact person on or before March 11, 2013. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact on or before March 11, 2013. Five minutes will be allotted for each presentation.

Substantive program information may be obtained after the meeting by accessing the SAMHSA Committee web site, *http://nac.samhsa.gov/,* or by contacting Ms. Wood. The transcript for the meeting will also be available on the SAMHSA Committee Web site within three weeks after the meeting.

Committee Names:

Substance Abuse and Mental Health Services Administration National Advisory Council,
Center for Mental Health Services National Advisory Council,
Center for Substance Abuse Prevention National Advisory Council,
Center for Substance Abuse Treatment National Advisory Council,
SAMHSA's Advisory Committee for Women's Services,
SAMHSA Tribal Technical Advisory Committee.

Date/Time/Type: March 15, 2013, 1:30 p.m.–3:00 p.m. EST OPEN.

Place: Teleconference.

Dial in number: 888–677–8206; Participant passcode: GWOOD.

Contact: Geretta Wood, Committee Management Officer and Designated Federal Official, SAMHSA National Advisory Council, SAMHSA's Advisory Committee for Women's Services, 1 Choke Cherry Road, Rockville, Maryland 20857, Telephone: (240) 276–2326, Fax: (240) 276–2253 and Email: *geretta.wood@samhsa.hhs.gov.*

Cathy Friedman,

SAMHSA, Public Health Analyst.

[FR Doc. 2013–04181 Filed 2–22–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR 5684–N–02]

Notice of Proposed Information Collection for Disaster Relief Appropriations Act, 2013 Public Comment Request

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 11, 2013.

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: LaRuth Harper, Department of Housing Urban and Development, 451 7th Street SW., Room 7233, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Stanley Gimont, Director, Office of Block Grant Assistance at (202) 708–3587.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35 as Amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Disaster Recovery Grant Reporting System—Revision to Add Hurricane Sandy and other Disaster Grants.

OMB Control Number: 2506–0165.

Description of the need for the Information and proposed use: The Disaster Recovery Grant Reporting (DRGR) System is a grants management system used by the Office of Community Planning and Development to monitor special appropriation grants under the Community Development Block Grant program. This collection pertains to Community Development Block Grant Disaster Recovery (CDBG–DR) and Neighborhood Stabilization Program (NSP) grant appropriations.

The CDBG program is authorized under Title I of the Housing and Community Development Act of 1974, as amended. Following major disasters, Congress appropriates supplemental CDBG funds for disaster recovery.

According to Section 104(e)(1) of the Housing and Community Development Act of 1974, HUD is responsible for reviewing grantees' compliance with applicable requirements and their continuing capacity to carry out their programs. Grant funds are made available to states and units of general local government, Indian tribes, and insular areas, unless provided otherwise by supplemental appropriations statute, based on their unmet disaster recovery needs.

The recent Hurricane Sandy supplemental appropriation (Pub. L. 113–2) provides funding for Hurricane Sandy disaster recovery efforts and other eligible events in 2011, 2012 and 2013. The appropriation directs the Department to address these efforts in areas of greatest unmet need. The Department estimates that this will add 40 new grants to the portfolio currently overseen by the Disaster Recovery and Special Issues Division in the Office of Block Grant Assistance. This revision updates the previously approved DRGR PRA information collection to account for the increase in burden hours associated with these new CDBG–DR grants. Information collection requirements for NSP and NSP–TA grants will remain unchanged from the previously approved collection.

Agency form numbers, if applicable: SF–424 Application for Federal Assistance.

Members of affected public: DRGR is used to monitor CDBG–DR, NSP, and NSP–TA grants, as well as several programs that do not fall under the Office of Block Grant Assistance. Separate information collections have been submitted and approved for these programs. CDBG–DR and NSP grant funds are made available to states and units of general local government, Indian tribes, and insular areas, unless provided otherwise by supplemental appropriations statute. NSP–TA grant funds are awarded on a competitive basis and are open to state and local governments, as well as non-profit groups and consortia that may include for-profit entities.

Estimation of the total numbers of hours needed to prepare the Information collection including number of respondents, frequency of response, and hours of response:

Community Development Block Grant Disaster Recovery (CDBG–DR) Grants: The DRGR system has approximately 72 open CDBG disaster recovery grants. An additional 40 grants are anticipated as a result of the Hurricane Sandy appropriation. HUD requires each grantee to report their performance into the system quarterly. In addition, grantees submit vouchers for drawdown of funds as needed. Some grantees have more than one open grant under different appropriation rules and are required to report on grants separately.

For average sized grantees (<$100m in grant funds), the Department estimates 9 hours for quarterly reporting in DRGR. Larger grantees with funds in excess of $100M+ require a substantially greater number of reporting activities, thus averaging approximately 57 hours per quarter. The estimated annual total number of hours for Disaster Grant reporting is 11,485 for the first year of this collection (which includes one-time only submissions) and 10,977 for the second year (recurring reporting only).

Status of the proposed information collection: This notice precedes a continuation of the existing burden hour request.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35, as amended.

Dated: February 14, 2013.

Mark Johnston,

Deputy Assistant Secretary for Special Needs Programs.

[FR Doc. 2013–04173 Filed 2–22–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

[Docket ID BSEE–2012–0015; OMB Number 1014–0019]

Information Collection Activities: Oil and Gas Production Requirements; Submitted for Office of Management and Budget (OMB) Review; Comment Request

ACTION: 30-day Notice.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the public that we have submitted to OMB an information collection request (ICR) to renew approval of the paperwork requirements in the regulations under Subpart K, *Oil and Gas Production Requirements.* This notice also provides the public a second opportunity to comment on the revised paperwork burden of these regulatory requirements.

DATES: You must submit comments by March 27, 2013.

ADDRESSES: Submit comments by either fax (202) 395–5806 or email (*OIRA_Submission@omb.eop.gov*) directly to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for the Department of the Interior (1014–0019). Please provide a copy of your comments to BSEE by any of the means below.

- *Electronically:* go to *http://www.regulations.gov.* In the entry titled, Enter Keyword or ID, enter BSEE–2012–0015 then click search. Follow the instructions to submit public comments and view all related materials. We will post all comments.
- *Email: cheryl.blundon@bsee.gov*, fax (703) 787–1546, or mail or hand-carry comments to: Department of the Interior; BSEE; Regulations and Standards Branch; Attention: Cheryl Blundon; 381 Elden Street, HE3313; Herndon, Virginia 20170–4817. Please reference 1014–0019 in your comment and include your name and return address.

FOR FURTHER INFORMATION CONTACT: Cheryl Blundon, Regulations and Standards Branch, (703) 787–1607, to request additional information about this ICR. To see a copy of the entire ICR submitted to OMB, go to *http://www.reginfo.gov* (select Information Collection Review, Currently Under Review).

SUPPLEMENTARY INFORMATION:

Title: 30 CFR 250, Subpart K, Oil and Gas Production Requirements.

Form(s): BSEE–0126 and -0128.

OMB Control Number: 1014–0019.

Abstract: The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior to prescribe rules and regulations to administer leasing of mineral resources on the OCS. Such rules and regulations will apply to all operations conducted under a lease, right-of-way, or a right-of-use and easement. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition.

Section 5(a) of the OCS Lands Act requires the Secretary to prescribe rules and regulations ''to provide for the prevention of waste, and conservation of the natural resources of the Outer Continental Shelf, and the protection of correlative rights therein'' and to include provisions ''for the prompt and efficient exploration and development of a lease area.''

Section 1334(g)(2) states ''* * * the lessee shall produce such oil or gas, or

both, at rates * * * to assure the maximum rate of production which may be sustained without loss of ultimate recovery of oil or gas, or both, under sound engineering and economic principles, and which is safe for the duration of the activity covered by the approved plan.''

In addition to the general authority of OCSLA, section 301(a) of the Federal Oil and Gas Royalty Management Act (FOGRMA), 30 U.S.C. 1751(a), grants authority to the Secretary to prescribe such rules and regulations as are reasonably necessary to carry out FOGRMA's provisions. While the majority of FOGRMA is directed to royalty collection and enforcement, some provisions apply to offshore operations. For example, section 109(c)(2) and (d)(1), 30 U.S.C. 1719(c)(2) and (d)(1), impose substantial civil penalties for failure to permit lawful inspections and for knowing or willful preparation or submission of false, inaccurate, or misleading reports, records, or other information. The Secretary has delegated some of the authority under FOGRMA to BSEE.

The Independent Offices Appropriations Act (31 U.S.C. 9701), the Omnibus Appropriations Bill (Pub. L. 104–133, 110 Stat. 1321, April 26, 1996), and OMB Circular A–25, authorize Federal agencies to recover the full cost of services that confer special benefits. Under the Department of the Interior's implementing policy, the Bureau of Safety and Environmental Enforcement (BSEE) is required to charge the full cost for services that provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those that accrue to the public at large. Several requests for approval required in Subpart K are subject to cost recovery and BSEE regulations specify service fees for these requests.

In addition, BSEE also issues various Notices to Lessees (NTLs) and Operators to clarify and provide additional guidance on some aspects of the regulations, as well as forms to capture the data and information. The current Subpart K regulations specify the use of forms BSEE–0126 (Well Potential Test Report) and BSEE–0128 (Semiannual Well Test Report). We have included a certification statement, on both forms, to state that false submissions are subject to criminal penalties. Also, we clarified some sections of Form BSEE–0126. These clarifications pose minor edits and they are as follows: In Block No. 88, TYPE OF REQUEST, we added the word 'Reestablish'; in Block No. 108, we revised what read 'API @ 60° F' to now read as 'API @ 14.73 PSI & 60° F'; and in Block No. 109, we revised what read 'SP GR GAS' to now read as 'SP GR GAS @ 14.73 PSI & 60°F'.

Regulations implementing these responsibilities are under 30 CFR part 250, subpart K. Responses are mandatory or are required to obtain or retain a benefit. No questions of a sensitive nature are asked. The BSEE protects information considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under regulations at 30 CFR 250.197, *Data and information to be made available to the public or for limited inspection,* 30 CFR Part 252, *OCS Oil and Gas Information Program.*

The information collected under Subpart K is used in our efforts to conserve natural resources, prevent waste, and protect correlative rights, including the Federal Government's royalty interest. Specifically, BSEE uses the information to:

- Evaluate requests to burn liquid hydrocarbons and vent and flare gas to ensure that these requests are appropriate;
- Determine if a maximum production or efficient rate is required; and,
- Review applications for downhole commingling to ensure that action does not result in harm to ultimate recovery.

We collect the information required under this Subpart for reservoir, reserves, and conservation analyses, including the determination of maximum production rates (MPRs) when necessary for certain oil and gas completions and to evaluate the results of well tests to determine if reservoirs are being depleted in a manner that will lead to the greatest ultimate recovery of hydrocarbons.

Frequency: On occasion, daily, monthly, semi-annual, annual, and as required by regulations.

Description of Respondents: Potential respondents comprise OCS Federal oil, gas, or sulphur lessees and/or operators.

Estimated Reporting and Recordkeeping Hour Burden: The estimated annual hour burden for this information collection is a total of 20,312 hours. The following chart details the individual components and estimated hour burdens. In calculating the burdens, we assumed that respondents perform certain requirements in the normal course of their activities. We consider these to be usual and customary and took that into account in estimating the burden.

30 CFR 250 Subpart K and related NTLs	Reporting and recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours (rounded)
WELL TESTS/SURVEYS and CLASSIFYING RESERVOIRS				
1151(a)(1), (c); 1167	Conduct well production test; submit Form BSEE–0126 (Well Potential Test Report) and supporting information within 15 days after end of test period.	3	1,210 forms	3,630
1151(a)(2), (c); 1167	Conduct well production test; submit Form BSEE–0128 (Semiannual Well Test Report) and supporting information within 45 days after end of calendar half-year.	0.1 to 3*	11,136 GOM forms 60 POCS forms	2,836
1151(b)	Request extension of time to submit results of semi-annual well test.	0.5	13 requests	7
1152(b), (c);	Request approval to conduct well testing using alternative procedures.	0.75	5 requests	4
1152(d)	Provide advance notice of time and date of well tests.	0.5	12 notices	6
Subtotal			12,616 responses	6,483

30 CFR 250 Subpart K and related NTLs	Reporting and recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours (rounded)
APPROVALS PRIOR TO PRODUCTION				
1156; 1167	Request approval to produce within 500 feet of a unit or lease line; submit supporting information/documentation; notify adjacent operators and provide BSEE proof of notice date.	5	15 requests	75
		$3,608 × 15 requests = $54,120		
1156(b); 1158(b)	Notify adjacent operators submit letters of acceptance or objection to BSEE within 30 days after notice; include proof of notice date.	.5	15 letters	8
1157; 1167	Request approval to produce gas-cap gas in an oil reservoir with an associated gas cap, or to continue producing an oil well showing characteristics of a gas well with an associated gas cap; submit producing an oil well showing characteristics of a gas well with an associated gas cap; submit supporting information.	12	48 requests	576
		$4,592 × 48 requests = $220,416		
1158; 1167	Request approval to downhole commingle hydrocarbons; submit supporting information; notify operators and provide proof of notice date.	6	30 applications	180
		$5,357 × 30 applications = $160,710		
Subtotal			108 responses	839
			$435,246 non-hour costs	
FLARING, VENTING, and BURNING HYDROCARBONS				
1160; 1161; 1163(e)	Request approval to flare or vent natural gas or exceed specified time limits/volumes; submit evaluation/documentation; report flare/vent information due to blow down of transportation pipelines within 72 hours after incident.	0.75	1,146 requests/reports	860
1160(b); 1164(b)(1), (2)	H_2S Contingency, Exploration, or Development and Production Plans and, Development Operations Coordination Documents–burdens covered under 1014–0018 and BOEM's 1010–0151. Monitor air quality and report—burdens covered under 1010–0057.			0
1162; 1163(e)	Request approval to burn produced liquid hydrocarbons; demonstrate no risk and/or submit documentation re transport. If approval needed, submit documentation with relevant information re hydrocarbons burned under the approval.	0.5	6 requests/reports	3
1163	Initial purchase or replacement of gas meters to measure the amount of gas flared or vented. This is a non-hour cost burden.	54 meters @ $77,000 each—$4,158,000		
1163(a)(1)	Notify BSEE when facility begins to process more than an average of 2,000 bopd per month.	1	32 notices	32
1163(b);	Report to ONRR hydrocarbons produced, including measured gas flared/vented and liquid hydrocarbon burned—burden covered under 1012–0004.			0
1163(a), (c), (d)	Maintain records for 6 years detailing on a daily and monthly cumulative basis gas flaring/venting, liquid hydrocarbon burning; and flare/vent meter recordings; make available for inspection or provide copies upon request.	13	892 platforms (gas flare/vent).	11,596
		.5	60 liquid hydrocarbon	30
1164(c)	Submit monthly reports of flared or vented gas containing H_2S.	3	3 operators × 12 mos. = 36.	108
Subtotal			2,172 responses	12,629

30 CFR 250 Subpart K and related NTLs	Reporting and recordkeeping requirement	Non-hour cost burdens		
		Hour burden	Average number of annual responses	Annual burden hours (rounded)
			$4,158,000 non-hour costs	
OTHER REQUIREMENTS				
1165	Submit proposed plan and supporting information for enhanced recovery operations.	12	16 plans	192
1165(c)	Submit periodic reports of volumes of oil, gas, or other substances injected, produced, or produced for a second time—burden covered under ONRR's 1012–0004.			0
1166	Alaska Region only: submit annual reservoir management report and supporting information.	1	1 (req'd by State, we get copy).	1
		100	1 new develop- ment not State lands..	100
		20	3 annual revisions	60
1150–1167	General departure or alternative compliance requests not specifically covered elsewhere in Subpart K.	1.5	5 submissions	8
Subtotal			26 responses	361
Total Burden			14,922 responses	20,312
			$4,593,246 non-hour cost burdens	

Estimated Reporting and Recordkeeping Non-Hour Cost Burden: We have identified four non-hour cost burdens associated with the collection of information for a total of $4,593,246. Three are service fees required to recover the Federal Government's processing costs of certain submissions. The fourth cost is an IC equipment expenditure. They are as follows:

§ 250.1156 requires a service fee when submitting a request for approval to produce within 500 feet of a unit or lease line—$3,608.

§ 250.1157 requires a service fee when submitting a request for approval before producing gas-cap gas from each completion in an oil reservoir known to have an associated gas cap, or to continue producing if an oil reservoir is not initially known to have an associated gas cap, but begins to show characteristics of a gas well—$4,592.

§ 250.1158 requires a service fee for submitting a request for approval to downhole commingle hydrocarbons—$5,357.

§ 250.1163 requires respondents to purchase and install gas meters to measure the amount of gas flared or vented gas for those that produce more than 2,000 bopd and do not already have a meter or need to replace a meter—$77,000.

We have not identified any other non-hour cost burdens associated with this collection of information.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.,)* provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3501, *et seq.,*) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *'' Agencies must specifically solicit comments to: (a) Evaluate whether the collection is necessary or useful; (b) evaluate the accuracy of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of technology.

To comply with the public consultation process, on September 26, 2012, we published a **Federal Register** notice (77 FR 59209) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day comment period. In addition, § 250.199 provides the OMB Control Number for the information collection requirements imposed by the 30 CFR part 250, subpart K regulations and forms. The regulation also informs the public that they may comment at any time on the collections of information and provides the address to which they should send comments. We received one comment in response to the **Federal Register**. We offer the following in response: the commenter states that we are not following the OMB guidance for reducing reporting and paperwork burdens. In our opinion, we believe that the commenter's proposal would not be ''reducing reporting and paperwork burden''. That is, it appears the commenter is suggesting that operators submit flare/vent records to BSEE via ''Web page, tablet device, or smartphone''. If that is the case, we would be increasing the reporting burden as industry is NOT now required to submit such information to BSEE, *i.e.,* operators only have to maintain the records on the facility and make them available during offshore inspections. Of course, new regulations would be needed to require such submittals to BSEE and we would not pursue such a requirement as operators report this information monthly to ONRR on the OGOR reports (which are submitted electronically). As far as reducing ''paperwork burdens'', we don't believe that is applicable under the commenter's proposal either as industry can store their records offshore in an electronic system as long as they are available for offshore inspection.

Relating to the Items on BSEE–0126, the commenter is correct. The items containing the ''θ'', are simply a ''check box'' on the physical form.

Public Availability of Comments: Before including your address, phone number, email address, or other personal identifying information in your

comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: January 29, 2013.

Robert W. Middleton,

Deputy Chief, Office of Offshore Regulatory Programs.

[FR Doc. 2013–04297 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R2–ES–2012–N301; FXES11130200000–134–FF02ENEH00]

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications; request for public comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered or threatened species. The Endangered Species Act of 1973, as amended (Act), prohibits activities with endangered and threatened species unless a Federal permit allows such activities. The Act and the National Environmental Policy Act also require that we invite public comment before issuing these permits.

DATES: To ensure consideration, written comments must be received on or before March 27, 2013.

ADDRESSES: Marty Tuegel, Section 10 Coordinator, by U.S. mail at Division of Endangered Species, U.S. Fish and Wildlife Service, P.O. Box 1306, Room 6034, Albuquerque, NM at (505) 248–6920. Please refer to the respective permit number for each application when submitting comments.

FOR FURTHER INFORMATION CONTACT: Susan Jacobsen, Chief, Endangered Species Division, P.O. Box 1306, Albuquerque, NM 87103; (505) 248–6651.

SUPPLEMENTARY INFORMATION:

Public Availability of Comments

The Act (16 U.S.C. 1531 et seq.) prohibits activities with endangered and threatened species unless a Federal permit allows such activities. Along with our implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR 17, the Act provides for permits, and requires that we invite public comment before issuing these permits.

A permit granted by us under section 10(a)(1)(A) of the Act authorizes applicants to conduct activities with U.S. endangered or threatened species for scientific purposes, enhancement of survival or propagation, or interstate commerce. Our regulations regarding implementation of section 10(a)(1)(A) permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Applications Available for Review and Comment

We invite local, State, Tribal, and Federal agencies, and the public to comment on the following applications. Please refer to the appropriate permit number (e.g., Permit No. TE–123456) when requesting application documents and when submitting comments.

Documents and other information the applicants have submitted with these applications are available for review, subject to the requirements of the Privacy Act (5 U.S.C. 552a) and Freedom of Information Act (5 U.S.C. 552).

Permit TE–022190

Applicant: Arizona-Sonora Desert Museum, Tucson, Arizona.

Applicant requests an amendment to a current permit for research and recovery purposes to conduct pollination on 36 individual adult Arizona hedgehog cactus (*Echinocereus arizonicus*) on Apache County and Cochise County, Arizona.

Permit TE–103480

Applicant: Carianne Campbell, Tucson, Arizona.

Applicant requests a renewal to a current permit for research and recovery purposes to conduct presence/absence surveys of Sonora tiger salamander (*Ambystoma tigrinum stebbinsi),* loach minnow (*Tiaroga cobitis*), and spikedace (*Mega fulgida*) within Arizona.

Permit TE–92222A

Applicant: Elena Pinto-Torres, Austin, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of golden-cheeked warblers (*Dendroica chrysoparia*) and black-capped vireos (*Vireo atricapilla*) within Texas.

Permit TE–92364A

Applicant: Patricia Ramirez, Austin, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of golden-cheeked warblers (*Dendroica chrysoparia*) and black-capped vireos (*Vireo atricapilla*) within Texas.

Permit TE–43777A

Applicant: Sea Life US, LLC, Grapevine, Texas.

Applicant requests an amendment to a current permit for husbandry and holding of hawksbill sea turtles (*Eretmochelys imbricata*) within Sea Life Aquarium, Grapevine, Texas.

Permit TE–92366A

Applicant: Kimley-Horn and Associates, Inc., Dallas, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of interior least tern (*Sterna antillarum*) within Texas.

Permit TE–92407A

Applicant: Raven Environmental Services, Inc., Huntsville, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of red-cockaded woodpecker (*Picoides borealis*) within Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Missouri, North Carolina, South Carolina, and Virginia.

Permit TE–88519A

Applicant: Texas Tech University, Lubbock,Texas.

Applicant requests a renewal to a current permit for research and recovery purposes to conduct presence/absence surveys and collect voucher specimens of the following species within Texas and New Mexico:

- Roswell springsnail (*Pyrgulopsis roswellensis*)
- Koster's springsnail (*Juturnia kosteri*)
- Pecos assiminea snail (*Assiminea pecos*)
- Noel's amphipod (*Gammarus desparatus*)

Permit TE–93447A

Applicant: San Antonio Zoo, San Antonio, Texas.

Applicant requests a new permit for research and recovery purposes to collect up to 500 individual Devils River minnow (Dionda diabolic) from Pinto Creek, Texas and relocate to the San Antonio Zoo for husbandry and captive propagation.

Permit TE–207893

Applicant: Robert Edwards, Edinburg, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys of and capture and release using non invasive techniques such as seining and minnow traps of the following species within Texas:

- Big Bend gambusia (*Gambusia gaigei*)
- Clear Creek gambusia (*Gambusia herochir*)
- Comanche Springs pupfish (*Cyprinodon elegans*)
- Devils River minnow (*Dionda diaboli*)
- Fountain darter (*Etheostoma fonticola*)
- Leon Springs pupfish (*Cyprinodon bovinus*)
- Pecos gambusia (*Gambusia nobilis*)
- Rio Grande silvery minnow (*Hybognathus amarus*)
- San Marco gambusia (*Gambusia georgei*)

Permit TE–64710A

Applicant: Jacob Jackson, Austin, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys and salvage of Houston toad (*Bufo houstonensis*) within Texas.

Permit TE–109028

Applicant: Susan Courage, San Antonio, Texas.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys and salvage of black-capped vireo (*Vireo atricapilla*) and golden-cheeked warbler (*Dendroica chrysoparia*) within Texas.

Permit TE–052634

Applicant: New Mexico Environment Department, Surface Water Quality Bureau, Santa Fe, New Mexico.

Applicant requests a renewal to a current permit for research and recovery purposes to conduct presence/absence surveys of Rio Grande silvery minnow (Hybognathus amarus), loach minnow (*Tiaroga cobitis*), and spikedace (*Mega fulgida*) within New Mexico.

Permit TE–94766A

Applicant: Carmen Greenwood, Oklahoma State University, Stillwater, Oklahoma.

Applicant requests a new permit for research and recovery purposes to conduct presence/absence surveys, trap and relocate activities and other research activities for the American burying beetle (Nicrophorus americanus) within Oklahoma.

Permit TE–001623

Applicant: American Southwest Ichthyological Researchers, LLC., Albuquerque, New Mexico.

Applicant requests an amendment to a current permit for research and recovery purposes to conduct population studies of razorback sucker (*Xyrauchen texanus*) and humpback chub (*Gila cypha*) in the lower Colorado River, Grand Canyon National Park, Arizona.

National Environmental Policy Act (NEPA)

In compliance with NEPA (42 U.S.C. 4321 *et seq.*), we have made an initial determination that the proposed activities in these permits are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement (516 DM 6 Appendix 1, 1.4C(1)).

Public Availability of Comments

All comments and materials we receive in response to this request will be available for public inspection, by appointment, during normal business hours at the address listed in the **ADDRESSES** section of this notice.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the Act (16 U.S.C. 1531 *et seq.*)

Date: February 13, 2013.

Joy E. Nicholopoulos,

Acting Regional Director, Southwest Region.

[FR Doc. 2013–04225 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2013–N042; FXIA16710900000P5–123–FF09A30000]

Endangered Species; Marine Mammals; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species, marine mammals, or both. With some exceptions, the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before March 27, 2013. We must receive requests for marine mammal permit public hearings, in writing, at the address shown in the **ADDRESSES** section by March 27, 2013.

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or email *DMAFR@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our

administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken. Under the MMPA, you may request a hearing on any MMPA application received. If you request a hearing, give specific reasons why a hearing would be appropriate. The holding of such a hearing is at the discretion of the Service Director.

III. Permit Applications

A. Endangered Species

Applicant: Cincinnati Zoo & Botanical Garden, Cincinnati, OH; PRT–76114A

The applicant requests a permit to import biological samples, including semen, from captive-held Sumatran rhinoceros (*Dicerorhinus sumatrensis*) from the Sabah Wildlife Department, Sabah, Malaysia, for the purpose of enhancement of the species through captive propagation and scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Cincinnati Zoo & Botanical Garden, Cincinnati, OH; PRT–96521A

The applicant requests a permit to export and re-export biological samples, including semen, from captive-born and captive-held Sumatran rhinoceros (*Dicerorhinus sumatrensis*) to the Sabah Wildlife Department, Sabah, Malaysia, for the purpose of enhancement of the species through captive propagation and scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: 4D Game Ranch, Sidney, TX; PRT–95026A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the barasingha (*Rucervus duvaucelii*), Eld's deer (*Rucervus eldii*), scimitar-horned oryx (*Oryx dammah*), Arabian oryx (*Oryx leucoryx*), addax (*Addax nasomaculatus*), dama gazelle (*Nanger dama*), and red lechwe (*Kobus leche*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: 4D Game Ranch, Sidney, TX; PRT–95027A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*), and addax (*Addax nasomaculatus*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: La Barronena Ranch East Partners, LP, Hebbronville, TX; PRT–94867A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Southwestern Medical Centers-Arizona Inc., Del Rio, TX; PRT–95424A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*), addax (*Addax nasomaculatus*), and dama gazelle (*Nanger dama*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Southwestern Medical Centers-Arizona Inc., Del Rio, TX; PRT–95422A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*), and addax (*Addax nasomaculatus*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Michael Burroughs, Las Vegas, NV; PRT–94167A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the radiated tortoise (*Astrochelys radiata*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Charles Crawford, Greenville, VA; PRT–96383A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the radiated tortoise (*Astrochelys radiata*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Greg Schmitt, Trafford, PA; PRT–96508A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the radiated tortoise (*Astrochelys radiata*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Brian Buchanan, Beckley, WV; PRT–96499A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*), addax (*Addax nasomaculatus*), and red lechwe (*Kobus leche*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Heart A Ranch, Sonora, TX; PRT–96457A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the scimitar-horned oryx (*Oryx dammah*), and addax (*Addax nasomaculatus*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Heart A Ranch, Sonora, TX; PRT–96459A

The applicant requests a permit authorizing interstate and foreign commerce, export, and cull of excess scimitar-horned oryx (*Oryx dammah*) from the captive herd maintained at their facility, for the purpose of enhancement of the survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Smithsonian National Zoo Park, Washington, DC; PRT–89695A

The applicant requests a permit to export and re-export semen samples, from captive-held and wild specimens of Cheetah (*Acinonyx jubatus*) to Canada for the purpose of enhancement of the species through scientific research.

Applicant: Zoological Wildlife Foundation, Inc., Miami, FL; PRT–96647A

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the ring-tailed lemur (*Lemur catta*), black and white ruffed lemur (*Varecia variegata*), red ruffed lemur (*Varecia rubra*), lar gibbon (*Hylobates lar*), leopard (*Panthera pardus*), and snow leopard (*Uncia uncia*) to enhance the species' propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: International Center For The Preservation of Wild Animals, Cumberland, OH; PRT–793628

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families, and species, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:
- Bovidae
- Cervidae
- Equidae
- Rhinocerotidae
- Gruidae

Species:
- Bactrian camel (*Camelus bactrianus*)
- Peninsular pronghorn (*Antilocapra americana peninsularis*)
- Cheetah (*Acinonyx jubatus*)
- African wild dog *(Lycaon pictus*)
- Dhole (*Cuon alpinus*)

Applicant: Randar's Reptiles, Mcdonough, GA; PRT–034669

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the golden parakeet (*Guarouba guarouba*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Peoria's Glen Oak Zoo, Peoria, IL; PRT–690797

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the following families, and species, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Families:
- Cebidae
- Cercopithecidae
- Felidae (*does not* include jaguar, margay or ocelot)
- Hominidae
- Hylobatidae
- Lemuridae
- Sturnidae (*does not* include *Aplonis pelzelni*)
- Alligatoridae
- Crocodylidae (*does not* include American crocodile)
- Testudinidae

Species:
- Grevy's zebra (*Equus grevyi*)
- Parma wallaby (*Macropus parma*)
- Panamanian golden frog (*Atelopus zeteki*)

Applicant: Exotic Feline Breeding Compound, Rosamond, CA; PRT–708685

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the family Felidae, to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Patricia Green, Willow, CA; PRT–793094

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the golden parakeet (*Guarouba guarouba*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Christopher Resnyk, Linwood, PA; PRT–01668A

The applicant requests renewal of their captive-bred wildlife registration under 50 CFR 17.21(g) for the radiated tortoise (*Astrochelys radiata*) to enhance their propagation or survival. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Rhodes Brothers Taxidermy, Kerrville, TX; PRT–88938A

The applicant requests a permit to export the sport-hunted trophy/trophies of one addax (*Addax nasomaculatus*), and one scimitar-horned oryx (*Oryx dammah*) culled from a captive herd maintained in the state of Texas, for the purpose of enhancement of the survival of the species.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Charles Wall, Greer, SC; PRT–96125A.

Applicant: Lyle Berry, Grand Rapids, MI; PRT–92657A.

B. Endangered Marine Mammals and Marine Mammals

Applicant: Karyn Rode, USGS, Anchorage, AK; PRT–95406A

The applicant requests a permit to take four polar bears (*Ursus maritimus*) captive-held at Alaska Zoo and Oregon Zoo by immobilization, biological sampling and fitting and removal of GPS collars for the purpose of scientific research on polar bears' diet and energetics. This notification covers activities to be conducted by the applicant over a 2-year period.

Concurrent with publishing this notice in the **Federal Register**, we are forwarding copies of the above applications to the Marine Mammal Commission and the Committee of Scientific Advisors for their review.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2013–04239 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–IA–2013–N040; FXIA16710900000P5–123–FF09A30000]

Endangered Species; Marine Mammals; Issuance of Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of issuance of permits.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have issued the following permits to conduct certain activities with endangered species, marine mammals, or both. We issue these permits under the Endangered Species Act (ESA) and Marine Mammal Protection Act (MMPA).

ADDRESSES: Brenda Tapia, Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280; or email *DMAFR@fws.gov*.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2280 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION: On the dates below, as authorized by the provisions of the ESA (16 U.S.C. 1531 *et seq.*), as amended, and/or the MMPA, as amended (16 U.S.C. 1361 *et seq.*), we issued requested permits subject to certain conditions set forth therein. For each permit for an endangered species, we found that (1) The application was filed in good faith, (2) The granted permit would not operate to the disadvantage of the endangered species, and (3) The granted permit would be consistent with the purposes and policy set forth in section 2 of the ESA.

Permit No.	Applicant	Receipt of application **Federal Register** notice	Permit issuance date
	Endangered Species		
83741A	Timothy Jackson	77 FR 58405; September 20, 2012	December 5, 2012.
83806A	Paul Maddison	77 FR 59961; October 1, 2012	December 12, 2012.
86415A	Gene Day	77 FR 61627; October 10, 2012	December 12, 2012.
88316A	David Moore	77 FR 66476; November 5, 2012	January 14, 2013.
84872A	Palm Beach Zoo at Dreher Park	77FR 66476; November 5, 2012	January 11, 2013.
022729	NOAA Fisheries/Pacific Islands Regional Office.	77 FR 68809; November 16, 2012	January 3, 2013.
89103A	Dallas Zoo	77FR 68809; November 16, 2012	February 12, 2013.
89908A	Joseph Borgesen	77 FR 70457; November 26, 2012	January 14, 2013.
89909A	Charles Kleiser	77 FR 70460; November 26, 2012	January 7, 2013.
91698A	Lonnie Henriksen	77 FR 74506; December 14, 2012	January 25, 2013.
91992A	David Combs	77 FR 74506; December 14, 2012	January 25, 2013.
89757A	Indiana University-Purdue University Fort Wayne.	77 FR 74506; December 14, 2012	February 5, 2013.
92768A	Steven Hanlon	78 FR 112; January 2, 2013	February 5, 2013.
91292A	Walter A. Wade	77 FR 74506; December 14, 2012	February 13, 2013.
91988A	Leslie I. Barnhart	77 FR 74506; December 14, 2012	February 13, 2013.
93273A	David Gainer	78 FR 4162; January 18, 2013	February 13, 2013.
	Marine Mammals		
81899A	Shannon Atkinson, University of Alaska	77 FR 58405; September 20, 2012	February 11, 2013.
83724A	SeaWorld Parks & Entertainment, Inc	77 FR 61627; October 10, 2012	February 15, 2013.

Availability of Documents

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to: Division of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 212, Arlington, VA 22203; fax (703) 358–2280.

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2013–04240 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX.13.GG00.99600.00]

Agency Information Collection Activities: Comment Request

AGENCY: U.S. Geological Survey (USGS), Interior.

ACTION: Notice of an extension of an information collection (1028–0051), Annual Announcement of Availability of Funds.

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), the U.S. Geological Survey (USGS) is inviting comments on an information collection request (ICR) that we have sent to the Office of Management and Budget (OMB) for review and approval. The Information Collection, which is summarized below, describes the nature and the estimated burden of the collection. As required by the Paperwork Reduction Act (PRA) of 1995, and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this ICR. This collection is scheduled to expire on February 28, 2013.

DATES: You must submit comments on or before March 27, 2013.

ADDRESSES: You may submit written comments on this information collection directly to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Attention: Desk Officer for the Department of the Interior via email to *OIRA_SUBMISSION@omb.eop.gov* or fax at 202–395–5806; and identify your submission with Information Collection

Number 1028–0051. Please also provide a copy of your comments to the Information Collection Clearance Officer, U.S. Geological Survey, 12201 Sunrise Valley Drive MS 807, Reston, VA 20192 (mail); (703)648–7199 (fax); or *smbaloch@usgs.gov* (email). Please reference Information Collection Number 1028–0051 in the subject line.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, Elizabeth Lemersal, Earthquake Hazards Program, (703) 648–6716. To see a copy of the entire ICR submitted to OMB, go to *http://www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Earthquake Hazards Program Research and Monitoring.

OMB Control Number: 1028–0051.

Type of Request: Extension of a currently approved collection.

Abstract: Research and monitoring findings are essential to fulfilling USGS's responsibility under the Earthquake Hazards Reduction Act to develop earthquake hazard assessments and recording and reporting earthquake activity nationwide. Residents, emergency responders, and engineers rely on the USGS for this accurate and scientifically sound information. Respondents to Program Announcements submit proposals to support research and monitoring related to earthquake hazard assessments, earthquake causes and effects, and earthquake monitoring. This information is used as the basis for selection and award of projects meeting the USGS's Earthquake Hazards Program objectives. Final reports of research and monitoring findings are required for each funded proposal; annual progress reports are required for awards of a two- to five-year duration. Final reports are made available to the public at the Web site *http://earthquake.usgs.gov/research/external/.*

I. Data

Title: National Earthquake Hazards reduction Program Annual Announcement of Availability of Funds.

OMB Control Number: 1028–0051.

Type of Request: Extension of a currently approved collection.

Affected Public: Research scientists, engineers, and the general public.

Respondent Obligation: Voluntary; necessary to receive benefits.

Frequency of Collection: Annually: Grant proposals and reporting; Every two to five years: Cooperative Agreement proposals and reporting.

Estimated Annual Number of and Description of Respondents: 250 Educational institutions, and profit and non-profit organizations.

Estimated Annual Number of Responses: 350 (250 applications and narratives and 100 annual and final reports).

Estimated Completion Time: 45 hours per application response and 12 hours per final report.

Estimated Annual Burden Hours: 12,450 (11,250 hours for applications and 1,200 hours for final reports).

Estimated Annual Reporting and Recordkeeping ''Hour'' Burden: We estimate the public reporting burden will average 45 hours per application response. This includes time to develop project goals, write the statement of work, perform internal proposal reviews, and submit the proposal through grants.gov. We estimate the public reporting burden will average 12 hours per final or annual report response. This includes summarizing accomplishments for the past year's funded efforts.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: We have not identified any ''non-hour cost'' burdens associated with this collection of information.

II. Request for Comments

On October 31, 2012, we published a **Federal Register** notice (77 FR 65903) soliciting comments announcing that we would submit this information to OMB for approval. We solicited comments for a period of 60 days, ending on December 31, 2012. We did not receive any comments concerning that notice.

We again invite comments concerning this information collection on: (1) Whether or not the collection of information is necessary, including whether or not the information will have practical utility; (2) the accuracy of our estimate of the burden for this collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents.

Please note that the comments submitted in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Dated: February 19, 2013.

William Leith,

Senior Science Advisor for Earthquake and Geologic Hazards.

[FR Doc. 2013–04219 Filed 2–22–13; 8:45 am]

BILLING CODE 4311–AM–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAZG03000.L16100000.DQ0000. LXSS085A0000.241A.00]

Notice of Availability of the Ironwood Forest National Monument Record of Decision and Approved Resource Management Plan, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD)/Approved Resource Management Plan (RMP) for the Ironwood Forest National Monument (IFNM), located in portions of Pima and Pinal counties, northwest of Tucson, Arizona. The IFNM was established by Presidential Proclamation on June 9, 2000, for the protection of the significant cultural, biological, geological, and natural resources. These resources were identified as Monument objects in the Proclamation. The Arizona State Director signed the ROD on February 19, 2013, which constitutes the final decision of the BLM and makes the Approved RMP effective immediately.

ADDRESSES: Copies in electronic format on compact disk of the ROD/Approved RMP are available in the Tucson Field Office, Bureau of Land Management, 3201 East Universal Way, Tucson, AZ 85756. It is also accessible on the Internet at *http://www.blm.gov/az/st/en/prog/planning/ironwood.html.* Printed copies of the ROD/Approved RMP are available for public inspection at the BLM Tucson Field Office.

FOR FURTHER INFORMATION CONTACT: Brian Bellew, Tucson Field Manager, telephone: 520–258–7235; address: 3201 East Universal Way, Tucson, AZ 85756; or email: *AZ_IFNM_RMP@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) can call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a

message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Through communication media such as meetings, newsletters, planning bulletins, and news releases, the public was provided opportunities to identify issues that needed to be addressed and to participate in the development of plan alternatives. The public provided comments during the 90-day public comment period on the Draft RMP/Draft Environmental Impact Statement (EIS) published on March 2, 2007 (72 FR 9576); these were addressed in the Proposed RMP/Final EIS published on September 23, 2011 (76 FR 59156).

The Proposed RMP/Final EIS was developed with input and cooperation with the following: Arizona Game and Fish Department, Ak Chin Indian Community, Gila River Indian Community, Tohono O'odham Nation, Salt River Pima-Maricopa Indian Community, Pascua Yaqui Tribe, Pima and Pinal counties, Natural Resources Conservation Service, U.S. Fish and Wildlife Service, Arizona State Historic Preservation Office, Arizona State Land Department, and Pima Natural Resource Conservation District.

The IFNM encompasses approximately 128,400 acres of Federal land administered by the BLM; approximately 54,700 acres of State Trust Land inholdings administered by the Arizona State Land Department; approximately 6,000 acres of private land inholdings, 641 acres of Pima County inholdings, and 326 acres of military withdrawal lands. The ROD/Approved RMP applies only to Federal lands and interests located within the established boundary of the IFNM. The BLM's Gila District Tucson Field Office has the responsibility of planning for and management of Federal lands within the IFNM.

The Approved RMP is the same as Alternative C in the Proposed RMP, with minor modifications made in preparing the Approved RMP. The BLM received eight protest letters on the Proposed RMP/Final EIS. The BLM Director denied all protest issues. The Director's Protest Resolution Report can be accessed at the following Web site: *http://www.blm.gov/wo/st/en/prog/planning/planning_overview/protest_resolution/protestreports.html.*

Key decisions in the ROD/Approved RMP include:

1. Off-highway vehicle use designations are established, limiting all motorized vehicle use to designated routes on approximately 117,520 acres and closing 10,880 acres to all motorized vehicle use. Guidance for management of the Monument access route network is provided, and a transportation plan with route-specific management objectives will be developed within 6 months of the effective date of the ROD/Approved RMP. Travel route designations include 124 miles of roads and primitive roads to provide motorized access and travel; 118 miles of routes to accommodate administrative use of motorized vehicles and public use for non-motorized and non-motorized mechanized travel; and 90 miles of routes to accommodate non-motorized non-mechanized travel for administrative and public use. Seventeen (17) miles of routes will be closed and restored.

2. Monument lands are closed to recreational target shooting. State Trust Land inholdings are already off limits to recreational target shooting. This change will help bring consistency in the way both Federal and State lands are managed and help reduce confusion for the public. Hunting will continue to be allowed in accordance with Arizona hunting laws and regulations.

The BLM determined that the IFNM ROD/Approved RMP provides a framework for long-term protection of Monument objects while allowing authorized uses, recreation activities, and scientific studies that are consistent with the protection of the objects of the Monument.

The Arizona Governor's Office did not identify any inconsistencies between the Proposed RMP/Final EIS and State or local plans, policies, and programs during the Governor's Consistency Review.

The ROD/Approved RMP for the IFNM contains implementation level decisions that identify travel route designations for roads, primitive roads, administrative roads and trails, and route closures for restoration, with specific management designations which are described in Appendix D of the ROD/Approved RMP. These implementation decisions establish the route network for motorized and non-motorized access for administrative purposes and public use within the IFNM.

Any party adversely affected by these implementation level decisions may file an appeal within 30 days of publication of this Notice of Availability pursuant to 43 CFR part 4, subpart E. The appeal should state the specific route(s), as identified in Appendix D of the ROD/Approved RMP, on which the decision is being appealed and describe the reasons for the appeal. The appeal must be filed with the Tucson Field Manager at the above address. Please consult the appropriate regulations for further appeal requirements.

Authority: 40 CFR 1502.2 and 43 CFR 1610.5.

Deborah K. Rawhouser,

Acting Arizona State Director.

[FR Doc. 2013–04259 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection; Request for Comments for 1029–0120

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

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection request for the Nomination and Request for Payment Form for OSM's Technical Training Courses, has been submitted to the Office of Management and Budget (OMB) for review and approval. This information collection activity was previously approved by OMB, and assigned control number 1029–0120. The information collection request describes the nature of the information collection and its expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, public comments should be submitted to OMB by March 27, 2013, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov*, or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0120 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection

request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted a request to OMB to renew its approval of the collection of information found in its Nomination and Request for Payment Form for OSM Technical Training Courses. OSM is requesting a 3-year term of approval for this collection. This collection is required to obtain or retain a benefit.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0120. State and Tribal regulatory and reclamation employees and industry personnel are required to respond to obtain a benefit.

As required by 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on December 11, 2012 (77 FR 73673). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: Nomination and Request for Payment Form for OSM Technical Training Courses.

OMB Control Number: 1029–0120.

Summary: The information is used to identify and evaluate the training courses requested by students to enhance their job performance, to calculate the number of classes and instructors needed to complete OSM's technical training mission, and to estimate costs to the training program.

Bureau Form Numbers: OSM–105.

Frequency of Collection: Once per training course.

Description of Respondents: State and Tribal regulatory and reclamation employees and industry personnel.

Total Annual Responses: 944 responses.

Total Annual Burden Hours: 5 minutes per response, or 79 total hours.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the offices listed in the **ADDRESSES** section. Please refer to OMB control number 1029–0120 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: February 19, 2013.

Andrew F. DeVito,

Chief, Division of Regulatory Support.

[FR Doc. 2013–04249 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection; Request for Comments for 1029–0057

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

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing that the information collection request for Reclamation on Private Land, has been forwarded to the Office of Management and Budget (OMB) for review and approval. This information collection activity was previously approved by OMB and assigned control number 1029–0057. This information collection request describes the nature of the information collection and its expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection requests but may respond after 30 days. Therefore, public comments should be submitted to OMB by March 27, 2013, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov,* or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0057 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review the information collection request online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSM has submitted the request to OMB to renew its approval for the collection of information found at 30 CFR part 882. OSM is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0057, and may be found in OSM's regulations at 30 CFR 882.10. States and Tribes are required to respond to obtain a benefit.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection was published on December 11, 2012 (77 FR 73674). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR part 882—Reclamation on Private Land.

OMB Control Number: 1029–0057.

Summary: Public Law 95–87 authorizes Federal, State, and Tribal governments to reclaim private lands and allows for the establishment of procedures for the recovery of the cost of reclamation activities on privately owned lands. These procedures are intended to ensure that governments have sufficient capability to file liens so that certain landowners will not receive a windfall from reclamation.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: State governments and Indian tribes.

Total Annual Responses: 1.

Total Annual Burden Hours: 120.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the places listed in **ADDRESSES**. Please refer to control number 1029–0057 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment–including your personal identifying information–may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: February 19, 2013.

Andrew F. DeVito,

Chief, Division of Regulatory Support.

[FR Doc. 2013–04241 Filed 2–22–13; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–919 (Second Review)]

Welded Large Diameter Line Pipe From Japan; Scheduling of a Full Five-Year Review Concerning the Antidumping Duty Order on Welded Large Diameter Line Pipe From Japan

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of a full review pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) (the Act) to determine whether revocation of the antidumping duty order on welded large diameter line pipe from Japan would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATES: *Effective Date:* February 19, 2013.

FOR FURTHER INFORMATION CONTACT: Edward Petronzio (202–205–3176), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION:

Background.—On January 4, 2013, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review pursuant to section 751(c)(5) of the Act should proceed (78 FR 3916, January 17, 2013). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's Web site.

Participation in the review and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. § 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the review will be placed in the nonpublic record on July 15, 2013, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the review beginning at 9:30 a.m. on August 1, 2013, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before July 25, 2013. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on July 29, 2013, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is July 24, 2013. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is August 12, 2013; witness testimony must be filed no later than three days before the hearing. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before August 12, 2013. On September 5, 2013, the Commission

will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before September 9, 2013, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to electronic filing have been amended. The amendments took effect on November 7, 2011. See 76 Fed. Reg. 61937 (Oct. 6, 2011) and the newly revised Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov*.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: February 19, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–04163 Filed 2–22–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–745]

Certain Wireless Communication Devices, Portable Music and Data Processing Devices, Computers and Components Thereof; Commission Decision To Review in Part a Remand Initial Determination Finding No Violation of Section 337; Request for Written Submissions

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part the presiding administrative law judge's (''ALJ'') remand initial determination (''Remand ID'') issued on December 18, 2012, finding no violation of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337 in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on November 8, 2010, based on a complaint filed by Motorola Mobility, Inc. of Libertyville, Illinois. 75 FR 68619–20 (Nov. 8, 2010). The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain wireless communication devices, portable music and data processing devices, computers and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 6,272,333 (''the '333 patent''); 6,246,862 (''the '862 patent''); 6,246,697 (''the '697 patent''); 5,359,317 (''the '317 patent''); 5,636,223 (''the '223 patent''); and 7,751,826 (''the '826 patent''). The complaint further alleges the existence of a domestic industry. The Commission's notice of investigation named Apple Inc. of Cupertino, California as respondent. The Office of Unfair Import Investigation (''OUII'') was named as a participating party, however, on July 29, 2011, OUII withdrew from further participation in the investigation. *See* Commission Investigative Staff's Notice of Nonparticipation (July 29, 2011). The Commission later partially terminated the investigation as to the '317 patent and the '826 patent. Notice (June 28, 2011); Notice (Jan 27, 2012).

On April 24, 2012, the ALJ issued his final ID, finding a violation of section 337 as to the '697 patent and finding no violation as to the '223, '333, and '697 patents. On May 9, 2012, the ALJ issued his recommended determination on remedy and bonding. On June 25, 2012, the Commission determined to review the final ID in part. 77 FR 38826–29 (June 29, 2012). On August 24, 2012, the Commission found no violation with respect to the '333 patent, the '697 patent, and the '223 patent. 77 FR 52759–761 (Aug. 30, 2012). The Commission remanded the investigation to the ALJ with respect to the '862 patent upon reversing his finding that the asserted claim of the patent is invalid as indefinite. *Id.; see* Order (Aug. 24, 2012). Specifically, the Commission instructed the ALJ to make findings regarding infringement, validity, and domestic industry concerning the asserted claim of the '862 patent. The Commission's Order instructed the ALJ to set a new target as necessary to accommodate the remand proceedings. On October 1, 2012, the ALJ issued Order No. 36, setting the target date for completion of the remand proceedings as April 22, 2013. Order No. 36 (Oct. 1, 2012). On October 18, 2012, the Commission determined not to review the ID setting the new target date. Notice (Oct. 18, 2012).

On December 18, 2012, the ALJ issued his Remand ID, finding no violation of section 337 with respect to the '862 patent. In particular, the ALJ found that the relevant accused products infringe claim 1 of the '862 patent literally and under the doctrine of equivalents. The ALJ also found, however, that claim 1 is invalid as anticipated by U.S. Patent No. 6,052,464 to Harris (''Harris '464''). The ALJ further found that claim 1 is not invalid for obviousness in light of Harris

'464 in combination with the knowledge of one of ordinary skill in the art or in combination with U.S. Patent No. 5,894,298 to Hoeksma (''Hoeksma '298''). The ALJ also found that Motorola has satisfied the economic and technical prongs of the domestic industry requirement with respect to the '862 patent.

On January 7, 2013, Motorola filed a petition for review of certain aspects of the Remand ID's findings concerning claim construction and validity. Also on January 7, 2013, Apple filed a petition for review of certain aspects of the final ID's findings concerning infringement. On January 15, 2013, Motorola filed a response to Apple's petition. Also on January 15, 2013, Apple filed a response to Motorola's petition.

Having examined the record of this investigation, including the ALJ's Remand ID, the petitions for review, and the responses thereto, the Commission has determined to review the Remand ID in part. Specifically, the Commission has determined to review the Remand ID's construction of the claim limitation ''touch sensitive input device'' in claim 1 of the '862 patent. The Commission has further determined to review the Remand ID's finding that the accused products literally infringe claim 1 of the '862 patent. The Commission has also determined to review the Remand ID's finding that Harris '464 anticipates claim 1 of the '862 patent. The Commission has further determined to review the Remand ID's finding of non-obviousness pursuant to section 210.44 of the Commission's Rules of Practice and Procedure (19 CFR 210.44).

The Commission has determined not to review the remaining issues decided in the Remand ID.

In connection with its review, the parties are requested to brief their positions on the issue of whether claim 1 of the '862 patent is obvious in view of Harris '464 in combination with the knowledge of one of ordinary skill in the art or in combination with Hoeksma '298. The Commission is particularly interested in responses to the following question:

> Does the evidence in the record support a finding that claim 1 of the '862 patent is obvious in view of Harris '464 in combination with the knowledge of one of ordinary skill in the art or in combination with Hoeksma '298 where the evidence demonstrates that the existence of portable communication devices using ''touch sensitive input devices,'' including touch screens, were known in the art prior to the filing of the application leading to the '862 patent and is disclosed in Hoeksma '298? In discussing this issue, please refer to the teachings of the references, the knowledge of one of ordinary skill in the art at the time of filing of the '862 patent application, and the evidence in the record regarding the motivation to combine Harris '464 with the knowledge of one of ordinary skill in the art or with Hoeksma '298. Also, please address whether there are any secondary considerations that would prevent a finding of obviousness.

The parties have been invited to brief only the discrete issues described above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or a cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury.

The Commission will consider the issues related to remedy, the public interest, and bonding based upon filings previously submitted by the parties to the investigation, interested government agencies, the Office of Unfair Import Investigations, and other interested parties. *See* Public Interest submissions filed on July 9, 2012. We also note that the Complainant has previously provided the dates that the patent-at-issue expires and the HTSUS numbers under which the accused products are imported. *See* Complainant Motorola Mobility LLC's Opening Brief on Commission Review (Public Ver.) at 70 (July 19, 2012). Complainant has also previously submitted proposed remedial orders for the Commission's consideration. *See id.* at Exhs. 7 & 8.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. The written submissions must be filed no later than close of business on March 8, 2013. Reply submissions must be filed no later than the close of business on March 15, 2013. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

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 investigation number (''Inv. No. 337–TA–745'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). 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. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.42–46 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 210.42–46 and 210.50).

Issued: February 19, 2013.

By order of the Commission.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–04183 Filed 2–22–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–540]

Digital Trade in the U.S. and Global Economies, Part 2; Institution of Investigation and Scheduling of Hearing

AGENCY: United States International Trade Commission.

ACTION: Institution of investigation, opportunity to appear at public hearing and provide written submissions, and extension of deadlines for filing requests to appear at hearing and pre-hearing briefs and statements.

SUMMARY: In response to a request from the Senate Committee on Finance (Committee) dated December 13, 2012 (received on December 14, 2012) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission has instituted the second of two investigations, investigation No. 332–540, *Digital Trade in the U.S. and Global Economies, Part 2.* The Commission's report in this investigation will build upon the approaches outlined in the Commission's report in the first investigation, No. 332–531, *Digital Trade in the U.S. and Global Economies, Part 1,* which is scheduled to be transmitted to the Committee by July 14, 2013. The Commission has previously announced that it will hold a public hearing in the two investigations on March 7, 2013.

DATES:

February 28, 2013: New deadline for filing requests to appear at the public hearing.
February 28, 2013: New deadline for filing pre-hearing briefs and statements.
March 7, 2013: Public hearing.
March 14, 2013: Deadline for filing post-hearing briefs and statements.
March 21, 2014: Deadline for filing all other written submissions.
July 14, 2014: Transmittal of Commission report to the Committee.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov/edis3-internal/app.*

FOR FURTHER INFORMATION CONTACT: Project Leader James Stamps (202–205–3227 or *james.stamps@usitc.gov*) or Deputy Project Leader David Coffin (202–205–2232 or *david.coffin@usitc.gov*) for information specific to this investigation. For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Web site (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: As requested by the Committee, the Commission will base its report in this second investigation on available information, including a survey of U.S. firms in selected industries particularly involved in digital trade and the application of approaches outlined in the first report. To the extent practicable, this second report will:

- Estimate the value of U.S. digital trade and the potential growth of this trade (with the potential growth estimates to highlight any key trends and discuss their implications for U.S. businesses and employment);
- Provide insight into the broader linkages and contributions of digital trade to the U.S. economy (such linkages and contributions may include effects on consumer welfare, output, productivity, innovation, business practices, and job creation);
- Present case studies that examine the importance of digital trade to selected U.S. industries that use or produce such goods and services, with some of the case studies to highlight, if possible, the impact of digital trade on small and medium-sized enterprises; and
- Examine the effect of notable barriers and impediments to digital trade on selected industries and the broader U.S. economy.

The Commission expects to transmit this second report to the Committee by July 14, 2014.

The Commission published notice of institution of the first investigation, investigation No. 332–531, *Digital Trade in the U.S. and Global Economies, Part 1,* and the scheduling of a public hearing for both investigations, in the **Federal Register** of January 14, 2013 (78 FR 2690). The Commission will transmit its report to the Committee in this first investigation by July 14, 2013. As requested by the Committee, in its first report the Commission will:

- Describe U.S. digital trade in the context of the broader economy;
- Examine U.S. and global digital trade, the relationship to other cross-border transactions (e.g., foreign direct investment), and the extent to which digital trade facilitates and enables trade in other sectors;
- Describe notable barriers and impediments to digital trade; and
- Outline potential approaches for assessing the linkages and contributions of digital trade to the U.S economy, noting any challenges associated with data gaps and limitations; such contributions and linkages may include effects on consumer welfare, output, productivity, innovation, business practices, and job creation.

For the purposes of these reports, the Commission is defining ''digital trade'' to encompass commerce in products and services delivered over digital networks. Examples include software, digital media files (e.g., e-books and digital audio files), and services such as data processing and hosting. The report will also examine how other industries, such as financial services and retailing, make use of digital products and services for production and trade.

Public Hearing: A public hearing in connection with these investigations will be held at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC, beginning at 9:30 a.m. on March 7, 2013. Requests to appear at the public hearing should be filed with the Secretary, no later than 5:15 p.m., February 28, 2013, in accordance with the requirements in the ''Submissions'' section below. All pre-hearing briefs and statements should be filed not later than 5:15 p.m., February 28, 2013; and all post-hearing briefs and statements responding to matters raised at the hearing should be filed not later than 5:15 p.m., March 14, 2013. In the event that, as of the close of business on February 28, 2013, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after February 28, 2013, for information concerning whether the hearing will be held.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to submit written statements concerning these

investigations. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., March 21, 2014. All written submissions must conform with the provisions of section 201.8 of the Commission's *Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any submissions that contain confidential business information (CBI) must also conform to the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''non-confidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

In its request letter, the Committee stated that it intends to make the Commission's reports available to the public in their entirety, and asked that the Commission not include any confidential business information or national security classified information in the reports that the Commission sends to the Committee. Any confidential business information received by the Commission in this investigation and used in preparing this report will not be published in a manner that would reveal the operations of the firm supplying the information.

By order of the Commission.

Issued: February 19, 2013.

Lisa Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–04161 Filed 2–22–13; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–870]

Certain Electronic Bark Control Collars; Notice of Institution of Investigation; Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint and a motion for temporary relief were filed with the U.S. International Trade Commission on January 14, 2013, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Radio Systems Corporation of Knoxville, Tennessee. Supplements to the complaint were filed on February 6, 2013. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain electronic bark control collars by reason of infringement of certain claims of U.S. Patent No. 5,927,233 (''the '233 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue an exclusion order and a cease and desist order.

The motion for temporary relief requests that the Commission issue a temporary limited exclusion order and temporary cease and desist order prohibiting the importation into and the sale within the United States after importation of certain electronic bark control collars that infringe claims 1, 3, 6, 8, 9, and 15 of the '233 patent during the course of the Commission's investigation.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2012).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on February 14, 2013, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain electronic bark control collars by reason of infringement of one or more of claims 1, 3, 6, 8, 9, and 15 of the '233 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.58 of the Commission's Rules of Practice and Procedure, 19 CFR 210.58, the motion for temporary relief under subsection (e) of section 337 of the Tariff Act of 1930, which was filed with the complaint, is provisionally accepted and referred to the presiding administrative law judge for investigation;

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is: Radio Systems Corporation, 10427 Petsafe Way, Knoxville, TN 37932.

(b) The respondent is the following entity alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Sunbeam Products, Inc., d/b/a Jarden Consumer Solutions, 2381 NW Executive Center Drive, Boca Raton, FL 33431.

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission,

shall designate the presiding Administrative Law Judge.

Responses to the complaint, the motion for temporary relief, and the notice of investigation must be submitted by the named respondent in accordance with sections 210.13 and 210.59 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13 and 210.59. Pursuant to 19 CFR. 201.16(d)–(e), 210.13(a), and 210.59, such responses will be considered by the Commission if received not later than 10 days after the date of service by the Commission of the complaint, the motion for temporary relief, and the notice of investigation. Extensions of time for submitting responses to the complaint, motion for temporary relief, and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint, in the motion for temporary relief, and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint, the motion for temporary relief, and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint, the motion for temporary relief, and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: February 19, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–04160 Filed 2–22–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0020]

Agency Information Collection Activities; Extension of a Currently Approved Collection: Office on Violence Against Women Solicitation Template

ACTION: 60-Day Notice.

The Department of Justice, Office on Violence Against Women (OVW) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. Comments are encouraged and will be accepted for ''sixty days'' until April 26, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the 8 digit OMB number for the collection or the title of the collection. If you have questions concerning the collection, please Cathy Poston, Office on Violence Against Women, at 202–514–5430.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* OVW Solicitation Template.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0020. U.S. Department of Justice, OVW.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: The affected public includes applicants to OVW grant programs authorized under the Violence Against Women Act of 1994 and reauthorized and amended by the Violence Against Women Act of 2000 and the Violence Against Women Act of 2005. These include States, territory, Tribe or unit of local government; State, territorial, tribal or unit of local governmental entity; institutions of higher education including colleges and universities; tribal organizations; Federal, State, tribal, territorial or local courts or court-based programs; State sexual assault coalition, State domestic violence coalition; territorial domestic violence or sexual assault coalition; tribal coalition; tribal organization; community-based organizations and non-profit, nongovernmental organizations. The purpose of the solicitation template is to provide a framework to develop program-specific announcements soliciting applications for funding. A program solicitation outlines the specifics of the funding program; describes the requirements for eligibility; instructs an applicant on the necessary components of an application under a specific program (e.g. project activities and timeline, proposed budget): and provides registration dates, due dates, and instructions on how to apply within the designated application system.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that information will be collect annually from the approximately 1800 respondents (applicants to the OVW grant programs). The public reporting burden for this collection of information is estimated at up to 30 hours per application. The 30-hour estimate is based on the amount of time to prepare a narrative, budget and other materials for the application as well to coordinate with and develop a memorandum of understanding with requisite project partners.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 54,000 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 20, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04231 Filed 2–22–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[OMB Number 1140–0025]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Limited Permittee Transaction Report

ACTION: 30-Day Notice.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 246, page 75660 on December 21, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 27, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the eight digit OMB number or the title of the collection.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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.

Summary of Information Collection

(1) *Type of Information Collection:* Extension of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Limited Permittee Transaction Report.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* ATF F 5400.4. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Other: Business or other for-profit.

Need for Collection

The limited permittees are required to complete ATF F 5400.4 prior to receiving explosive materials. The form is used to verify that all persons who are purchasing explosive materials have the proper Federal permit and to ensure that such persons have appropriate facilities for storage of the explosive materials.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 175 respondents will complete the form within approximately 20 minutes.

(6) *An estimate of the total burden (in hours) associated with the collection:* There are an estimated 350 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 20, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04227 Filed 2–22–13; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0075]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Transactions Among Licensees/Permittees, Limited

ACTION: 30-Day Notice.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 246, page 75661 on December 21, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 27, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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.

Summary of Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Transactions Among Licensees/Permittees, Limited.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: None. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None.

Need for Collection

A licensed importer, licensed manufacturer, or licensed dealer may distribute explosive materials to a holder of a limited permit if the holder of such permit is a resident of the same State in which the licensee's business premise is located. A holder of a limited permit may receive explosive materials on no more than 6 separate occasions during the one-year period of the permit. A holder of a user permit may dispose of surplus stocks of explosive materials to the holder of a limited permit who is a resident of the same State in which the premises of the holder of the user permit are located. A licensed importer, licensed manufacturer, licensed dealer or permittee, must, prior to delivering the explosive materials, obtain from the limited permittee a current list of the persons who are authorized to accept deliveries of the explosive materials on behalf of the limited permittee.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 175 respondents will take approximately 30 minutes to comply with the required information.

(6) An estimate of the total burden (in hours) associated with the collection: There are an estimated 88 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 20, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04230 Filed 2–22–13; 8:45 am]

BILLING CODE 4810–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms, and Explosives

[OMB Number 1140–0043]

Agency Information Collection Activities; Proposed Collection; Comments Requested: National Tracing Center Trace Request

ACTION: 30-Day Notice.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 246, page 75663 on December 21, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 27, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the eight digit OMB number or the title of the collection.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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.

Summary of Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* National Tracing Center Trace Request.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 3312.1. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Federal Government. Other: State, Local, or Tribal Government.

Need for Collection

The form is used by the Federal, State, Local, and International law enforcement community to request that ATF trace firearms used, or suspected to have been used, in crimes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated 6,103 respondents, who will complete the form within approximately 6 minutes.

(6) *An estimate of the total burden (in hours) associated with the collection:* There are an estimated 34,448 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 20, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04228 Filed 2–22–13; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0064]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Application for Restoration of Explosives Privileges

ACTION: 30-Day Notice.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 246, page 75662 on December 21, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 27, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the eight digit OMB number or the title of the collection.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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.

Summary of Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Restoration of Explosives Privileges.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 5400.29. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Other: Business or other for-profit.

Need for Collection

ATF F 5400.29 is required in order to determine whether or not explosives privileges may be restored. The form is used to conduct an investigation to establish if it is likely that the applicant will act in a manner dangerous to pubic safety or contrary to public interest.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 500 respondents will complete the form within approximately 30 minutes.

(6) *An estimate of the total burden (in hours) associated with the collection:* There are an estimated 250 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street NE., Room 3W–1407B, Washington, DC 20530.

Dated: February 20, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04229 Filed 2–22–13; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0024]

Agency Information Collection Activities; Proposed Collection; Comments Requested: Report of Firearms Transactions—Demand 2

ACTION: 30-Day Notice.

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 77, Number 246, page 75662, on December 21, 2012, allowing for a 60 day comment period.

The purpose of this notice is to allow for an additional 30 days for public comment until March 27, 2013. This process is conducted in accordance with 5 CFR 1320.10.

Written comments concerning this information collection should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: DOJ Desk Officer. The best way to ensure that your comments are received is to email them to *oira_submission@omb.eop.gov* or fax them to 202–395–7285. All comments should reference the eight digit OMB number or the title of the collection.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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.

Summary of Information Collection

(1) *Type of Information Collection:* Revision of a currently approved collection.

(2) *Title of the Form/Collection:* Report of Firearms Transactions—Demand 2.

(3) *Form Number:* ATF F 5300.5. Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None.

Need for Collection

The information collection documents transactions of firearms for law enforcement purposes. ATF uses the information to determine that the transaction is in accordance with laws and regulations, and establishes the person(s) involved in the transactions. Changes to the form are to simplify reporting by clarifying required information, removing information that is no longer needed and reducing the form size to 8 ½″ x 11″.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 865 respondents will complete a 30 minute form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 1,730 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, Department of Justice, Two Constitution Square, Room 3W–1407B, 145 N Street NE., Washington, DC 20530.

Dated: February 20, 2013.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2013–04226 Filed 2–22–13; 8:45 am]

BILLING CODE 4410–FYP

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Equal Employment Opportunity in Apprenticeship Training

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employment and Training Administration (ETA) sponsored information collection request (ICR) titled, ''Equal Employment Opportunity in Apprenticeship Training,'' to the Office of Management and Budget (OMB) for review and approval for continued use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before March 27, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site, *http://www.reginfo.gov/public/do/PRAMain,* on the day following publication of this notice or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ETA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: Regulations 29 CFR part 30 sets forth policies and procedures to promote equal opportunity in apprenticeship programs registered with the DOL and recognized State Apprenticeship Agencies. This information collection also includes the requirements for a person who believes his or her rights under part 30 have been violated to file a complaint, Form ETA–9039.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the 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. The DOL obtains OMB approval for this information collection under Control Number 1205–0224. The current approval is scheduled to expire on February 28, 2013; however, it should be noted that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional information, see the related notice published in the **Federal Register** on November 27, 2013 (77 FR 70833).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the ADDRESSES section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1205–0224. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ETA.

Title of Collection: Equal Employment Opportunity in Apprenticeship Training.

OMB Control Number: 1205–0224.

Affected Public: Individuals or Households; Private Sector—businesses or other for-profits and not-for-profit institutions; and State, Local, and Tribal Governments.

Total Estimated Number of Respondents: 23,667.

Total Estimated Number of Responses: 40,407.

Total Estimated Annual Burden Hours: 3,582.

Total Estimated Annual Other Costs Burden: $0.

Dated: February 19, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–04257 Filed 2–22–13; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers by (TA–W) number issued during the period of *February 11, 2013 through February 19, 2013.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Under Section 222(a)(2)(A), the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The sales or production, or both, of such firm have decreased absolutely; and

(3) One of the following must be satisfied:

(A) Imports of articles or services like or directly competitive with articles produced or services supplied by such firm have increased;

(B) Imports of articles like or directly competitive with articles into which one or more component parts produced by such firm are directly incorporated, have increased;

(C) Imports of articles directly incorporating one or more component parts produced outside the United States that are like or directly competitive with imports of articles incorporating one or more component parts produced by such firm have increased;

(D) Imports of articles like or directly competitive with articles which are produced directly using services supplied by such firm, have increased; and

(4) The increase in imports contributed importantly to such workers' separation or threat of separation and to the decline in the sales or production of such firm; or

II. Section 222(a)(2)(B) all of the following must be satisfied:

(1) A significant number or proportion of the workers in such workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) One of the following must be satisfied:

(A) There has been a shift by the workers' firm to a foreign country in the production of articles or supply of services like or directly competitive with those produced/supplied by the workers' firm;

(B) There has been an acquisition from a foreign country by the workers' firm of articles/services that are like or directly competitive with those produced/supplied by the workers' firm; and

(3) The shift/acquisition contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in public agencies and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) A significant number or proportion of the workers in the public agency have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The public agency has acquired from a foreign country services like or directly competitive with services which are supplied by such agency; and

(3) The acquisition of services contributed importantly to such workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected secondary workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(c) of the Act must be met.

(1) A significant number or proportion of the workers in the workers' firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) The workers' firm is a Supplier or Downstream Producer to a firm that employed a group of workers who received a certification of eligibility under Section 222(a) of the Act, and such supply or production is related to the article or service that was the basis for such certification; and

(3) Either—

(A) The workers' firm is a supplier and the component parts it supplied to the firm described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) A loss of business by the workers' firm with the firm described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for an affirmative determination to be made for adversely affected workers in firms identified by the International Trade Commission and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(f) of the Act must be met.

(1) The workers' firm is publicly identified by name by the International Trade Commission as a member of a domestic industry in an investigation resulting in—

(A) An affirmative determination of serious injury or threat thereof under section 202(b)(1);

(B) An affirmative determination of market disruption or threat thereof under section 421(b)(1); or

(C) An affirmative final determination of material injury or threat thereof under section 705(b)(1)(A) or 735(b)(1)(A) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)(1)(A) and 1673d(b)(1)(A));

(2) The petition is filed during the 1-year period beginning on the date on which—

(A) A summary of the report submitted to the President by the International Trade Commission under section 202(f)(1) with respect to the affirmative determination described in paragraph (1)(A) is published in the **Federal Register** under section 202(f)(3); or

(B) Notice of an affirmative determination described in subparagraph (1) is published in the **Federal Register**; and

(3) The workers have become totally or partially separated from the workers' firm within—

(A) The 1-year period described in paragraph (2); or

(B) Notwithstanding section 223(b)(1), the 1-year period preceding the 1-year period described in paragraph (2).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
82,035	Georgia Pacific LLC, dba Duluth Hardboard Plant, Specialty Mfg. Division, Koch Industries.	Duluth, MN	October 2, 2011.
82,165	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Wyoming, MI	November 19, 2011.
82,165A	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Montgomery, AL	November 19, 2011.
82,165AA	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Rochester, NH	November 19, 2011.
82,165B	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Anchorage, AK	November 19, 2011.
82,165BB	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Somerset, NJ	November 19, 2011.
82,165C	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Payson, AZ	November 19, 2011.
82,165CC	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Black River, NY	November 19, 2011.
82,165D	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Paragould, AR	November 19, 2011.
82,165DD	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Wilmington, NC	November 19, 2011.
82,165E	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Auburn, CA	November 19, 2011.
82,165EE	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Bismarck, ND	November 19, 2011.
82,165F	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Professional Drivers of Georgia, Inc dba Prodrivers.	Ft. Morgan, CO	November 19, 2011.
82,165FF	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Geneva, OH	November 19, 2011.
82,165G	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Montville, CT	November 19, 2011.
82,165GG	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Seminole, OK	November 19, 2011.
82,165H	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Cheswold, DE	November 19, 2011.
82,165HH	Interstate Brands Corporation (IBC), Hostess Brands, Inc	La Grande, OR	November 19, 2011.
82,165I	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Madison, FL	November 19, 2011.
82,165II	Interstate Brands Corporation (IBC), Hostess Brands, Inc. Randstad Professional US LP (Accounts International).	Berwick, PA	November 19, 2011.
82,165J	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Waycross, GA	November 19, 2011.
82,165JJ	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Warwick, RI	November 19, 2011.
82,165K	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Bellevue, ID	November 19, 2011.
82,165KK	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Rock Hill, SC	November 19, 2011.
82,165L	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Stivers Temporary Personnel.	Oswego, IL	November 19, 2011.
82,165LL	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Sioux Falls, SD	November 19, 2011.
82,165M	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Rushville, IN	November 19, 2011.
82,165MM	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Stinson Industrial Maintenance.	Knoxville, TN	November 19, 2011.
82,165N	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Waterloo, IA	November 19, 2011.
82,165NN	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Insource Group and Accenture LLP.	Houston, TX	November 19, 2011.
82,165O	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Anytime Labor KC Metro, LLC, Arnold Group.	Salina, KS	November 19, 2011.
82,165OO	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Tremonton, UT	November 19, 2011.
82,165P	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Professional Drivers of Georgia, Inc. dba Prodrivers.	Danville, KY	November 19, 2011.
82,165PP	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Brattleboro, VT	November 19, 2011.
82,165Q	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Hammond, LA	November 19, 2011.
82,165QQ	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Rustburg, VA	November 19, 2011.
82,165R	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Portland, ME	November 19, 2011.
82,165RR	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Moses Lake, WA	November 19, 2011.
82,165S	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Rockville, MD	November 19, 2011.
82,165SS	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Wheeling, WV	November 19, 2011.
82,165T	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Fitchburg, MA	November 19, 2011.
82,165TT	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Oshkosh, WI	November 19, 2011.
82,165U	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Mankato, MN	November 19, 2011.
82,165UU	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Rock Springs, WY	November 19, 2011.
82,165V	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Moselle, MS	November 19, 2011.
82,165W	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Great Plains Technical Services, Ridgway's LLC, etc.	Caruthersville, MO	November 19, 2011.
82,165X	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Bookkeeping by Design.	Livingston, MT	November 19, 2011.
82,165Y	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Bookkeeping by Design.	Omaha, NE	November 19, 2011.
82,165Z	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Elko, NV	November 19, 2011.

The following certifications have been issued. The requirements of Section 222(a)(2)(B) (shift in production or services) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
82,166	Technicolor, Inc., Creative Services Division, Apple One, Select Staffing.	Glendale, CA	November 20, 2011.
82,237	State Street Corporation, Information Technology Group, 607 Boylston Street.	Boston, MA	November 16, 2011.
82,237A	State Street Corporation, Information Technology Group, 100 Huntington Avenue.	Boston, MA	November 16, 2011.
82,237B	State Street Corporation, Information Technology Group, 100 Summer Street.	Boston, MA	November 16, 2011.
82,237C	State Street Corporation, Information Technology Group, 200 Clarendon Street.	Boston, MA	November 16, 2011.
82,237D	State Street Corporation, Information Technology Group, 2 Avenue De LaFayette.	Boston, MA	November 16, 2011.
82,237E	State Street Corporation, Information Technology Group, 800 Boylston Street.	Boston, MA	November 16, 2011.
82,237F	State Street Corporation, Information Technology Group, One Lincoln Street.	Boston, MA	November 16, 2011.
82,237G	State Street Corporation, Information Technology Group, 8 Centennial Drive.	Grafton, MA	November 16, 2011.
82,237H	State Street Corporation, Information Technology Group, 1776 Heritage Drive.	North Quincy, MA	November 16, 2011.
82,237I	State Street Corporation, Information Technology Group, 200 Newport Avenue.	Quincy, MA	November 16, 2011.
82,237J	State Street Corporation, Information Technology Group, 1200 Crown Colony Drive.	Quincy, MA	November 16, 2011.
82,242	Burroughs Inc., Pinnacle Staffing and Snelling	Plymouth, MI	January 20, 2013.
82,326	YP Western Directory LLC, Publishing Operations Group, YP Subsidiary Holdings LLC, Zero Chaos.	San Francisco, CA	January 8, 2012.
82,356	Stowe Woodward, LLC, d/b/a Mount Hope, Ajilon Professional Staffing.	Charlotte, NC	January 18, 2012.
82,391	Bacova Guild, Ltd., Ronile Inc., inc., Manpower	Covington, VA	January 30, 2012.
82,392	ABB Inc., PPHV Division	Mount Pleasant, PA	July 3, 2012.
82,392A	Leased Workers from HEG Company and Beeline, ABB Inc., PPHV Division.	Mount Pleasant, PA	January 30, 2012.
82,393	Royal Appliance Mfg. Co., RMP Personnel, Inc	El Paso, TX	January 29, 2012.
82,395	A.E. Petsche Company, Randstad and Synergy Services Corporation.	Arlington, TX	January 29, 2012.
82,403	City Shirt Company, Elbeco Incorporated	Frackville, PA	January 31, 2012.
82,404	NGN—New Generation Network, Inc., NGN—New Generation Network GMBH.	Portland, ME	January 31, 2012.
82,412	Buth-Na-Bodhaige, Inc., d/b/a/The Body Shop, Aerotek	Wake Forest, NC	January 17, 2012.

The following certifications have been issued. The requirements of Section 222(c) (supplier to a firm whose workers are certified eligible to apply for TAA) of the Trade Act have been met.

TA–W No.	Subject firm	Location	Impact date
82,319	Art Print Company, OneSource Staffing Solutions	Taylor, PA	January 4, 2012.

Negative Determinations for Worker Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

The investigation revealed that the criterion under paragraph (a)(1), or (b)(1), or (c)(1)(employment decline or threat of separation) of section 222 has not been met.

TA–W No.	Subject firm	Location	Impact date
82,318	San Francisco Shopping Centre Associates, LP, Kiosk Leasing Department.	San Francisco, CA.	

The investigation revealed that the criteria under paragraphs(a)(2)(A) (increased imports) and (a)(2)(B) (shift in production or services to a foreign country) of section 222 have not been met.

TA–W No.	Subject firm	Location	Impact date
81,668	Vertis Inc., Insert Advertising Division, Ethan Allen Staffing and Manpower Incorporated.	Saugerties, NY.	

TA–W No.	Subject firm	Location	Impact date
82,296	Lattice Semiconductor Corporation, U.S. Field Sales throughout the US reporting to Hillsboro, Oregon.	Hillsboro, OR.	
82,311	SFI Holding, LLC, Personnel Services Unlimited, Inc	Forest City, NC.	
82,335	Wellpoint, Inc., Anthem Blue Cross & Blue Shield, Individual Sales—Captive Agents.	Worthington, OH.	
82,347	Performance Motorsports, Inc., A subsidiary of Dover Corporation ..	Huntington Beach, CA.	

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

TA–W No.	Subject firm	Location	Impact date
82,193	Green Innovation and Technology, Inc	South Holland, IL.	
82,362	Hewlett-Packard Company	Corvallis, OR.	
82,450	HP Software	Palo Alto, CA.	
82,451	Hewlett-Packard Enterprise Services	Palo Alto, CA.	
82,452	HP Global Functions	Palo Alto, CA.	

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

TA–W No.	Subject firm	Location	Impact date
82,167	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Seattle, WA.	
82,181	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Salem, OR.	
82,207	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Operating Throughout the State of Nevada, NV.	
82,208	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Boise, ID.	
82,222	Interstate Brands Corporation (IBC), Bostess Brands, Inc	Operating Throughout the State Maine, ME.	
82,226	Interstate Brands Corporation (IBC), Hostess Brands, Inc	La Grande, OR.	
82,228	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Operating Throughout the State of Connecticut, CT.	
82,233	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Cheswick, PA.	
82,234	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Los Angeles—Hostess Plant.	Los Angeles, CA.	
82,248	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Lafayette, IN.	
82,255	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Northwood, OH.	
82,256	Verizon Business Networks Services, Inc., Senior Coordinator-Oder Management, Voice Over Internet Protocol.	San Antonio, TX.	
82,265	State Street Corporation, Information Technology Group	Boston, MA.	
82,265A	State Street Corporation, Information Technology Group	Quincy, MA.	
82,267	Interstate Brands Corporation (IBC), Hostess Brands, Inc., Tulsa -Wonder/Hostess Plant.	Tulsa, OK.	
82,278	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Operating Throughout the State of Illinois, IL.	
82,298	Interstate Brands Corporation, Hostess Brands, Inc	Redding, CA.	
82,314	Interstate Brands Corporation (IBC), Hostess Brands	Defiance, OH.	
82,327	State Street Corporation, Information Technology Group	North Quincy, MA.	
82,329	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Operating Throughout the State of New York, NY.	
82,341	Interstate Brands Corporation (IBC), Hostess Brands, Inc	West Virginia, WV.	
82,366	Interstate Brands Corporation (IBC), Hostess Brands	Mansfield, OH.	
82,372	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Wichita, KS.	
82,397	Interstate Brands Corporation (IBC), Hostess Brands, Inc	Erie, PA.	

The following determinations terminating investigations were issued because the petitions are the subject of ongoing investigations under petitions filed earlier covering the same petitioners.

TA–W No.	Subject firm	Location	Impact date
82,358	YP Holdings LLC	San Francisco, CA.	

I hereby certify that the aforementioned determinations were issued during the period of *February 11, 2013 through February 19, 2013*. These determinations are available on the Department's Web site *tradeact/taa/taa* search *form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Dated: February 19, 2013.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2013–04258 Filed 2–22–13; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Office of Labor-Management Standards

Extension of Information Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Labor-Management Standards (OLMS) of the Department of Labor (Department) is soliciting comments concerning the proposed extension of the collection of information requirements implementing Executive Order (E.O.) 13496: Notification of Employee Rights Under Federal Labor Laws. A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before April 26, 2013.

ADDRESSES: Andrew R. Davis, Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–5609, Washington, DC 20210, *olms-public@dol.gov,* (202) 693–0123 (this is not a toll-free number), (800) 877–8339 (TTY/TDD).

Please use only one method of transmission for comments (mail or Email).

SUPPLEMENTARY INFORMATION:

I. Background

President Barack Obama signed Executive Order 13496 (E.O. 13496 on January 30, 2009, requiring certain Government contractors and subcontractors to post notices informing their employees of their rights as employees under Federal labor laws. The Order also provides the text of contractual provisions that Federal Government contracting departments and agencies must include in every Government contract, except for collective bargaining agreements and contracts for purchases under the Simplified Acquisition Threshold.

OLMS administers the enforcement provisions of Executive Order 13496, while the compliance evaluation and investigatory provisions are handled by the Department's Office of Federal Contract Compliance Programs (OFCCP), pursuant to the Order's implementing regulatory provisions (29 CFR Part 471). Complaints can be filed with both agencies.

II. Review Focus

The Department is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

The Department seeks extension of the current approval to collect this information. An extension is necessary because if this information collection is not conducted, E.O. 13496 could not be enforced through the complaint procedure.

E.O. 13496 advances the Administration's goal of promoting economy and efficiency of Federal government procurement by ensuring that workers employed in the private sector as a result of Federal government contracts are informed of their rights to engage in union activity and collective bargaining. Knowledge of such basic statutory rights promotes stable labor-management relations, thus reducing costs to the Federal government.

The contractual provisions require contractors and subcontractors to post a notice, created by the Secretary of Labor, informing employees of their rights under the National Labor Relations Act. The notice also provides a statement of the policy of the United States to encourage collective bargaining, as well as a list of activities that are illegal under the Act. The notice concludes with a general description of the remedies to which employees may be entitled if these rights have been violated and contact information for further information about those rights and remedies, as well as enforcement procedures.

The clause also requires contractors to include the same clause in their nonexempt subcontracts and purchase orders, and describes generally the sanctions, penalties, and remedies that may be imposed if the contractor fails to satisfy its obligations under the Order and the clause.

The regulatory provisions implementing E.O. 13496 (29 CFR part 471) include the language of the required notices, and they explain posting and contractual requirements, the complaint process, the investigatory process, and sanctions, penalties, and remedies that may be imposed if the contractor or subcontractor fails to comply with its obligations under the Order. Specifically, 29 CFR part 471.11(c) sets forth the procedures that the Department must use when accepting written complaints alleging that a contractor doing business with the Federal government has failed to post the notice required by the Executive Order.

Type of Review: Extension.

Agency: Office of Labor-Management Standards.

OMB Number: 1245–0004.

Affected Public: Employees of Federal Contractors and Subcontractors.

Total Respondents: 25.

Total Annual Responses: 25.

Estimated Total Burden Hours: 32.

Estimated Time per Response: 1.28 hours.

Frequency: On occasion of employee of a Federal contractor or subcontractor filing a complaint alleging a violation of proposed 29 CFR part 471.

Total Burden Cost (capital/startup): $12.50 ($0.50 per response × 25 respondents).

Total Burden Cost (operating/maintenance): $0.

Employee Complaints Cost: $761 ($30.44 per response × 25 respondents).

Total Annual Burden Cost: $773.50 ($12.50 + $761).

Total respondent and responses estimates are based upon the estimate in the E.O. 13496 final rule of 50. See 75 FR 28368. However, since the Department has no record of employee complaints received, the Department has lowered its complaint estimate to 25.

The Department has not adjusted its total employee complaint hour estimate of 1.28 hours, which it estimated in the E.O. 13496 final rule. *Id.*

The Department has updated the employee cost burden per complaint from the past estimates in the supporting statement sent to OMB and the Notice of Proposed Rulemaking. See 74 FR 38496. The Department estimates that it will take an average of 1.28 hours to complete a complaint. Based on the average seasonally-adjusted hourly earnings on private non-farm payrolls for all workers of $23.78, we estimate that an employee will incur a cost of $30.44 for the 1.28 hours involved ($23.78 × 1.28) in preparing a complaint. Additionally, employees will incur costs of $0.50 per complaint in capital/start-up costs ($0.46 for postage + $0.03 for an envelope + $0.01 for paper) for a total cost per complaint of $30.94. The total cost for the estimated 25 complaints is $773.50. There are no ongoing operation/maintenance costs associated with this information collection.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: February 13, 2013.

Andrew R. Davis,

Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor.

[FR Doc. 2013–04267 Filed 2–22–13; 8:45 am]

BILLING CODE P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 13–005]

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 U.S. Patent Application Serial No. US 13/534,804, Alpha-Stream Convertor, LEW 18802–1; and U.S. Provisional Patent Application Serial No. US 61/677,116, Magnetostrictive Alternator—Low Cost, No Moving Part, High Efficiency, Oscillating Acoustic Pressure Wave to Electric Power Transducer, LEW 18939–1, to Nirvana Energy Systems, having its principal place of business in Portolo Valley, California. The fields of use may be limited to power systems for residential, commercial and transportation industries. The patent rights in these inventions as applicable 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.

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 Intellectual Property Counsel, Office of Chief Counsel, MS 21–14, NASA Glenn Research Center, 21000 Brookpark Rd, Cleveland OH 44135. Phone (216) 433–5754. Facsimile (216) 433–6790.

FOR FURTHER INFORMATION CONTACT: Kaprice Harris, Intellectual Property Counsel, Office of Chief Counsel, Office of Chief Counsel, MS 21–14, NASA Glenn Research Center, 21000 Brookpark Rd, Cleveland OH 44135. Phone (216) 433–5754. Facsimile (216) 433–6790. Information about other NASA inventions available for licensing can be found online at *https://technology.grc.nasa.gov.*

Sumara M. Thompson-King,

Deputy General Counsel.

[FR Doc. 2013–04186 Filed 2–22–13; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

SUPPLEMENTARY INFORMATION: On January 17, 2013, the National Science Foundation published a notice in the **Federal Register** of permit applications received. Permit were issued on February 19, 2013 to:

Matthew C. Lamanna—Permit No. 2013–026

Paul Koch—Permit No. 2013–027

Nadene G. Kennedy,

Permit Officer.

[FR Doc. 2013–04164 Filed 2–22–13; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for Innovation Corps; Notice of Meeting; Correction

SUMMARY: On Tuesday, February 12, 2013 (78 FDR 9945), the National Science Foundation published a notice announcing a meeting of the Advisory Committee for Innovation Corps. The location and time of the business meeting are updated to reflect the accurate plans.

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science

Foundation announces the following meeting:

Name: Innovation Corps Advisory Committee, #80463.

Dates/Time: March 6, 2013, 10:00 a.m.–2:00 p.m.

Places: Sheraton Crystal City Hotel, 1800 Eads Street, Arlington, VA 22202. National Science Foundation, 4201 Wilson Boulevard, Stafford I, Room 1295, Arlington, VA 22230.

Type of Meeting: Partially Open.

Contact Person: Dedric Carter, Suite 1205, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone Number: (703) 292–8002 *dacarter@nsf.gov.*

Purpose of Meeting: To provide advice and recommendations concerning I-Corps.

Agenda

10:00 a.m.–11:30 a.m.: Closed: Sheraton Crystal City Hotel

Meeting with current I-Corps teams

12:00 p.m.–2:00 p.m.: Open: National Science Foundation

Opening Remarks
Review and discussion of the current I-Corps activities and future directions
Summary
Adjourn

Reason for Closing: The committee will review information of a proprietary or confidential nature, including technical information; financial data; and personal information. These matters are exempt under 5 U.S.C. 552b(c), (4) of the Government in the Sunshine Act.

Dated: February 20, 2013.

Susanne Bolton,

Committee Management Officer.

[FR Doc. 2013–04255 Filed 2–22–13; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS), Meeting of the ACRS Subcommittee on Plant License Renewal; Notice of Meeting

The ACRS Subcommittee on Plant License Renewal will hold a meeting on March 6, 2013, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, March 6, 2013—8:30 a.m. Until 12:00 p.m.

The Subcommittee will review and discuss the Grand Gulf Nuclear Station, Unit 1, License Renewal Application (LRA). The Subcommittee will hear presentations by and hold discussions with the NRC staff, Entergy Operations Inc., and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Kent Howard (Telephone 301–415–2989 or Email: *Kent.Howard@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: February 12, 2013.

Antonio Dias,

Technical Advisor, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–04295 Filed 2–22–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS), Meeting of the ACRS Subcommittee on Planning and Procedures; Notice of Meeting

The ACRS Subcommittee on Planning and Procedures will hold a meeting on March 6, 2013, Room T–2B1, 11545 Rockville Pike, Rockville, Maryland.

The meeting will be open to public attendance with the exception of a portion that may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to the internal personnel rules and practices of the ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.

The agenda for the subject meeting shall be as follows:

Wednesday, March 6, 2013—12:00 p.m. Until 1:00 p.m.

The Subcommittee will discuss proposed ACRS activities and related matters. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Antonio Dias (Telephone 301–415–6805 or Email: *Antonio.Dias@nrc.gov*) five days prior to the meeting, if possible, so that arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147).

Information regarding changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS

meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the DFO if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North building, 11555 Rockville Pike, Rockville, MD. After registering with security, please contact Mr. Theron Brown (240–888–9835) to be escorted to the meeting room.

Dated: February 14, 2013.

Cayetano Santos,

Chief, Reactor Safety Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2013–04294 Filed 2–22–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Notice of Meeting

In accordance with the purposes of Sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2039, 2232b), the Advisory Committee on Reactor Safeguards (ACRS) will hold a meeting on March 7, 2013, 11545 Rockville Pike, Rockville, Maryland.

Thursday, March 7, 2013, Conference Room T2–B1, 11545 Rockville Pike, Rockville, Maryland

1:00 p.m.–1:05 p.m.: Opening Remarks by the ACRS Chairman (Open)—The ACRS Chairman will make opening remarks regarding the conduct of the meeting.

1:05 p.m.–2:30 p.m.: Proposed Draft Final Revision 1 to Regulatory Guide (RG) 1.163, ''Performance-Based Containment Leak-Test Program'' (Open)—The Committee will hear presentations by and hold discussions with representatives of the NRC staff regarding the proposed revision to RG 1.163, ''Performance-Based Containment Leak-Test Program.''

2:45 p.m.–4:15 p.m.: Future ACRS Activities/Report of the Planning and Procedures Subcommittee (Open/Closed)—The Committee will discuss the recommendations of the Planning and Procedures Subcommittee regarding items proposed for consideration by the Full Committee during future ACRS Meetings, and matters related to the conduct of ACRS business, including anticipated workload and member assignments. [**Note:** A portion of this meeting may be closed pursuant to 5 U.S.C. 552b (c)(2) and (6) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of ACRS, and information the release of which would constitute a clearly unwarranted invasion of personal privacy.]

4:15 p.m.–4:30 p.m.: Reconciliation of ACRS Comments and Recommendations (Open)—The Committee will discuss the responses from the NRC Executive Director for Operations to comments and recommendations included in recent ACRS reports and letters.

4:45 p.m.–7:00 p.m.: Preparation of ACRS Reports (Open)—The Committee will discuss proposed ACRS reports on matters discussed during this meeting.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 18, 2012, (77 FR 64146–64147). In accordance with those procedures, oral or written views may be presented by members of the public, including representatives of the nuclear industry. Persons desiring to make oral statements should notify Antonio Dias, Cognizant ACRS Staff (Telephone: 301–415–6805, Email: *Antonio.Dias@nrc.gov*), five days before the meeting, if possible, so that appropriate arrangements can be made to allow necessary time during the meeting for such statements. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the Cognizant ACRS staff if such rescheduling would result in major inconvenience.

Thirty-five hard copies of each presentation or handout should be provided 30 minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the Cognizant ACRS Staff one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the Cognizant ACRS Staff with a CD containing each presentation at least 30 minutes before the meeting.

In accordance with Subsection 10(d) Public Law 92–463, and 5 U.S.C. 552b(c), certain portions of this meeting may be closed, as specifically noted above. Use of still, motion picture, and television cameras during the meeting may be limited to selected portions of the meeting as determined by the Chairman. Electronic recordings will be permitted only during the open portions of the meeting.

ACRS meeting agenda, meeting transcripts, and letter reports are available through the NRC Public Document Room at *pdr.resource@nrc.gov*, or by calling the PDR at 1–800–397–4209, or from the Publicly Available Records System (PARS) component of NRC's document system (ADAMS) which is accessible from the NRC Web site at *http://www.nrc.gov/reading-rm/adams.html* or *http://www.nrc.gov/reading-rm/doc-collections/ACRS/*.

Video teleconferencing service is available for observing open sessions of ACRS meetings. Those wishing to use this service should contact Mr. Theron Brown, ACRS Audio Visual Technician (301–415–8066), between 7:30 a.m. and 3:45 p.m. (ET), at least 10 days before the meeting to ensure the availability of this service. Individuals or organizations requesting this service will be responsible for telephone line charges and for providing the equipment and facilities that they use to establish the video teleconferencing link. The availability of video teleconferencing services is not guaranteed.

Dated: February 19, 2013.

Andrew L. Bates,

Advisory Committee Management Officer.

[FR Doc. 2013–04237 Filed 2–22–13; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2013–39 and CP2013–51; Order No. 1663]

New Postal Product; Negotiated Service Agreement

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recently-filed Postal Service request to add Parcel Return Service Contract 3 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 26, 2013.

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: Stephen L. Sharfman, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
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I. Introduction

Pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a request and associated supporting information to add Parcel Return Service Contract 3 to the competitive product list.[1] The Postal Service asserts that Parcel Return Service Contract 3 is a competitive product ''not of general applicability'' within the meaning of 39 U.S.C. 3632(b)(3). *Id.* at 1. The Request has been assigned Docket No. MC2013–39.

The Postal Service contemporaneously filed an agreement related to the proposed new product (Agreement). *Id.* Attachment B. The Agreement has been assigned Docket No. CP2013–51.

Request. In support of its Request, the Postal Service filed six attachments:

- Attachment A—a redacted copy of Governors' Decision No. 11–6;
- Attachment B—a redacted copy of the Agreement;
- Attachment C—a proposed change in the Mail Classification Schedule competitive product list;
- Attachment D—a Statement of Supporting Justification as required by 39 CFR 3020.32;
- Attachment E—a certification of compliance with 39 U.S.C. 3633(a); and
- Attachment F—an application for non-public treatment of materials to maintain redacted portions of the Agreement and supporting documents under seal.

In the Statement of Supporting Justification, Dennis R. Nicoski, Manager, Field Sales Strategy and Contracts, asserts that the service to be provided under the Agreement will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service's total institutional costs. *Id.* Attachment D at 1. Thus, Mr. Nicoski contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.*

Related contract. A redacted version of the Agreement is included with the Request. The Agreement will become effective the day following the day that the Commission provides all necessary regulatory approval. The Agreement is scheduled to expire 2 years after its effective date but may be terminated earlier by either party with 6 months' written notice. *Id.* Attachment B at 3. The Postal Service represents that the Agreement is consistent with 39 U.S.C. 3633(a). *Id.* Attachment D.

The Postal Service filed much of the supporting materials, including the Agreement, under seal. *Id.* Attachment F. It maintains that the Agreement and related financial information, including the customer's name and the accompanying analyses that provide prices, terms, conditions, cost data, and financial projections, should remain confidential. *Id.* Attachment F. It also requests that the Commission order that non-public treatment of all customer-identifying information be extended indefinitely, instead of ending after 10 years. *Id.* at 7.

II. Notice of Filings

The Commission establishes Docket Nos. MC2013–39 and CP2013–51 for consideration of the Request pertaining to the proposed Parcel Return Service Contract 3 product and the related Agreement, respectively.

Interested persons may submit comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642 and 39 CFR part 3015 and 39 CFR 3020, subpart B. Comments are due no later than February 26, 2013. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2013–39 and CP2013–51 for consideration of the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these proceedings.

3. Comments by interested persons in these proceedings are due no later than February 26, 2013.

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

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2013–04168 Filed 2–22–13; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Parcel Return Service Contract 3 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, February 15, 2013 (Request).

PRIVACY AND CIVIL LIBERTIES OVERSIGHT BOARD

[Notice–PCLOB–2013–02; Docket No. 2013–0004; Sequence No. 2]

Sunshine Act Meetings

TIME AND DATE: Open: 10:00 a.m.–12:00 p.m. (Eastern Time); Closed: 1:30 p.m.–3:30 p.m. on Tuesday, March 5, 2013.

PLACE: The open meeting will be held at General Services Administration (GSA), 301 7th Street SW., Room 1034, Washington, DC 20417. The closed meeting will be held at 2100 K Street NW., 4th Floor, Washington, DC 20427.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED: The Privacy and Civil Liberties Oversight Board will meet in open session to discuss the status of its startup activities, and related management and administrative matters, continue development of the Board's Fiscal Year 2013 and 2014 agenda, and to receive public input. The Board will meet in closed session to discuss internal personnel rules and practices and classified information.

PORTION OPEN TO THE PUBLIC: 10:00 a.m.–12:00 p.m.; at GSA, 301 7th Street SW., Room 1034, Washington, DC 20417.

All visitors must contact the Board Office, 202–331–1986, at least 24 hours prior to the meeting and provide name and organizational affiliation. All visitors must report to the visitor desk located in the lobby at GSA, 301 7th Street SW., Washington, DC 20417 to receive a visitor's badge. Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Susan Reingold, Chief Administrative Officer, 202–331–1986, at least 72 hours prior to the meeting date.

Procedures for Public Participation

Individuals wishing to address the meeting orally must provide advance notice to Claire McKenna, at *claire.mckenna.pclob@dot.gov,* no later than 5:00 p.m. on Friday, March 1, 2013. The notice must include the individual's name, title, organization, and a concise summary of the subject matter to be presented. Oral presentations may not exceed ten (10) minutes. The time for individual presentations will be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard. Participants wishing to submit a written statement for the record must

submit a copy of such statement no later than 5:00 p.m. Friday, March 1, 2013. Such statement must be typewritten, double-spaced, and may not exceed ten (10) pages. Upon receipt of the required notice, the Board will prepare an agenda, which will be available at the hearing, that identifies speakers and the time allotted for each presentation.

PORTION CLOSED TO THE PUBLIC: 1:30 p.m.–3:30 p.m.; 2100 K Street NW., 4th Floor, Washington, DC 20427.

CONTACT PERSON FOR MORE INFORMATION: Susan Reingold, Chief Administrative Officer, 202–331–1986.

Dated: February 21, 2013.

Claire McKenna,

Legal Counsel, Privacy and Civil Liberties Oversight Board.

[FR Doc. 2013–04380 Filed 2–21–13; 4:15 pm]

BILLING CODE 6820–B3–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–68951; File No. SR–BATS–2013–012]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

February 19, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on February 11, 2013, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the fee schedule applicable to Members[5] and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at *http://www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify pricing applicable to the Exchange's options platform (''BATS Options'') with respect to orders routed away by the Exchange and executed at BOX Options Exchange LLC (''BOX'') and C2 Options Exchange, Inc. (''C2''). The Exchange also proposes to modify BATS Options pricing for certain directed intermarket sweep orders (''Directed ISOs'') routed to BOX [sic], C2, NYSE Arca, Inc. (''ARCA'') and NASDAQ OMX BX, Inc. (''BX Options''), as further described below.

BATS Options currently charges certain flat rates for routing to other options exchanges that have been placed into groups based on the approximate cost of routing to such venues. The grouping of away options exchanges is based on the cost of transaction fees assessed by each venue as well as costs to the Exchange for routing (*i.e.,* clearing fees, connectivity and other infrastructure costs, membership fees, etc.) (collectively, ''Routing Costs''). As explained below, the Exchange proposes to impose the same pricing for executions at C2 as is currently charged by the Exchange for orders routed to and executed at BX Options in non-Penny Pilot Securities and to eliminate fees for Customer orders executed at BOX.[6]

Based on applicable Routing Costs, the Exchange currently charges $0.11 per contract for Customer[7] orders executed at BOX, NYSE MKT LLC (''AMEX''), Chicago Board Options Exchange, Inc. (''CBOE''), the MIAX Options Exchange (''MIAX''), BX Options in Penny Pilot Securities, International Securities Exchange, LLC (''ISE'') in Classic issues, and NASDAQ OMX PHLX LLC (''PHLX''). The Exchange currently charges $0.57 per contract for Professional,[8] Firm, and Market Maker[9] orders executed at BOX, AMEX, CBOE, MIAX, BX Options in Penny Pilot Securities, ISE in Classic issues, and PHLX. BOX currently charges an initial base fee for transactions that remove liquidity and then certain credits are applied to such transactions that remove liquidity. This results in variable rebates for Customer orders routed by the Exchange to BOX. Based on this fee structure, the Exchange proposes to provide routing of Customer orders to BOX without imposing a fee, which is the same pricing currently applied by the Exchange to executions of Customer orders routed to BX Options in non-Penny Pilot Securities, which, like BOX,

[5] A Member is any registered broker or dealer that has been admitted to membership in the Exchange.

[6] The Exchange currently charges different fees and provides different rebates depending on whether an options class is an options class that qualifies as a Penny Pilot Security pursuant to Exchange Rule 21.5, Interpretation and Policy .01 or is a non-Penny Pilot Security. Certain other options exchanges also have different pricing for Penny Pilot Securities and non-Penny Pilot Securities. Accordingly, in certain cases, the Exchange's routing fees also vary with respect to the fees for orders executed at such exchanges. However, in order to maintain a simple routing table, depending on the level of applicable fees and the affect of such fees upon Exchange Routing Costs, the Exchange has also chosen to charge all executions at certain venues a flat rate rather than differentiating between Penny Pilot Securities and non-Penny Pilot Securities. This is the case with respect to routing to BOX and C2, as proposed to be amended by this filing.

[7] As defined on the Exchange's fee schedule, a ''Customer'' order is any transaction identified by a Member for clearing in the Customer range at the Options Clearing Corporation (''OCC''), except for those designated as ''Professional''.

[8] The term ''Professional'' is defined in Exchange Rule 16.1 to mean any person or entity that (A) is not a broker or dealer in securities, and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

[9] As defined on the Exchange's fee schedule, the terms ''Firm'' and ''Market Maker'' apply to any transaction identified by a member for clearing in the Firm or Market Maker range, respectively, at the Options Clearing Corporation (''OCC'').

also provides rebates for Customer orders. The Exchange is not proposing to change pricing for executions for Professional, Firm and Market Maker orders at BOX and will continue to charge $0.57 per contract for such orders.

Based on applicable Routing Costs, the Exchange currently charges $0.52 per contract for Customer orders executed at C2, ARCA in Penny Pilot Securities, and the NASDAQ Options Market (''NOM'') in Penny Pilot Securities. The Exchange currently charges $0.57 per contract for Professional, Firm, and Market Maker orders executed at C2, ARCA in Penny Pilot Securities, and NOM in Penny Pilot Securities. Recent pricing changes by C2 will result in a maximum fee of $0.85 per contract for Professional, Firm and Market Maker orders executed at C2 and rebates or free executions for Customer orders executed at C2. Based on such changes, the Exchange proposes to align the pricing for orders routed to and executed at C2 with the pricing currently charged by the Exchange for orders routed to and executed at BX Options in non-Penny Pilot Securities. Accordingly, with respect to orders routed to C2, the Exchange proposes to provide executions of Customer orders without imposing a fee and to charge $0.95 per contract for Professional, Firm and Market Maker orders.

In order to cover the cost of removing liquidity in non-Penny Pilot Securities at NOM, including Routing Costs, the Exchange currently charges a flat fee of $0.95 per contract for all executions of Directed ISOs routed to NOM in non-Penny Pilot Securities. This is the same fee as the Exchange charges for executions of Professional, Firm and Market Maker orders routed to NOM in non-Penny Pilot Securities generally. The fee of $0.95 per contract is slightly more than the Exchange's standard fee of $0.90 per contract for Customer orders executed at NOM in non-Penny Pilot Securities.

In order to achieve consistency with the Exchange's fees for Directed ISOs routed to NOM, the Exchange proposes to extend its Directed ISO pricing to all other types of routed executions for which the Exchange charges a routing fee of $0.90 or more. Specifically, in addition to continuing to charge $0.95 per contract for all executions of Directed ISOs routed to NOM in non-Penny Pilot Securities, the Exchange proposes to charge a flat fee of $0.95 per contract for Directed ISOs routed to and executed by: (1) ARCA in non-Penny Pilot Securities, (2) BX Options in non-Penny Pilot Securities to the extent such Directed ISOs are Professional, Firm or Market Maker orders, and (3) C2 to the extent such Directed ISOs are Professional, Firm or Market Maker orders.

The Exchange will continue to impose a flat fee of $0.60 per contract for any other Directed ISO.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[10] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[11] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

As explained above, the Exchange generally attempts to approximate the cost of routing to other options exchanges, including other applicable costs to the Exchange for routing. The Exchange believes that a pricing model based on approximate Routing Costs is a reasonable, fair and equitable approach to pricing. Specifically, the Exchange believes that its proposal to modify fees to BOX and C2 is fair, equitable and reasonable because the fees are generally an approximation of the cost to the Exchange for routing orders to such exchanges. The Exchange believes that its flat fee structure for orders routed to various venues is a fair and equitable approach to pricing, as it provides certainty with respect to execution fees at groups of away options exchanges. Under its flat fee structure, taking all costs to the Exchange into account, the Exchange may operate at a slight gain or a slight loss for orders routed to and executed at C2 and will operate at a gain for Customer orders routed to BOX. As a general matter, the Exchange believes that the proposed fees will allow it to recoup and cover its costs of providing routing services to such exchanges. The Exchange also believes that the proposed fee structure for orders routed to and executed at these away options exchanges is fair and equitable and not unreasonably discriminatory in that it applies equally to all Members.

The Exchange notes that under their pricing models, BOX and C2 provide certain rebates for executions that the Exchange is not proposing to pass on to the entering Member; instead, the Exchange proposes to provide such executions free of charge. The Exchange specifically believes that its pricing structure for Customer orders routed to BOX and C2 is reasonable because, although not an approximation of the cost of routing per se, Customer orders will still receive executions free of charge, whereas all other routed orders (other than Customer orders to BX Options) are charged a fee that includes applicable Routing Costs. The Exchange believes that the proposed pricing for Customer orders routed to BOX and C2 is fair and equitable and non-discriminatory because it will apply equally to all Members, and because Members can and will likely route directly to BX Options to the extent they are specifically seeking the rebate provided for such orders. Finally, the Exchange believes that its proposed fee for routing of Professional, Firm and Market Maker orders to C2 is reasonable because it is an approximation of the maximum fees the Exchange will be charged for such executions, including Routing Costs.

As explained above, the Exchange has also proposed to increase fees for Directed ISO's to ARCA in non-Penny Pilot Securities, to BX Options in non-Penny Pilot Securities (Professional, Firm or Market Maker orders only), and to C2 (Professional, Firm or Market Maker orders) to $0.95 per contract (from the current charge of $0.60 per contract for all Directed ISO's other than in non-Penny Pilot Securities routed to NOM). The Exchange believes that this increase is fair, equitable and reasonable because the fees are also an approximation of the cost to the Exchange for routing orders to such options exchanges. The Exchange also believes that the proposed fee structure for orders routed to and executed at these away options exchanges is fair and equitable and not unreasonably discriminatory in that it applies equally to all Members.

The Exchange reiterates that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels to be excessive or providers of routing services if they deem fee levels to be excessive. Finally, the Exchange notes that it constantly evaluates its routing fees, including profit and loss attributable to routing, as applicable, in

[10] 15 U.S.C. 78f.

[11] 15 U.S.C. 78f(b)(4).

connection with the operation of a flat fee routing service, and would consider future adjustments to the proposed pricing structure to the extent it was recouping a significant profit from routing to another options exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes will assist the Exchange in recouping costs for routing orders to other options exchanges on behalf of its participants. The Exchange also notes that Members may choose to mark their orders as ineligible for routing to avoid incurring routing fees.[12] As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels to be excessive or providers of routing services if they deem fee levels to be excessive.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Pursuant to Section 19(b)(3)(A)(ii) of the Act[13] and Rule 19b–4(f)(2) thereunder,[14] the Exchange has designated this proposal as establishing or changing a due, fee, or other charge applicable to the Exchange's Members and non-members, which renders the proposed rule change effective upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

[12] *See* BATS Rule 21.1(d)(8) (describing ''BATS Only'' orders for BATS Options) and BATS Rule 21.9(a)(1) (describing the BATS Options routing process, which requires orders to be designated as available for routing).

[13] 15 U.S.C. 78s(b)(3)(A)(ii).

[14] 17 CFR 240.19b–4(f)(2).

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–BATS–2013–012 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number *SR–BATS–2013–012.* This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2013–012 and should be submitted on or before March 18, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–04268 Filed 2–22–13; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13492 and #13493]

Mississippi Disaster #MS–00064

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of Mississippi (FEMA–4101–DR), dated 02/13/2013.

Incident: Severe Storms, Tornadoes, and Flooding.

Incident Period: 02/10/2013 and continuing.

Effective Date: 02/13/2013.

Physical Loan Application Deadline Date: 04/15/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 11/13/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 02/13/2013, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties (Physical Damage and Economic Injury Loans): Forrest, Lamar.

Contiguous Counties (Economic Injury Loans Only):

Mississippi: Covington, Jefferson Davis, Jones, Marion, Pearl River, Perry, Stone.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.375

	Percent
Homeowners Without Credit Available Elsewhere	1.688
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 13492C and for economic injury is 134930.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator

for Disaster Assistance.

[FR Doc. 2013–04175 Filed 2–22–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13488 and #13489]

Tennessee Disaster #TN–00074

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Tennessee dated 02/14/2013.

Incident: Severe Storms and Tornadoes.

Incident Period: 01/29/2013.

Effective Date: 02/14/2013.

Physical Loan Application Deadline Date: 04/15/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 11/14/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Henderson.

Contiguous Counties:

Tennessee: Carroll, Chester, Decatur, Hardin, Madison.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.375
Homeowners Without Credit Available Elsewhere	1.688
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 13488C and for economic injury is 134890.

The State which received an EIDL Declaration # is Tennessee.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: February 14, 2013.

Karen G. Mills,

Administrator.

[FR Doc. 2013–04178 Filed 2–22–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #13490 and #13491]

North Carolina Disaster #NC–00048

AGENCY: U.S. Small Business Administration.

ACTION: Notice

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of North Carolina dated 02/15/2013.

Incident: Severe Storms and Flooding.

Incident Period: 01/30/2013.

Effective Date: 02/15/2013.

Physical Loan Application Deadline Date: 04/16/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 11/15/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Watauga.

Contiguous Counties:

North Carolina: Ashe, Avery, Caldwell, Wilkes.

Tennessee: Johnson.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.375
Homeowners Without Credit Available Elsewhere	1.688
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	4.000
Non-Profit Organizations With Credit Available Elsewhere	2.875
Non-Profit Organizations Without Credit Available Elsewhere	2.875
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000
Non-Profit Organizations Without Credit Available Elsewhere	2.875

The number assigned to this disaster for physical damage is 13490 6 and for economic injury is 13491 0.

The States which received an EIDL Declaration # are North Carolina, Tennessee.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: February 15, 2013.

Karen G. Mills,

Administrator.

[FR Doc. 2013–04179 Filed 2–22–13; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 13463 and # 13464]

Pennsylvania Disaster Number PA–00057

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 2.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Pennsylvania (FEMA–4099–DR), dated 01/10/2013.

Incident: Hurricane Sandy.

Incident Period: 10/26/2012 through 11/08/2012.

Effective Date: 02/13/2013.

Physical Loan Application Deadline Date: 03/11/2013.

Economic Injury (EIDL) Loan Application Deadline Date: 10/10/2013.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the Commonwealth of Pennsylvania, dated 01/10/2013, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Philadelphia.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2013–04172 Filed 2–22–13; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 8197]

Call for Expert Reviewers to the U.S. Government Review of the Working Group III Contribution to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change (IPCC), Mitigation of Climate Change

SUMMARY: The United States Global Change Research Program, in cooperation with the Department of State, request expert review of the Second Order Draft of the Working Group III Contribution to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change (IPCC), *Mitigation of Climate Change.*

The United Nations Environment Programme (UNEP) and the World Meteorological Organization (WMO) established the IPCC in 1988. In accordance with its mandate and as reaffirmed in various decisions by the Panel, the major activity of the IPCC is to prepare comprehensive and up-to-date assessments of policy-relevant scientific, technical, and socio-economic information for understanding the scientific basis of climate change, potential impacts, and options for mitigation and adaptation. The IPCC develops a comprehensive assessment spanning all the above topics approximately every six years. The First Assessment Report was completed in 1990, the Second Assessment Report in 1995, the Third Assessment Report in 2001, and the Fourth Assessment in 2007.

Three working group volumes and a synthesis report comprise the Fifth Assessment Report. Working Group I assesses the scientific aspects of the climate system and climate change; Working Group II assesses the vulnerability of socio-economic and natural systems to climate change, potential negative and positive consequences, and options for adapting to it; and Working Group III assesses options for limiting greenhouse gas emissions and otherwise mitigating climate change. Procedures for the IPCC and its preparation of reports can be found at the following Web sites: *http://www.ipcc.ch/organization/organization_review.shtml#.UEY0LqSe7x8 http://ipcc.ch/organization/organization_procedures.shtml.*

In October 2009, the IPCC approved the outline for the Working Group III contribution to the 5th Assessment Report (Working Group III Table of Contents: *http://www.ipcc-wg3.de/.files/WGIII-Outline-AR5.pdf*). Authors were nominated starting in January 2010 and selected in May 2010. All IPCC reports go through two broad reviews: a ''first-order draft'' reviewed by experts, and a ''second-order draft'' reviewed by both experts and governments. The Second Order Draft of the Working Group III contribution to the 5th Assessment Report will be available for review beginning on 25 February 2013.

As part of the U.S. Government Review of the Second Order Draft of the Working Group III Contribution to the 5th Assessment Report, the U.S. Government is soliciting comments from experts in relevant fields of expertise (Again, the Table of Contents for the Working Group contribution can be viewed here: *http://www.ipcc-wg3.de/.files/WGIII-Outline-AR5.pdf*).

Beginning on 25 February, experts may register to review the draft report at: *http://review.globalchange.gov,* the same day the draft report will be made available. To be considered for inclusion in the U.S. Government submission, comments must be received by 27 March 2013.

The United States Global Change Research Program will coordinate collection and compilation of U.S. expert comments and the review of the report by a Review Committee of Federal scientists and program managers in order to develop a consolidated U.S. Government submission, which will be provided to the IPCC by April 22, 2013. Instructions for review and submission of comments are available at: *http://review.globalchange.gov.*

Experts may choose to provide comments directly through the IPCC's expert review process, which occurs in parallel with the U.S. government review. More information on the IPCC's comment process can be found at *http://www.ipcc.ch/activities/activities.shtml* and *http://www.ipcc.ch/pdf/ar5/review_of_wg_contributions.pdf.* To avoid duplication, reviewers who participate in the U.S. Government Review should not also submit comments directly to the IPCC Secretariat through the Expert Review process. Comments to the U.S. government review should be submitted using the Web-based system at: *http://review.globalchange.gov.*

This certification will be published in the **Federal Register**.

Dated: February 19, 2013.

Trigg Talley,

Director, Office of Global Change, Department of State.

[FR Doc. 2013–04263 Filed 2–22–13; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2013–04]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Title 14, Code of Federal Regulations (14 CFR). The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of the FAA's regulatory activities. 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 involved and must be received on or before March 18, 2013.

ADDRESSES: You may send comments identified by docket number FAA–2013–0106 using any of the following methods:

• *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments digitally.

• *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

• *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.

• *Hand Delivery:* Bring comments to the Docket Management Facility 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.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility 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: Mark Forseth, ANM–113, (425) 227–2796, Federal Aviation Administration, 1601 Lind Avenue SW., Renton, WA 98057–3356. Andrea Copeland, ARM–208, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW; Washington, DC 20591; email *andrea.copeland@faa.gov;* (202) 267–8081.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on February 15, 2013.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2013–0106.

Petitioner: The Boeing Company.

Section of 14 CFR Affected: § 25.901(c) at Amdt. 25–126 and 25.981(a)(3) at Amdt. 25–125.

Description of Relief Sought: Relief from the requirements pertaining to changes to the Fuel Quantity Indication System (FQIS).

[FR Doc. 2013–04285 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: This notice provides information regarding the FHWA's finding that a Buy America waiver is appropriate for the use of non-domestic (1) Electrical Controls and Electrical Equipment; (2) Main Drive Electrical Motor; (3) Auxiliary Drive Electric Motor; (4) Span Lock Electric Motor & Controls for a specific project in the State of Washington.

DATES: The effective date of the waiver is February 26, 2013.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, (202) 366–1562, or via email at *gerald.yakowenko@dot.gov.* For legal questions, please contact Mr. Michael Harkins, FHWA Office of the Chief Counsel, (202) 366–4928, or via email at *michael.harkins@dot.gov.* Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara.*

Background

The FHWA's Buy America policy in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. This notice provides information regarding the FHWA's finding that a Buy America waiver is appropriate to use (1) Electrical Controls and Electrical Equipment; (2) Main Drive Electrical Motor; (3) Auxiliary Drive Electric Motor; (4) Span Lock Electric Motor & Controls for a specific project in the State of Washington.

In accordance with Division A, section 122 of the ''Consolidated and Further Continuing Appropriations Act, 2012'' (Pub. L. 112–55), the FHWA published a notice of intent to issue a waiver on its Web site for (1) Electrical Controls and Electrical Equipment; (2) Main Drive Electrical Motor; (3) Auxiliary Drive Electric Motor; (4) Span Lock Electric Motor & Controls for a specific project in the State of Washington (*http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=76*) on May 22nd. The FHWA received three comments in response to the publication. The first commenter (Donald Pearsal) stated that ''if'' there are manufacturers of this equipment in the United States, we should use it. The FHWA agrees with this comment. Unfortunately, however, the FHWA has been unable to locate a manufacturer who is able to produce these products in compliance with the FHWA Buy America requirements. The second commenter (Muhamad A. Naboulsi) opposed the waiver saying that ''we have this type of technology,'' but he did not provide information regarding which domestic manufacturer may produce these products in compliance with the FHWA's Buy America requirements. The third commenter (Rich) supports the waiver if the American product is more than 50 percent over non-domestic product. However, this is not the standard for the application of Buy America. Under Buy America, all steel and iron of predominantly steel or iron products must manufactured in the United States.

During the 15-day comment period, the FHWA conducted additional nationwide review to locate potential domestic manufacturers of (1) Electrical Controls and Electrical Equipment; (2) Main Drive Electrical Motor; (3) Auxiliary Drive Electric Motor; (4) Span Lock Electric Motor & Controls. Based on all the information available to the agency, including the consideration of

the comments, the FHWA concludes that there are no manufacturers of (1) Electrical Controls and Electrical Equipment; (2) Main Drive Electrical Motor; (3) Auxiliary Drive Electric Motor; (4) Span Lock Electric Motor & Controls for the project in the State of Washington that produce the products in compliance with the FHWA's Buy America requirements.

Therefore, in accordance with the provisions of section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572), the FHWA is providing this notice as its finding that a waiver of Buy America requirements is appropriate. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to the FHWA's Web site via the link provided to the Washington State waiver page noted above.

Authority: 23 U.S.C. 313; Pub. L. 110–161, 23 CFR 635.410.

Issued on: February 13, 2013.

Victor M. Mendez,

Federal Highway Administrator.

[FR Doc. 2013–04247 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Buy America Waiver Notification

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: This notice provides information regarding the FHWA's finding that a Buy America waiver is appropriate for the use of non-domestic iron and steel products in (1) Auxiliary two speed motor, (2) Auxiliary back up drive clutch, (3) Main span and backup span motor, and (4) Brakes for the Memorial Bridge project in the State of New Hampshire.

DATES: The effective date of the waiver is February 26, 2013.

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Gerald Yakowenko, FHWA Office of Program Administration, (202) 366–1562, or via email at *gerald.yakowenko@dot.gov.* For legal questions, please contact Mr. Michael Harkins, FHWA Office of the Chief Counsel, (202) 366–4928, or via email at *michael.harkins@dot.gov.* Office hours for the FHWA are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara.*

Background

The FHWA's Buy America policy in 23 CFR 635.410 requires a domestic manufacturing process for any steel or iron products (including protective coatings) that are permanently incorporated in a Federal-aid construction project. The regulation also provides for a waiver of the Buy America requirements when the application would be inconsistent with the public interest or when satisfactory quality domestic steel and iron products are not sufficiently available. This notice provides information regarding the FHWA's finding that a Buy America waiver is appropriate to use some non-domestic iron and steel products in (1) Auxiliary two speed motor, (2) Auxiliary back up drive clutch, (3) Main span and backup span motor, and (4) Brakes for a the Memorial Bridge project in the State of New Hampshire. The Memorial Bridge project will build a new crossing to replace the existing structurally deficient bridge carrying US–1 over the Piscataqua River between Portsmouth, NH, and Kittery, ME. The project is scheduled to reopen to traffic on July 6, 2013.

In accordance with Division A, section 122 of the ''Consolidated and Further Continuing Appropriations Act, 2012'' (Pub. L. 112–284), the FHWA published a notice of intent to issue a waiver on its Web site for iron and steel products in (1) Auxiliary two speed motor, (2) Auxiliary back up drive clutch, (3) Main span and backup span motor, and (4) Brakes in the State of New Hampshire (*http://www.fhwa.dot.gov/construction/contracts/waivers.cfm?id=81*) on October 4th. The FHWA received no comment in response to the publication. During the 15-day comment period, the FHWA conducted additional nationwide review to locate potential domestic manufacturers of the iron and steel products in (1) Auxiliary two speed motor, (2) Auxiliary back up drive clutch, (3) Main span and backup span motor, and (4) Brakes. Based on all the information available to the agency, the FHWA concludes that there are no manufacturers of the iron and steel products in (1) Auxiliary two speed motor, (2) Auxiliary back up drive clutch, (3) Main span and backup span motor, and (4) Brakes that produce the products in compliance with the FHWA's Buy America requirements.

Therefore, in accordance with the provisions of section 117 of the SAFETEA–LU Technical Corrections Act of 2008 (Pub. L. 110–244, 122 Stat. 1572), the FHWA is providing this notice as its finding that a waiver of Buy America requirements is appropriate. The FHWA invites public comment on this finding for an additional 15 days following the effective date of the finding. Comments may be submitted to the FHWA's Web site via the link provided to the New Hampshire waiver page noted above.

Authority: 23 U.S.C. 313; Pub. L. 110–161, 23 CFR 635.410.

Issued on: February 13, 2013.

Victor M. Mendez,

Federal Highway Administrator.

[FR Doc. 2013–04244 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0332]

Qualification of Drivers; Application for Exemptions; Hearing

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

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces that 9 individuals have applied for a medical exemption from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). In accordance with the statutory requirements concerning applications for exemptions, FMCSA requests public comments on these requests. The statute and implementing regulations concerning exemptions require that exemptions must provide an equivalent or greater level of safety than if they were not granted. If the Agency determines the exemptions would satisfy the statutory requirements and decides to grant theses requests after reviewing the public comments submitted in response to this notice, the exemptions would enable these 9 individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before March 27, 2013.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2012–0332] using any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

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

• *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

• *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8–785.pdf*.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov*, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

The Federal Motor Carrier Safety Administration has authority to grant exemptions from many of the Federal Motor Carrier Safety Regulations (FMCSRs) under 49 U.S.C. 31315 and 31136(e), as amended by Section 4007 of the Transportation Equity Act for the 21st Century (TEA- 21) (Pub. L. 105–178, June 9, 1998, 112 Stat. 107, 401). FMCSA has published in 49 CFR part 381, subpart C final rules implementing the statutory changes in its exemption procedures made by section 4007, 69 FR 51589 (August 20, 2004).[1] Under the rules in part 381, subpart C, FMCSA must publish a notice of each exemption request in the **Federal Register**. The Agency must provide the public with an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted and any research reports, technical papers and other publications referenced in the application. The Agency must also provide an opportunity to submit public comment on the applications for exemption.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to or greater than the level that would be achieved without the exemption. The decision of the Agency must be published in the **Federal Register**. If the Agency denies the request, it must state the reason for doing so. If the decision is to grant the exemption, the notice must specify the person or class of persons receiving the exemption and the regulatory provision or provisions from which an exemption is granted. The notice must also specify the effective period of the exemption (up to 2 years) and explain the terms and conditions of the exemption. The exemption may be renewed.

The current provisions of the FMCSRs concerning hearing state that a person is physically qualified to drive a CMV if that person

> First perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

49 CFR 391.41(b)(11). This standard was adopted in 1970, with a revision in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971).

FMCSA also issues instructions for completing the medical examination report and includes advisory criteria on the report itself to provide guidance for medical examiners in applying the hearing standard. See 49 CFR 391.43(f). The current advisory criteria for the hearing standard include a reference to a report entitled ''Hearing Disorders and Commercial Motor Vehicle Drivers'' prepared for the Federal Highway Administration, FMCSA's predecessor, in 1993.[2]

FMCSA Requests Comments on the Exemption Applications

FMCSA requests comments from all interested parties on whether a driver who cannot meet the hearing standard should be permitted to operate a CMV in interstate commerce. Further, the Agency asks for comments on whether a driver who cannot meet the hearing standard should be limited to operating only certain types of vehicles in interstate commerce, for example, vehicles without air brakes. The statute and implementing regulations concerning exemptions require that the Agency request public comments on all applications for exemptions. The Agency is also required to make a determination that an exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption before granting any such requests. 49 U.S.C. 31315(b)(1). See also 49 CFR 381.305(a).

Information on Individual Applicants

Mark Cole

Mr. Cole holds a driver's license from the state of Ohio. He would like to drive tractor trailer trucks in interstate commerce, if he is granted an exemption.

Nelson De Leon

Mr. De Leon holds a CDL from the state of Florida. He has been driving in intrastate commerce for 17 years and would like to drive a CMV in interstate commerce, if he is granted an exemption.

William Wallace Larson

Mr. Larson holds a class A Commercial driver's license (CDL) from the state of North Carolina. He has been

[1] This action adopted as final rules the interim final rules issued by FMCSA's predecessor in 1998 (63 FR 67600 (Dec. 8, 2008)), and adopted by FMCSA in 2001 (66 FR 49867 (Oct. 1, 2001)).

[2] This report is available on the FMCSA web site at *http://www.fmcsa.dot.gov/facts-research/research-technology/publications/medreport_archives.htm*.

driving a dump truck in intrastate commerce for 20 years and recently lost his hearing. He would like to continue to drive dump trucks if granted an exemption.

Bryan Lewis

Mr. Lewis holds a driver's license from the District of Columbia (DC). He would like to drive rental box trucks in interstate commerce, if granted an exemption.

Donald Lynch

Mr. Lynch holds a driver's license from the state of Florida. He would like to drive tractor trailer trucks in interstate commerce, if he is granted an exemption.

Zachary Rietz

Mr. Reitz holds a driver's license from the state of Texas. He has been driving straight trucks and vans locally for a trucking company. He would like to obtain a Class A CDL license and drive tractor trailers in interstate commerce if granted an exemption.

Benton Scott

Mr. Scott holds a Class A CDL license from the state of Mississippi. He has driven over the road tractor trailers for 34 years until recently when he was unable to pass the hearing requirement for his DOT physical. He would like to resume driving tractor trailer trucks in interstate commerce, if granted an exemption.

Bryon Smith

Mr. Smith holds a driver's license from the state of Louisiana. He would like to drive tractor trailer trucks in interstate commerce, if he is granted an exemption.

Steve Queen

Mr. Queen holds a Class A license from the state of Florida. He has been driving a CMV in interstate commerce until recently when he failed to pass the hearing test. He would like to continue to drive tractor trailer trucks in interstate commerce, if he is granted an exemption.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b)(4), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business March 27, 2013. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: February 4, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04312 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0338]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 9 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective February 25, 2013. The exemptions expire on February 25, 2015.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR-2010-12-29/pdf/2010-32876.pdf.*

Background

On December 17, 2012, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (77 FR 74731). That notice listed 9 applicants' case histories. The 9 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 9 applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision

of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 9 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including amblyopia, corneal scar, arterial occlusion, complete loss of vision, retinal detachment, a central retinal hole, and a macular scar. In most cases, their eye conditions were not recently developed. Four of the applicants were either born with their vision impairments or have had them since childhood.

The five individuals that sustained their vision conditions as adults have had it for a period of 4 to 30 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 9 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 4 to 36 years. In the past 3 years, none of the drivers were involved in crashes or convicted of moving violations in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the December 17, 2012, notice (77 FR 74731).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 9 applicants, none of the drivers was involved in crashes or convicted of moving violations in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without

the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 9 applicants listed in the notice of December 17, 2012 (77 FR 74731).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 9 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received no comments in this proceeding.

Conclusion

Based upon its evaluation of the 9 exemption applications, FMCSA exempts Sava Andjelich (IN), William Audinwood (NY), Keith E. Breeding (IN), Manual Chancey (FL), David L. Ellis (TX), Jack A. Hemelgarn (MN), Bobby L. Rupe (TX), Gary Wanek (NE), and Richard A. Wilt (OH) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: January 31, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04193 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2000–7363; FMCSA–2002–12432; FMCSA–2002–12844; FMCSA–2004–17984; FMCSA–2004–19477; FMCSA–2006–26066; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2008–0340; FMCSA–2009–0321; FMCSA–2010–0114; FMCSA–2010–0187; FMCSA–2010–0327; FMCSA–2010–0354; FMCSA–2010–0385]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 19 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective February 25, 2013. Comments must be received on or before March 27, 2013.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [FMCSA–2000–7363; FMCSA–2002–12432; FMCSA–2002–12844; FMCSA–2004–17984; FMCSA–2004–19477; FMCSA–2006–26066; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2008–0340; FMCSA–2009–0321; FMCSA–2010–0114; FMCSA–2010–0187; FMCSA–2010–0327; FMCSA–2010–0354; FMCSA–2010–0385], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the FDMS published in the **Federal Register** on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from

the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 19 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 19 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Jose C. Azuara (TX)	Dennis R. O'Dell, Jr. (OK).
Kenneth L. Bowers, Jr. (MN)	Jerry W. Parker (OH).
Eddie A. Branham (NC)	Gary W. Phelps (PA).
Timothy A. DeFrange (TX)	Billy R. Pierce (AL).
Andrew G. Fornsel (NY)	Myriam Rodriguez (CA).
Wilfred J. Gagnon (VT)	Jules M. Sancho, Jr. (LA).
Ricky G. Jacks (AL)	Henry A. Shelton (AL).
Lester G. Kelley, II (OH)	Kenneth J. Weaver (WY).
Thomas D. Laws (IN)	Cameron R. Whitford (NY).
Harry J. McSuley, Jr. (PA)	

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 19 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (65 FR 45821; 65 FR 77066; 67 FR 54525; 67 FR 68719; 68 FR 1654; 68 FR 2629; 68 FR 8794; 69 FR 33997; 69 FR 61293; 69 FR 64806; 69 FR 71098; 69 FR 71100; 70 FR 2705; 70 FR 8659; 71 FR 63380; 72 FR 1050; 72 FR 1054; 72 FR 184; 72 FR 5489; 73 FR 46973; 73 FR 51689; 73 FR 54888; 73 FR 63047; 73 FR 75803; 73 FR 78421; 73 FR 78422; 74 FR 6207; 74 FR 6209; 74 FR 981; 75 FR 1835; 75 FR 9482; 75 FR 34209; 75 FR 47883; 75 FR 47886; 75 FR 63255; 75 FR 65057; 75 FR 72863; 75 FR 77942; 75 79081; 75 FR 79083; 76 FR 2190; 76 FR 4413; 76 FR 4414; 76 FR 5425; 76 FR 8809). Each of these 19 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by March 27, 2013.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 19 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: February 12, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04187 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2013–0022]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 21 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce.

DATES: Comments must be received on or before March 27, 2013.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2013–0022 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR–2010–12–29/pdf/2010–32876.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' FMCSA can renew exemptions at the end of each 2-year period. The 21 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

Qualifications of Applicants

Keith Bell

Mr. Bell, age 40, has complete loss of vision in his right eye due to a traumatic incident in 2008. The best corrected visual acuity in his right eye is light perception, and in his left eye, 20/20. Following an examination in 2012, his ophthalmologist noted, ''His vision is sufficient to perform the driving tasks required to operate a commercial vehicle.'' Mr. Bell reported that he has driven straight trucks for 10 years, accumulating 1 million miles. He holds a Class B operator's license from Florida. His driving record for the last 3 years shows no crashes and one conviction for a moving violation in a CMV; he exceeded the speed limit by 9 mph.

Russell A. Bolduc

Mr. Bolduc, 53, has had a choroidal rupture in his right eye due to a traumatic incident in 1984. The visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''In my opinion, Mr. Bolduc has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Bolduc reported that he has driven straight trucks for 35 years, accumulating 350,000 miles, and tractor-trailer combinations for 33 years, accumulating 990,000 miles. He holds a Class A Commercial Driver's License (CDL) from Connecticut. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

David B. Bowman

Mr. Bowman, 30, has nerve damage in his right eye due to a traumatic incident in 2008. The visual acuity in his right eye is 20/100, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''I feel the Mr. Bowman has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Bowman reported that he has driven tractor-trailer combinations for 10 years, accumulating 400,000 miles. He holds a Class B CDL from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Ronnie Clark

Mr. Clark, 47, has amblyopia in his right eye since birth. The best corrected visual acuity in his right eye is 20/100, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''Exam reveals amblyopia, refractive. Lifelong. Stable. Visual fields WNL. Color WNL. No contraindications for commercial driving.'' Mr. Clark reported that he has driven tractor-trailer combinations for 26 years, accumulating 1.9 million miles. He holds a Class A CDL from Maine. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Earl R. Gould, Jr.

Mr. Gould, 47, has had a retinal detachment in his right eye since childhood due to a traumatic incident. The best corrected visual acuity in his right eye is counting fingers, and in his left eye, 20/15. Following an examination in 2012, his ophthalmologist noted, ''Based on his normal vision and visual field in his left eye, and his history of driving a commercial motor vehicle safely in the past with his current level of visual functioning, I conclude that he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Gould reported that he has driven straight trucks for 9 years, accumulating 517,500 miles, and tractor-trailer combinations for 27 years, accumulating 2.9 million miles. He holds a Class A CDL from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Matthew J. Hahn

Mr. Hahn, 42, has a retinal scar in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2012, his optometrist noted, ''It is my opinion that Matthew has a stable retinal scar. It should not progress. I feel that he has adequate vision to operate a commercial vehicle.'' Mr. Hahn reported that he has driven straight trucks for 15 years, accumulating 390,000 miles. He holds a Class C operator's license from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Terry R. Hunt

Mr. Hunt, 35, has a macular hole in his left eye due to a traumatic incident in 2000. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/60. Following an examination in 2012, his ophthalmologist noted, ''Commercial truck driver, good color vision, 180 degrees of peripheral vision, no medical contraindication to commercial truck driving.'' Mr. Hunt reported that he has driven tractor-trailer combinations for 13 years, accumulating 1.2 million miles. He holds a Class A CDL from Florida. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Sebastian G. Jachymiak

Mr. Jachymiak, 34, has a prosthetic in his left eye due to a traumatic incident in 1993. The best corrected visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2012, his optometrist noted, ''After evaluation of the above data, Sebastian Jachymiak has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Jachymiak reported that he has driven straight trucks for 15 years, accumulating 150,000 miles. He holds a Class D operator's license from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James P. O'Berry

Mr. O'Berry, 58, has a macular scar in his right eye since childhood. The best corrected visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2012, his optometrist stated that, ''In his opinion, Mr. O'Berry has sufficient vision to operate a commercial motor vehicle safely.'' Mr. O'Berry reported that he has driven straight trucks for 41 years, accumulating 2 million miles, and tractor-trailer combinations for 41 years, accumulating 1.4 million miles. He holds a Class A CDL from Georgia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Mark A. Omps

Mr. Omps, 56, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2012, his optometrist noted, ''In my opinion, testing provides satisfactory evidence that Mr. Omps possess sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Omps reported that he has driven straight trucks for 1 year, accumulating 38,000 miles, and tractor-trailer combinations for 23 years, accumulating 1.4 million miles. He holds a Class A CDL from West Virginia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Gerson Lopez-Padilla

Mr. Lopez-Padilla, 39, has had choroidal atrophy in his right eye since childhood. The best corrected visual acuity in his right eye is 20/50, and in his left eye, 20/20. Following an examination in 2012, his ophthalmologist noted, ''I certify that in my medical opinion, Mr. Gerson Lopez-Padilla has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Lopez-Padilla reported that he has driven straight trucks for 3 years, accumulating 78,000 miles, and tractor-trailer combinations for 3 years, accumulating 78,000 miles. He holds a Class A CDL from Connecticut. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Jerry D. Paul

Mr. Paul, 57, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/400. Following an examination in 2012, his optometrist noted, ''The pt has in my opinion the ability to operate a commercial vehicle with the vision that he currently possesses.'' Mr. Paul reported that he has driven straight trucks for 38 years, accumulating 266,000 miles, and tractor-trailer combinations for 16 years, accumulating 80,000 miles. He holds a Class A CDL from Arkansas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Larry B. Peterson

Mr. Peterson, 51, has had a corneal scar in his right eye since childhood. The best corrected visual acuity in his right eye is light perception, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''In my opinion patient has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Peterson reported that he has driven buses for 8 years, accumulating 340,000. He holds a Class B CDL from Arkansas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Franklin P. Reigle, III

Mr. Reigle, 58, has had a prosthetic in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2012, his optometrist noted, ''Mr. Reigle has been safely driving a commercial vehicle ever since he has been a patient here and it is my opinion that he can continue to do so.'' Mr. Reigle reported that he has driven straight trucks for 41 years, accumulating 717,500 miles, and tractor-trailer combinations for 31 years, accumulating 310,000 miles. He holds a Class AM CDL from Maryland. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Phillip Schaub

Mr. Schaub, 64, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/80. Following an examination in 2012, his ophthalmologist noted, ''It is my medical opinion that his vision meets all the criteria to perform the driving tasks required to operate a commercial vehicle.'' Mr. Schaub reported that he has driven straight trucks for 11 years, accumulating 330,000 miles. He holds a Class B CDL from Colorado. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Reginald Smart

Mr. Smart, 48, has had optic nerve atrophy in his left eye due to a traumatic incident during childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/400. Following an examination in 2012, his optometrist noted, ''In summary, Mr. Smart has good vision, good color vision, and a good field of vision when using both eyes. His condition is stable and he should qualify to drive commercially.'' Mr. Smart reported that he has driven tractor-trailer combinations for 16 years, accumulating 1.2 million miles. He holds a Class A CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

George Stapleton

Mr. Stapleton, 61, has had a parafoveal scar in his left eye since 2009. The best corrected visual acuity in his right eye is 20/30, and in his left eye, 20/80. Following an examination in 2012, his opthalmologist noted, ''He has, in my opinion, sufficient vision to perform driving tasks required to operate a commercial vehicle.'' Mr. Stapleton reported that he has driven tractor-trailer combinations for 21 years, accumulating 1.3 million miles. He holds a Class A CDL from Georgia. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Mark E. Studer

Mr. Studer, 57, has had true aphakia in his right eye since 1992. The best corrected visual acuity in his right eye is 20/150, and in his left eye, 20/20. Following an examination in 2012, his optometrist noted, ''His uncorrected vision is hand motion at 20 feet in the right eye and 20/30 in the left eye. Mr. Studer has 100 degrees of horizontal field in the right eye and 100 degrees of horizontal in the left eye. The total horizontal visual field is greater than 120 degrees. Mr. Studer has no color vision abnormalities. Therefore, it is my opinion that Mark can safely operate a commercial vehicle.'' Mr. Studer reported that he has driven straight trucks for 40 years, accumulating 40,000 miles, and tractor-trailer combinations for 19 years, accumulating 285,000 miles. He holds a Class A CDL from Kansas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

James K. Waites

Mr. Waites, 43, has had a macular scar in his right eye due to a traumatic incident in 2003. The best corrected visual acuity in his right eye is 20/60, and in his left eye, 20/15. Following an examination in 2012, his ophthalmologist noted, ''In my opinion he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Waites reported that he has driven straight trucks for 25 years, accumulating 875,000 miles, and tractor-trailer combinations for 21 years, accumulating 42,000 miles. He holds a Class A CDL from Arkansas. His driving record for the last 3 years shows no crashes and one conviction for a moving violation in a CMV; he exceeded the speed limit by 20 mph.

Scott Wallbank

Mr. Wallbank, 49, has had refractive amblyopia in his right eye since childhood. The best corrected visual acuity in his right eye is 20/60, and in his left eye, 20/20. Following an examination in 2012, his ophthalmologist noted, ''In my medical opinion, given the longstanding nature of Mr. Wallbank's visual deficiency in his right eye and his long experience as a commercial truck driver, I am comfortable stating that he does have sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Wallbank reported that he has driven straight trucks for 18 years, accumulating 374,400 miles. He holds an operator's license from Massachusetts. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Michael D. Zecha

Mr. Zecha, 34, has had amblyopia in his left eye since childhood. The best corrected visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2012, his ophthalmologist noted, ''In my medical opinion, Mr. Michael D. Zecha would be able to safely perform the driving tasks required for a commercial license. He has demonstrated this ability by driving with a similar waiver in the state of Kansas.'' Mr. Zecha reported that he has driven straight trucks for 5 years, accumulating 25,000 miles, and tractor-trailer combinations for 2 months, accumulating 4,000 miles. He holds a Class A CDL from Kansas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. The Agency will consider all comments received before the close of business March 27, 2013. Comments will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. The Agency will file comments received after the comment closing date in the public docket, and will consider them to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should monitor the public docket for new material.

Issued on: February 15, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04191 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0339]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 14 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or

greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective February 25, 2013. The exemptions expire on February 25, 2015.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202)-366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR-2010-12-29/pdf/2010-32876.pdf.*

Background

On January 9, 2013, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (78 FR 1919). That notice listed 14 applicants' case histories. The 14 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 14 applications on their merits and made a determination to grant exemptions to each of them.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing requirement red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 14 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including central scotoma, a branch retinal vein occlusion, amblyopia, hyperopia with amblyopia, a mature cataract, refractive amblyopia, and complete loss of vision. In most cases, their eye conditions were not recently developed. Eleven of the applicants were either born with their vision impairments or have had them since childhood.

The three individuals that sustained their vision conditions as adults have had it for a period of 8 to 20 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 14 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 4 to 31 years. In the past 3 years, one of the drivers was involved in crash for which he was not cited, and one was convicted of a moving violation in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the January 9, 2013 notice (78 FR 1919).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA–1998–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver

study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 14 applicants, one of the drivers was involved in crash for which he was not cited, and one was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 14 applicants listed in the notice of January 9, 2013 (78 FR 1919).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 14 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

FMCSA received no comments in this proceeding.

Conclusion

Based upon its evaluation of the 14 exemption applications, FMCSA exempts Benny L. Bailey (TN), Bobby R. Carter, Sr. (MI), Brent Coleman (TX), Adan Cortes-Juarez (WA), Lisa M. Durey (IL), David P. Elliot (OH), Matthew T. Eggers (IA), Jerry Hall (KY), Jerry L. Parker (NM), Colin Passmore (MN), Dennis W. Pevey (GA), Charles D. Reddick (GA), Frank Santak (DE), and Curtis E. Way (TX) from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: February 15, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04189 Filed 2–22–13; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2012–0351]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 20 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions will enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions are effective February 25, 2013. The exemptions expire on February 25, 2015.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

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Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR-2010-12-29/pdf/2010-32876.pdf.*

Background

On January 9, 2013, FMCSA published a notice of receipt of Federal diabetes exemption applications from 20 individuals and requested comments from the public (78 FR 1927). The public comment period closed on February 8, 2013, and no comments were received.

FMCSA has evaluated the eligibility of the 20 applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These 20 applicants have had ITDM over a range of 1 to 11 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the January 9, 2013, **Federal Register** notice and they will not be repeated in this notice.

Discussion of Comments

FMCSA received no comments in this proceeding.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Conclusion

Based upon its evaluation of the 20 exemption applications, FMCSA exempts Angel Bergendale (MA), Sean P. Borsky (FL), Uvena S. Brown (IN), Cody R. Floerchinger (MA), Sean P. Glynn (WI), Spiro J. Jonovich (AZ), Jaron L. Lindell (GA), Travis J. Martinez (NC), Victor D. Mayberry (TN), Larry L. McDaniel (OK), Barry C. McKay (MN), Robert B. McKendry (IL), Jamie W. Moore (NC), William L. Phelps (IN), Raby L. Ratliff (TX), Richard J. Rembisz (NY), Richard L. Smith (GA), Darrin L. Stoneberg (MN), Gary J. Tricarico, and Lacy I. Wallace, Jr. (NC) from the ITDM requirement in 49 CFR 391.41(b)(3), subject to the conditions listed under ''Conditions and Requirements'' above.

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption will be valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the 1/exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: February 19, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04192 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2012–0350]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

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

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 16 individuals from its rule prohibiting persons with insulin-treated diabetes mellitus (ITDM) from operating commercial motor vehicles (CMVs) in interstate commerce. The exemptions will enable these individuals to operate CMVs in interstate commerce.

DATES: The exemptions are effective February 25, 2013. The exemptions expire on February 25, 2015.

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Room W64–224, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* and/or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone may search the electronic form of all comments received into any of DOT's dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR-2010-12-29/pdf/2010-32876.pdf.*

Background

On January 9, 2013, FMCSA published a notice of receipt of Federal diabetes exemption applications from 16 individuals and requested comments from the public (78 FR 1923). The public comment period closed on February 8, 2013, and no comments were received.

FMCSA has evaluated the eligibility of the 16 applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

Diabetes Mellitus and Driving Experience of the Applicants

The Agency established the current requirement for diabetes in 1970 because several risk studies indicated that drivers with diabetes had a higher rate of crash involvement than the general population. The diabetes rule provides that ''A person is physically qualified to drive a commercial motor vehicle if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control'' (49 CFR 391.41(b)(3)).

FMCSA established its diabetes exemption program, based on the Agency's July 2000 study entitled ''A Report to Congress on the Feasibility of a Program to Qualify Individuals with Insulin-Treated Diabetes Mellitus to Operate in Interstate Commerce as Directed by the Transportation Act for the 21st Century.'' The report concluded that a safe and practicable protocol to allow some drivers with ITDM to operate CMVs is feasible. The September 3, 2003 (68 FR 52441), **Federal Register** notice in conjunction with the November 8, 2005 (70 FR 67777), **Federal Register** notice provides the current protocol for allowing such drivers to operate CMVs in interstate commerce.

These 16 applicants have had ITDM over a range of 1 to 23 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the past 5 years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes-related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

The qualifications and medical condition of each applicant were stated and discussed in detail in the January 9, 2013 **Federal Register** notice and they will not be repeated in this notice.

Discussion of Comments

FMCSA received one comment in this proceeding. Mark Sokolow stated he is in favor of all exemptions.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the diabetes requirement in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered medical reports about the applicants' ITDM and vision, and reviewed the treating endocrinologists' medical opinion related to the ability of the driver to safely operate a CMV while using insulin.

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

Conditions and Requirements

The terms and conditions of the exemption will be provided to the applicants in the exemption document and they include the following: (1) That each individual submit a quarterly

monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) that each individual reports within 2 business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (4) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Conclusion

Based upon its evaluation of the 16 exemption applications, FMCSA exempts Shawn J. Ball (ID), Buck H. Bowers (OH), Jeffrey S. Bublitz (WI), Ira S. Chamberlain (ME), Victor W. Dannenbrink (IA), James K. Dowden (MN), Myron P. Egbert (UT), Michael T. Evans (OH), Stephen P. Honen (OH), Charles E. Johnston (MS), Steve A. Rau (ND), Jack M Sipich (IL), Roger N. Stauffer (MI), Tyrone Taylor (NC), Michael E. Westley (FL), and Travis M. Whitt (CA) from the ITDM requirement in 49 CFR 391.41(b)(3), subject to the conditions listed under ''Conditions and Requirements'' above.

In accordance with 49 U.S.C. 31136(e) and 31315 each exemption will be valid for two years unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the 1/exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315. If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: February 15, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04190 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–4334; FMCSA–2000–7363; FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–12844; FMCSA–2002–13411; FMCSA–2006–24015; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2008–0266; FMCSA–2008–0340; FMCSA–2010–0385; FMCSA–2010–0413]

Qualification of Drivers; Exemption Applications; Vision

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 24 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective March 23, 2013. Comments must be received on or before March 27, 2013.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: [Docket No. FMCSA–1998–4334; FMCSA–2000–7363; FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–12844; FMCSA–2002–13411; FMCSA–2006–24015; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2008–0266; FMCSA–2008–0340; FMCSA–2010–0385; FMCSA–2010–0413], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement for the Federal Docket Management System (FDMS) published in the **Federal Register** on December 29, 2010 (75 FR 82132), or you may visit *http://www.gpo.gov/fdsys/pkg/FR–2010–12–29/pdf/2010–32876.pdf.*

FOR FURTHER INFORMATION CONTACT: Elaine M. Papp, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

Exemption Decision

This notice addresses 24 individuals who have requested renewal of their

exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 24 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

David W. Ball (MO)	Thomas F. Marczewski (WI)
Willie Burnett, Jr. (FL)	Roy E. Mathews (FL)
Marcus L. Conner (TX)	James T. McGraw, Jr. (PA)
Thomas G. Danclovic (MO)	Robert S. Metcalf (AZ)
Donald K. Driscoll (MA)	Carl A. Michel, Sr. (MD)
Richard G. Gruber (SC)	Donald R. Pointer (CO)
Kenneth L. Handy (IA)	Bobby G. Pool, Sr. (TX)
William G. Holland (AR)	Mark A. Steckmyer (KY)
Bruce G. Horner (WA)	Jeremichael Steele (NC)
Thomas J. Ivins (FL)	Wade D. Taylor (MO)
Leon E. Jackson (GA)	Ronald J. Watt (ND)
Gerald D. Larson (WI)	Yu Weng (NJ)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 24 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (63 FR 66226; 64 FR 16517; 65 FR 45817; 65 FR 66286; 65 FR 77066; 65 FR 78256; 66 FR 13825; 66 FR 16311; 67 FR 68719; 67 FR 76439; 68 FR 10298; 68 FR 10300; 68 FR 13360; 68 FR 2629; 69 FR 71100; 70 FR 12265; 70 FR 7545; 70 FR 7546; 71 FR 14566; 71 FR 30227; 71 FR 63379; 72 FR 1050; 72 FR 1053; 72 FR 11426; 72 FR 180; 72 FR 7812; 72 FR 9397; 73 FR 27014; 73 FR 51689; 73 FR 63047; 73 FR 75803; 74 FR 6209; 74 FR 8302; 75 FR 77942; 75 FR 77949; 76 FR 11215; 76 FR 12408; 76 FR 1493; 76 FR 4413; 76 FR 5425; 76 FR 9861). Each of these 24 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

Request for Comments

FMCSA will review comments received at any time concerning a particular driver's safety record and determine if the continuation of the exemption is consistent with the requirements at 49 U.S.C. 31136(e) and 31315. However, FMCSA requests that interested parties with specific data concerning the safety records of these drivers submit comments by March 27, 2013.

FMCSA believes that the requirements for a renewal of an exemption under 49 U.S.C. 31136(e) and 31315 can be satisfied by initially granting the renewal and then requesting and evaluating, if needed, subsequent comments submitted by interested parties. As indicated above, the Agency previously published notices of final disposition announcing its decision to exempt these 24 individuals from the vision requirement in 49 CFR 391.41(b)(10). The final decision to grant an exemption to each of these individuals was made on the merits of each case and made only after careful consideration of the comments received to its notices of applications. The notices of applications stated in detail the qualifications, experience, and medical condition of each applicant for an exemption from the vision requirements. That information is available by consulting the above cited **Federal Register** publications.

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

Issued on: February 15, 2013.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2013–04188 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2013–0004]

Notice of Joint Application for Approval of Discontinuance or Modification of a Railroad Signal System

In accordance with Part 235 of Title 49 Code of Federal Regulations and 49 U.S.C. 20502(a), this document provides the public notice that by a document dated January 10, 2013, The Belt Railway Company of Chicago (BRC) and

CSX Transportation, Inc. (CSX) have jointly petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of a signal system. FRA assigned the petition Docket Number FRA–2013–0004.

Applicants:

The Belt Railway Company of Chicago, Mr. Randall D. Smith, Chief Engineer, 6900 South Central Avenue, Bedford Park, Illinois 60638.

CSX Transportation, Inc., Mr. David B. Olson, Chief Engineer Communication and Signals, 500 Water Street, Speed Code J–350, Jacksonville, Florida 32202.

BRC and CSX seek joint approval of the proposed discontinuance and removal of the power operated derails, Numbers 11 and 13, on BRC Main Track (MT) 1 and MT 2 at Milepost 13.32 on the Kenton Subdivision, in Chicago, IL. The location is referred to as the Forest Hill Interlocking by BRC and as the 75th Street Interlocking by CSX. The subject interlocking is equipped with absolute signals in all quadrants and is controlled by CSX. The maximum authorized speed is 25 mph. BRC and CSX seek to make these changes in order to improve fluidity through the interlocking.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 11, 2013 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on February 20, 2013.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2013–04246 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2002–14116]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From Requirements

In accordance with Part 235 of Title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that by a document dated January 21, 2013, the Grand Trunk Western Railroad Company (GTW), which operates under the trade name of the Canadian National Railway Company (CN), has petitioned the Federal Railroad Administration (FRA) for an extension of relief from the requirements of the rules, standards, and instructions contained in 49 CFR part 236. FRA assigned the petition Docket Number FRA–2002–14116.

In 2002, CN sought relief from 49 CFR 236.408 so that route locking need not be provided for the power-operated switches at the 32nd Street crossover at Milepost 333.28 in the existing traffic control system at Port Huron, MI, on the Midwest Division, Flint Subdivision. The request was based on the fact that the design of the 32nd Street crossover is not uncommon in the railroad industry, and it provides all the requisite components and safety features of a standard interlocking, or an electric lock location. FRA issued the initial relief to CN in 2003. CN subsequently requested an extension of relief, which FRA granted in 2008.

GTW has operated under this waiver for nearly 10 years without incident, and it therefore believes that extending this waiver and making it permanent is appropriate.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Ave. SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 11, 2013 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov

or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on February 20, 2013.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2013–04287 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–1999–5102]

Petition for Extension of Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated February 1, 2012, the Southeastern Pennsylvania Transportation Authority (SEPTA) has petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 213, Track Safety Standards. The docket number associated with this petition is FRA–1999–5102.

Specifically, SEPTA seeks to extend a waiver from 49 CFR 213.233(c), relating to the frequency of the required visual track inspections. FRA issued the initial waiver that granted SEPTA relief on July 24, 2000, and FRA extended the waiver on August 4, 2003, and February 28, 2008.

SEPTA requests an extension of approval to reduce the frequency of required, visual track inspections for certain tracks that carry passenger traffic, specifically only those tracks that are constructed with continuous welded rail. SEPTA proposes to conduct one visual track inspection per week, instead of the two inspections per week that are required in 49 CFR part 213, and to supplement its visual inspections with the operation of an automated track geometry measuring vehicle over the affected main tracks and sidings four times per year. SEPTA has owned and operated such a measuring vehicle since 1990.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's Docket Operations Facility, 1200 New Jersey Ave. SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comments, they should notify FRA in writing before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal Holidays.

Communications received by April 11, 2013 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on February 20, 2013.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2013–04290 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2009–0077]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations, this document provides the public notice that by a document dated December 5, 2011, the Central California Traction Company (CCT) and the United Transportation Union (UTU) have jointly petitioned the Federal Railroad Administration (FRA) for an extension of their waiver of compliance from certain provisions of the Federal hours of service laws contained at 49 U.S.C. 21103(a)(4). FRA assigned the petition Docket Number FRA–2009–0077.

In their petition, CCT and UTU seek relief from 49 U.S.C. 21103(a)(4), which, in part, requires a train employee to receive 48 hours off duty after initiating an on-duty period for 6 consecutive days. Specifically, CCT and UTU seek an extension of the existing waiver to allow a train employee to initiate an on-duty period for 6 consecutive days followed by 24 hours off duty. In support of their request, CCT explained that the waiver allows for better flexibility and responsiveness to its customers, and that FRA inspectors monitoring CCT's operations have found no violations of the regulations. CCT also stated that this type of schedule has not compromised rail safety.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.

• *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 11, 2013 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on February 20, 2013.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2013–04245 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–1999–6254]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated December 21, 2012, Santa Clara Valley Transportation Authority (VTA) has petitioned the Federal Railroad Administration (FRA) for an extension of a waiver of compliance from certain provisions of the Federal railroad safety regulations. FRA assigned the petition Docket Number FRA–1999–6254.

VTA's 42.2-mile light rail transit (LRT) system began service in December 1987. The initial 9-mile segment from Santa Clara through downtown San Jose, CA, was completed in June 1988. By April 1991, VTA had extended its service to a 20.8-mile LRT system with 33 stations and 11 park-and-ride lots.

In December 1999, VTA began operations on its 7.6-mile Tasman West Extension, which connects Mountain View, CA, with VTA's existing light rail line. The Tasman East Extension followed in two phases. Phase I, which provides LRT service from VTA's Baypointe Transfer Station to its I–880/Milpitas Station, was completed in May 2001. Phase II, which provides LRT service from VTA's I–880/Milpitas Station to its Hostetter Station, was completed in June 2004, in conjunction with the Capitol Light Rail Extension south of Hostetter Station to Alum Rock Station. On October 1, 2005, VTA's Vasona Extension—which runs from downtown San Jose, CA, to the Winchester Transit Center—began service.

The Vasona Extension is an LRT line that features ''limited connections'' to the general railroad system of transportation due to a shared corridor of operation with Union Pacific Railroad (UP). Specifically, the Vasona Extension includes 5 miles of an existing 15-mile long freight railroad industrial lead that is serviced by UP. VTA owns the 5-mile section of track along the shared corridor with UP. VTA and UP maintain an Operations and Maintenance Agreement (Agreement), which includes an exclusive operating easement for UP. The Agreement allows UP to fulfill its common carrier obligation to operate freight service along the shared corridor. This Agreement also requires VTA to inspect, maintain, and repair all track, signal systems, and automatic warning devices along the shared corridor. UP's freight operations are minimal and limited to daylight hours, with a maximum authorized speed of 10 mph.

By letter dated September 26, 2005, FRA granted VTA partial relief from certain provisions of the Federal railroad safety regulations for VTA's operations on the Vasona Extension. In a July 11, 2011, letter, VTA requested that FRA extend the terms and conditions of the waivers for another 5 years. FRA's subsequent reply letter, dated November 16, 2011, denied the requested 5-year extension, citing ''certain instances of noncompliance by [VTA] with applicable FRA safety regulations.'' Instead, FRA granted VTA an 18-month extension of the waivers, with the possibility of a further extension, subject to VTA addressing FRA's safety concerns.

In a December 21, 2012, letter, VTA requested that FRA extend the terms and conditions of the subject waivers for another 5 years. VTA states that it has worked diligently to address the issues raised by FRA in its November 16, 2011, reply letter. Since 2011, VTA has written to and met with FRA officials to clarify specific areas of concern, as well as to obtain guidance on complying with the applicable FRA regulations. VTA maintains that as a result of the discussions with FRA, it has implemented a number of changes to address FRA's concerns and to achieve full regulatory compliance. VTA therefore believes that it is appropriate to request, and for FRA to grant, a 5-year extension of the waivers.

VTA also falls under the safety oversight of the California Public Utilities Commission, which is authorized by the Federal Transit Administration. See *Statement of Agency Policy Concerning Jurisdiction Over the Safety of Railroad Passenger Operations and Waivers Related to Shared Use of the Tracks of the General Railroad System by Light Rail and Conventional Equipment,* 65 FR 42529 (July 10, 2000). See also *Joint Statement of Agency Policy Concerning Shared Use of the Tracks of the General Railroad System by Conventional Railroads and Light Rail Transit Systems,* 65 FR 42626 (July 10, 2000).

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.

• *Fax:* 202–493–2251.

• *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.

• *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m.

and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 11, 2013 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on February 20, 2013.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2013–04243 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2002–12409]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated November 30, 2012, Port Authority Trans-Hudson (PATH) has petitioned the Federal Railroad Administration (FRA) for an extension of Waiver Docket Number FRA–2002–12409, which provides relief from certain provisions of 49 CFR part 238—Passenger Equipment Safety Standards. Specifically, PATH requests extension of the waiver of compliance from the requirements of 49 CFR 238.305(c)(10)—*Interior calendar day mechanical inspection of passenger cars,* 238.305.(d), and 238.317(a)(1)—*Movement of passenger equipment with other than power brake defects.* These regulations are associated with the interior calendar-day inspection and Class 2 brake test, respectively.

PATH requests relief from the requirement to remove a car from service on the calendar day following the interior calendar-day mechanical inspection, and requests that the car be permitted to remain in passenger service until the car can be brought to the PATH running repair or main repair facility at the earliest practical time, but not to exceed 8 calendar days following notification, providing all of the specific conditions contained in 49 CFR 238.305(c)(10) and 49 CFR 238.305(d)(1)–(d)(3) are met. PATH further requests partial relief from the requirement to perform a Class 2 brake test during specific periods of time at terminal locations in which terminal dwell times are less than 5 minutes. PATH asserts that the conductor does not have adequate time to remain at the rear of the train to perform the brake test while the engineer changes operating position and then walk forward to the conductor's operating position between the first and second cars. FRA assigned the petition Docket Number FRA–2002–12409.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Web site: http://www.regulations.gov/.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by April 11, 2013 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). See *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov or interested parties may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Issued in Washington, DC, on February 20, 2013.

Robert C. Lauby,

Deputy Associate Administrator for Regulatory and Legislative Operations.

[FR Doc. 2013–04286 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2013–0017; Notice 1]

Fuji Heavy Industries U.S.A., Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Receipt of Petition.

SUMMARY: Fuji Heavy Industries U.S.A., Inc., on behalf of Subaru of America (Fuji),[1] has determined that certain 2013 Subaru XV Crosstrek Multipurpose Passenger Vehicles manufactured between May 17, 2012, and February 7, 2013, do not fully comply with paragraphs S6.1 and S6.2 of Federal Motor Vehicle Safety Standard (FMVSS) No. 205, *Glazing Materials.* Fuji has filed an appropriate report dated January 29, 2013, pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports.*

Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Fuji submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Fuji's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Vehicles Involved: Affected are approximately 23,600 model year 2013 Subaru XV Crosstrek passenger vehicles

[1] Fuji North America, Inc., is a manufacturer of motor vehicles and is registered under the laws of the state of New Jersey.

manufactured between May 17, 2012, and February 7, 2013.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, these provisions only apply to the subject 23,600 [2] model year 2013 Subaru XV Crosstrek multipurpose passenger vehicles that Fuji no longer controlled at the time it determined that the noncompliance existed.

Noncompliance: Fuji explains that the noncompliance is that, due to a labeling error, the glazing markings on the rear window of the subject vehicles lack the symbol ''DOT'', the manufacturer's code mark (i.e. 44), and the AS3 code mark and thus do not conform to the requirements of 49 CFR 571.205 paragraphs S6.1 and S6.2.

Rule Text: Paragraphs S6.1 and S6.2 of FMVSS No. 205 requires in pertinent part:

S6.1 A prime glazing material manufacturer must certify, in accordance with 49 U.S.C. 30115, each piece of glazing material to which this standard applies that is designed—

(a) As a component of any specific motor vehicle or camper; or

(b) To be cut into components for use in motor vehicles or items of motor vehicle equipment.

S6.2 A prime glazing manufacturer certifies its glazing by adding to the marks required by section 7 of ANSI Z26.1–1996, in letters and numerals of the same size, the symbol ''DOT'' and a manufacturer's code mark that NHTSA assigns to the manufacturer.

Summary of Fuji's Analysis and Arguments

Fuji explains that while the noncompliant vehicle's rear window glazing lack the following markings: The symbol ''DOT'', the manufacturer's code mark (i.e. 44) and the AS3 code mark; on the glazing of the rear window as required by FMVSS No. 205, the rear glazing of the affected vehicles otherwise meet or exceed all other marking and performance requirements as required by FMVSS No. 205 and ANSI Z26.1–1996.

Fuji has additionally informed NHTSA that it has corrected future production and that all other glazing labeling information is correct.

Fuji also expressed its belief that NHTSA has previously granted similar petitions involving the omission of FMVSS No. 205 markings.

In summation, Fuji believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt it from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Comments: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods:

a. By mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

b. By hand delivery to U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal holidays.

c. Electronically: by logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/*. Follow the online instructions for submitting comments. Comments may also be faxed to 1–202–493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard *with the comments. Note that all comments received will be posted without change to http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment Closing Date: March 27, 2013.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at CFR 1.95 and 501.8.

Issued on: February 15, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–04171 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–59–P

[2] Fuji's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt Fuji as a motor vehicle manufacturer from the notification and recall responsibilities of 49 CFR Part 573 for the 23,600 affected vehicles. However, a decision on this petition will not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Fuji notified them that the subject noncompliance existed.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0073; Notice 2]

Guizhou Tyre Corporation; Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of petition.

SUMMARY: GTC North America, Inc., on behalf of Guizhou Tyre I/E Co. LTD (collectively referred to as ''GTC'') has determined that certain Samson and Advance brand ST trailer Tires, do not fully comply with paragraph S6.5(j) of Federal Motor Vehicle Safety Standard (FMVSS) No. 119, *New pneumatic tires for motor vehicles with a GVWR of more than 4,536 kilograms (10,000 pounds) and motorcycles.* GTC has filed an appropriate report dated March 22, 2012, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, GTC has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of the petition was published, with a 30-day public

comment period, on June 25, 2012 in the **Federal Register** (77 FR 37957). No comments were received. To view the petition, and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2012–0073.''

For further information on this decision contact Mr. Jack Chern, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–0661, facsimile (202) 366–7002.

Tires involved: Affected are approximately 4,291 size ST235/ 85R16/ 14 ply Samson and Advance brand ST Trailer Tires manufactured from December 4, 2011 through March 31, 2012.

Noncompliance: GTC explains that the noncompliance is that, due to a mold labeling error, the sidewall marking on the tires incorrectly identifies the load range as ''F'' when in fact it should be ''G''.

Summary of GTS's Analysis and Arguments

GTC states that while the tire sidewall labeling incorrectly identifies the load range as ''F'' when in fact it should be identified as ''G'' it does not pose a safety issue because if a consumer followed the load range ''F'' designation they would actually fall below the actual recommended load carrying capacity. Since the tire load range designation ''F'' falls below the actual recommended load carrying capacity, the tires will perform without incident causing no safety issue.

GTC also stated that all other required sidewall markings are present and correct.

GTC has additionally informed NHTSA that it has stopped production of the subject tires, is correcting the tire molds so that the subject noncompliance does not occur in future production, and has notified dealers to discontinue selling the tires.

In summation, GTC believes that the described noncompliance of its tires is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA Decision

The primary safety purpose of requiring the load range label on a motor vehicle tire is to ensure that the end-users can select a tire load range appropriate for their vehicles. The absence of the vehicle label specifying the tire load range would likely result in an improper tire selection by the tire dealer or vehicle owner. In this case, GTC understated the load carrying capability of the tire. GTC's tire, in effect, is has more load carrying capability than the label would indicate to the end-user. The agency agrees with GTC''s rational that a vehicle equipped with the subject tires and loaded per the incorrect maximum load rating would not cause an unsafe condition, because the end-user would carry a lighter load than the load for which the tires are designed.

In consideration of the foregoing, NHTSA has decided that GTC has met its burden of persuasion that the FMVSS No. 119 noncompliance in the tires identified in GTC's Noncompliance Information Report is inconsequential to motor vehicle safety. Accordingly, GTC's petition is granted and the petitioner is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the tires [1] that GTC no longer controlled at the time that it determined that a noncompliance existed in the subject vehicles.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8).

Issued on: February 11, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–04170 Filed 2–22–13; 8:45 am]

BILLING CODE 4910–59–P

[1] GTC's petition, which was filed under 49 CFR Part 556, requests an agency decision to exempt GTC as a manufacturer from the notification and recall responsibilities of 49 CFR Part 573 for the affected tires. However, the decision on this petition does not relieve distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after GTC notified them that the subject noncompliance existed.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for EFTPS Individual Enrollment with Third Party Authorization Form

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning EFTPS Individual Enrollment with Third Party Authorization Form.

DATES: Written comments should be received on or before April 26, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this form should be directed to Martha R. Brinson, at (202) 622–3869, or at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet, at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: EFTPS Individual Enrollment with Third Party Authorization Form.

OMB Number: 1545–2077.

Form Name: EFTPS Individual Enrollment with Third Party Authorization Form.

Abstract: The information derived from the EFTPS Individual Enrollment with Third Party Authorization Form will allow individual taxpayers to authorize a Third Party to pay their federal taxes on their behalf using the Electronic Federal Tax Payment System (EFTPS).

Current Actions: There are no changes being made to this form at this time.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 1,000.

Estimated Average Time Per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 167 hrs.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 13, 2013.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013–04174 Filed 2–22–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 14420

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 14420, Verification of Reported Income.

DATES: Written comments should be received on or before April 26, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to Yvette Lawrence, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, (202) 622–3869, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Verification of Reported Income.

OMB Number: 1545–2236.

Form Number: Form 14420.

Abstract: The Pilots are aimed at determining the best method for and value of using the new Form 1099–K information to identify and treat non-compliance. This is expected to result in the identification of many new cases of gross receipts underreporting. As a result, this effort will also test new treatment streams to allow the IRS to work these cases. One of these treatment streams is a new notice process. Requesting the books and records needed to verify the gross receipts discrepancy through a notice process would result in extensive taxpayer burden. Instead, the taxpayer can fill out this form, which requests the minimum information needed for us to refine our analysis of the taxpayer's return and determine if there are any reporting errors/business characteristics that may explain their outlier reported figures.

Current Actions: There are no changes being made to this form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations, Individuals or Households.

Estimated Number of Respondents: 5,600.

Estimated Time per Respondent: 4 hours.

Estimated Total Annual Burden Hours: 22,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: February 19, 2013.

Yvette Lawrence,

IRS Reports Clearance Officer.

[FR Doc. 2013–04177 Filed 2–22–13; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the annual meeting of the Department of Veterans Affairs Voluntary Service (VAVS) National Advisory Committee (NAC) will be held on March 4–6, 2013, at the Embassy Suites, Raleigh-Durham Research Triangle Park, 201 Harrison Oaks Boulevard, Cary, North Carolina. On March 14, the meeting will begin at 8 a.m. and end at 11:30 a.m. On March 5–6, the meetings will begin at 8:30 a.m. and end at 4:30 p.m. on March 5 and at 4 p.m. on March 6. The meeting is open to the public.

The Committee, comprised of fifty-four national voluntary organizations, advises the Secretary, through the Under Secretary for Health, on the coordination and promotion of volunteer activities within VA facilities. The purposes of this meeting are to provide for Committee review of volunteer policies and procedures; to

accommodate full and open communications between organization representatives and the Voluntary Service Office and field staff; to provide educational opportunities geared towards improving volunteer programs with special emphasis on methods to recruit, retain, place, motivate, and recognize volunteers; and to provide Committee recommendations.

The March 4 session will include a National Executive Committee Meeting, Health Fair, and VAVS Representative and Deputy Representative training session.

The March 5 business session will include remarks from local officials, the Voluntary Service Report, Veterans Health Administration Update, and remarks by VA officials on the My HealtheVet initiative, Patient Centered-Care, and Homelessness. The James H. Parke Memorial Scholarship recipient will be honored at the Parke Awards Luncheon (requires prepayment) to be held at 12 noon. Educational workshops will be held in the afternoon and will focus on student volunteers, developing adaptive sports programs at the facility level, My HealtheVet volunteer program, and national cemetery volunteering.

On March 6, the morning business session will include subcommittee reports, presentations on No One Dies Alone program, suicide prevention, and Make the Connection resources. The educational workshops will be repeated in the afternoon. The meeting will conclude with a Closing Awards Dinner (requires prepayment) recognizing the recipients of the American Spirit Awards, VAVS Award for Excellence, and the NAC male and female Volunteer of the Year awards.

No time will be allocated at this meeting for receiving oral presentations from the public. However, the public may submit written statements for the Committee's review to Ms. Laura Balun, Designated Federal Officer, Voluntary Service Office (10B2A), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC, 20420, or email at *Laura.Balun@va.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Ms. Balun at (202) 461–7300.

Dated: February 20, 2013.

By Direction of the Secretary.

Vivian Drake,

Acting Committee Management Officer.

[FR Doc. 2013–04250 Filed 2–22–13; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Disability Compensation, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Advisory Committee on Disability Compensation will meet on March 18–19, 2013, in Suite 800 at the United States Access Board, 1331 F Street NW., Washington, DC. The sessions will begin at 8:30 a.m. and end at 4 p.m. on both days. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the maintenance and periodic readjustment of the VA Schedule for Rating Disabilities. The Committee is to assemble and review relevant information relating to the nature and character of disabilities arising during service in the Armed Forces, provide an ongoing assessment of the effectiveness of the rating schedule, and give advice on the most appropriate means of responding to the needs of Veterans relating to disability compensation.

The Committee will receive briefings on issues related to compensation for Veterans with service-connected disabilities and other VA benefits programs. Time will be allocated for receiving public comments in the afternoon. Public comments will be limited to three minutes each. Individuals wishing to make oral statements before the Committee will be accommodated on a first-come, first-served basis. Individuals who speak are invited to submit 1–2 page summaries of their comments at the time of the meeting for inclusion in the official meeting record.

The public may submit written statements for the Committee's review to Nancy Copeland, Acting Designated Federal Officer, Department of Veterans Affairs, Veterans Benefits Administration, Compensation Service, Regulation Staff (211D), 810 Vermont Avenue NW., Washington, DC 20420 or email at *nancy.copeland@va.gov.* Any member of the public wishing to attend the meeting or seeking additional information should contact Mrs. Copeland at (202) 461–9685.

Dated: February 20, 2013.

By Direction of the Secretary.

Vivian Drake,

Committee Management Officer.

[FR Doc. 2013–04276 Filed 2–22–13; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Geriatrics and Gerontology Advisory Committee, Notice of Meeting Amendment

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that a meeting of the Geriatrics and Gerontology Advisory Committee has been rescheduled on April 11–12, 2013, in Room 830 on April 11 and in Room 630 on April 12 at the Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC, and not on April 10–11, 2013, as originally announced in the **Federal Register** on January 30, 2013. On April 11, the session will begin at 8:30 a.m. and end at 5 p.m. On April 12, the session will begin at 8 a.m. and end at 12 noon. This meeting is open to the public.

The purpose of the Committee is to provide advice to the Secretary of Veterans Affairs and the Under Secretary for Health on all matters pertaining to geriatrics and gerontology. The Committee assesses the capability of VA health care facilities and programs to meet the medical, psychological, and social needs of older Veterans and evaluates VA programs designated as Geriatric Research, Education, and Clinical Centers.

The meeting will feature presentations and discussions on VA's geriatrics and extended care programs, aging research activities, updates on VA's employee staff working in the area of geriatrics (to include training, recruitment and retention approaches), Veterans Health Administration (VHA) strategic planning activities in geriatrics and extended care, recent VHA efforts regarding dementia and program advances in palliative care, and performance and oversight of VA Geriatric Research, Education, and Clinical Centers.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee to Mrs. Marcia Holt-Delaney, Program Analyst, Geriatrics and Extended Care Services (10P4G), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, or via email at *Marcia.Holt-Delaney@va.gov.* Individuals who wish to attend the meeting should contact Mrs. Holt-Delaney at (202) 461–6769.

Dated: February 20, 2013.

By Direction of the Secretary.

Vivian Drake,

Committee Management Officer.

[FR Doc. 2013–04253 Filed 2–22–13; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Request for Information: Public-Private Collaborations in Pain Research

AGENCY: Office of Research and Development, VA.

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) publishes this Request for Information (RFI) on public-private collaborations in pain research, seeking to connect the Veterans Health Administration's (VHA) Office of Research and Development (ORD) with commercial organizations that are conducting, or have an interest in conducting, pain research through a Cooperative Research and Development Agreement (CRADA). The CRADA is to develop public-private collaborations in pain research with the intent of developing novel therapies that will benefit Veterans suffering from chronic pain conditions.

DATES: This notice will remain open indefinitely to accept inquiries and responses.

FOR FURTHER INFORMATION CONTACT: Interested parties should contact Audrey Kusiak, Ph.D., Scientific Program Manager, at (202) 443–5770 or by email at *vhacoordpain@va.gov*. Please use the subject line: ''VHA CO ORD PAIN PUBLIC PRIVATE COLLABORATIONS.'' You may also write to Veterans Health Administration, Office of Research and Development (10P9R), 810 Vermont Avenue NW., Washington, DC 20420. When responding, please provide the name of your organization, the main area of research interest, your name and title, and contact information (including mailing address, email address, and phone number). Do not include proprietary, classified, confidential, or sensitive information in your response.

SUPPLEMENTARY INFORMATION: VA is seeking to identify commercial organizations that are interested in the development and translation of novel therapies for chronic pain. Collaboration will be made via a CRADA under the authority of the Federal Technology Transfer Act of 1986 (FTTA), Public Law 99–502, October 20, 1986, codified at 15 U.S.C. 3710a. Under the FTTA, VA and the private party may exchange personnel, services, facilities, equipment, intellectual property, or other resources. No Federal funds may be provided to the collaborator, but the VA laboratory is authorized to accept Federal funds. VA may grant to the collaborating party a license or an assignment to inventions made under the CRADA. VA will select collaborators based on a mutually beneficial relationship that is fair and equitable, with the goal of alleviating pain in the Veteran population.

Under the CRADA, VA's duties will include connecting industry collaborators with appropriate VA investigators conducting pain research. Further, VA will provide expertise in the development and implementation of pre-clinical testing (e.g., good laboratory practice) of viable therapies to investigational new drugs; design and implementation of clinical trials; and development of a data-sharing plan.

This RFI invites feedback from private entities that are interested in conducting public-private collaborations with VA that is focused on translational research of chronic pain. Area(s) of interest to VA include, but are not limited to, the following:

(a) Building on the clinical usefulness of animal models and outcome measures;

(b) Capitalizing on the heterogeneity and complexity of the VA pain population;

(c) Developing relevant therapeutic strategies for the treatment of polytrauma associated pain, including phantom limb, neuropathic pain, headaches, complex regional pain syndrome, burns, chronic back pain, arthritic (joint) pain, etc.;

(d) Conditions co-existing with chronic pain such as Post-traumatic Stress Disorder, fibromyalgia, irritable bowel syndrome, and chronic fatigue syndrome, and how these conditions contribute to pain perception;

(e) Understanding the mechanisms in the development of acute to chronic pain and how to modulate them; and

(f) Safety and the abusive nature of opioid medication.

VA will evaluate submissions, and selected candidates will be requested to enter into a CRADA with VA. Special consideration will be given to small business firms and consortia involving small business firms. Preference will also be given to businesses located in the United States, which agree that those products embodying inventions made under the CRADA will be manufactured substantially in the United States as provided for in 15 U.S.C. 3710a(c)(4).

This RFI does not obligate VA to enter into a CRADA with any respondents. VA reserves the right to establish a CRADA based on scientific analysis and capabilities found by way of this announcement or other searches, if determined to be in the best interest of the government.

Approved: February 14, 2013.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

[FR Doc. 2013–04248 Filed 2–22–13; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

45 CFR Parts 147, 155, and 156
Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 147, 155, and 156

[CMS–9980–F]

RIN 0938–AR03

Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

AGENCY: Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule sets forth standards for health insurance issuers consistent with title I of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, referred to collectively as the Affordable Care Act. Specifically, this final rule outlines Exchange and issuer standards related to coverage of essential health benefits and actuarial value. This rule also finalizes a timeline for qualified health plans to be accredited in Federally-facilitated Exchanges and amends regulations providing an application process for the recognition of additional accrediting entities for purposes of certification of qualified health plans.

DATES: Effective April 26, 2013.

FOR FURTHER INFORMATION CONTACT:
Leigha Basini at (301) 492–4307, for general information.
Adam Block at (410) 786–1698, for matters related to essential health benefits, actuarial value, and minimum value.
Tara Oakman at (301) 492–4253, for matters related to accreditation.

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Acronym List:

Because of the many organizations and terms to which we refer by acronym in this final rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AV Actuarial Value
CHIP Children's Health Insurance Program
CMS Centers for Medicare & Medicaid Services
DOL U.S. Department of Labor
EHB Essential Health Benefits
ERISA Employee Retirement Income Security Act (29 U.S.C. section 1001, et seq.)
FDA U.S. Food and Drug Administration
FEDVIP Federal Employees Dental and Vision Insurance Program
FEHBP Federal Employees Health Benefits Program
FSA Flexible Spending Arrangement
HEDIS Healthcare Effectiveness Data and Information Set
HHS U.S. Department of Health and Human Services
HIOS Health Insurance Oversight System
HMO Health Maintenance Organization
HRA Health Reimbursement Arrangement
HSA Health Savings Account
IOM Institute of Medicine
ICR Information Collection Requirements
IRS Internal Revenue Service
MV Minimum Value
NAIC National Association of Insurance Commissioners
OMB Office of Management and Budget
OPM U.S. Office of Personnel Management
PHSAct Public Health Service Act
PRA Paperwork Reduction Act
QHP Qualified Health Plan
SHOP Small Business Health Options Program
SSA Social Security Administration
The Act Social Security Act
The Code Internal Revenue Code of 1986
USP United States Pharmacopeia

Executive Summary: Beginning in 2014, all non-grandfathered health insurance coverage in the individual and small group markets, Medicaid benchmark and benchmark-equivalent plans, and Basic Health Programs (if applicable) will cover essential health benefits (EHB), which include items and services in 10 statutory benefit categories, such as hospitalization, prescription drugs, and maternity and newborn care, and are equal in scope to a typical employer health plan. In addition to offering EHB, non-grandfathered health insurance plans will meet specific actuarial values (AVs): 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. These AVs, called ''metal levels,'' will assist consumers in comparing and selecting health plans by allowing a potential enrollee to compare the relative payment generosity of available plans. Taken together, EHB and AV will significantly increase consumers' ability to compare and make an informed choice about health plans.

The Department of Health and Human Services (HHS) has provided information on EHB and AV standards in several phases. On December 16, 2011, HHS released a bulletin [1] (the EHB Bulletin) following a report from the U.S. Department of Labor (DOL) [2] describing the scope of benefits typically covered under employer-sponsored coverage and an HHS-commissioned study from the Institute of Medicine (IOM) [3] recommending the criteria and methods for determining and updating the EHB. The EHB Bulletin outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. Shortly thereafter, on January 25, 2012, HHS released an illustrative list of the largest three small group market products by state, which was updated on July 2, 2012.[4] HHS further clarified the approach described in the EHB Bulletin through a series of Frequently Asked Questions (FAQs),[5] released on

[1] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at: *http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.*

[2] ''Selected Medical Benefits: A report from the Department of Labor to the Department of Health and Human Services.'' April 15, 2011. Available at: *http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf.*

[3] Institute of Medicine, ''Essential Health Benefits: Balancing Coverage and Cost.'' October 6, 2011. Available at: *http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx.*

[4] ''Essential Health Benefits: List of the Largest Three Small Group Products by State.'' July 3, 2012. Available at: *http://cciio.cms.gov/resources/files/largest-smgroup-products-7-2-2012.pdf.PDF.*

[5] ''Frequently Asked Questions on Essential Health Benefits Bulletin.'' February 17, 2012.

February 17, 2012. On July 20, 2012, HHS published a final rule [6] authorizing the collection of data to be used under the intended process for states to select from among several benchmark options to define EHB.

HHS also published a bulletin [7] outlining an intended regulatory approach to calculations of AV and implementation of cost-sharing reductions on February 24, 2012 (the AV/CSR Bulletin). Specifically, HHS outlined an intended regulatory approach for the calculation of AV, de minimis variation standards, and silver plan variations for individuals eligible for cost-sharing reductions among other topics. As described in section IB of this preamble, ''Stakeholder Consultation and Input,'' HHS reviewed and considered comments on both the EHB and AV/CSR bulletins in developing the notice of proposed rulemaking and this final rule.

In addition, this rule finalizes an amendment to 45 CFR 156.275, as published on July 20, 2012 (77 FR 42658), which established the first phase of an intended two-phase approach to recognizing accrediting entities. As directed under law, recognized entities will implement the standards established under the Affordable Care Act for qualified health plans (QHPs) to be accredited on the basis of local performance on a timeline established by the Exchange. The amendment to phase one included here does not alter recognition of the National Committee for Quality Assurance (NCQA) and URAC as published in the **Federal Register** notice on November 23, 2012 (77 FR 70163). The amendment provides an opportunity for additional accrediting entities meeting the conditions in listed § 156.275 to be recognized by the Secretary, until phase two is in effect. This opportunity includes an application and review process. This final rule also sets forth a timeline for the accreditation standard for the purposes of QHP certification in Federally-facilitated Exchanges.

I. Background

A. Legislative Overview

Section 1302 of the Affordable Care Act provides for the establishment of an EHB package that includes coverage of EHB (as defined by the Secretary of the Department of Health and Human Services (the Secretary)), cost-sharing limits, and AV requirements. The law directs that EHB be equal in scope to the benefits covered by a typical employer plan and cover at least the following 10 general EHB categories: Ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral [8] and vision care. Sections 1302(b)(4)(A) through (D) of the Affordable Care Act establish that the Secretary must define EHB in a manner that (1) reflects appropriate balance among the 10 statutory EHB categories; (2) is not designed in such a way as to discriminate based on age, disability, or expected length of life; (3) takes into account the health care needs of diverse segments of the population; and (4) does not allow denials of EHB based on age, life expectancy, or disability. Sections 1302(b)(4)(E) and (F) of the Affordable Care Act further direct the Secretary to consider the provision of emergency services and dental benefits when determining whether a particular health plan covers EHB. Finally, sections 1302(b)(4)(G) and (H) of the Affordable Care Act specify that the Secretary periodically review the EHB, report the findings of such review to the Congress and to the public, and update the EHB as needed to address any gaps in access to care or advances in the relevant evidence base. Section 1311(d)(3)(B) of the Affordable Care Act establishes that states may require a QHP to cover additional benefits beyond those in the EHB, provided that the state defrays the costs of such required benefits.

As first described in Public Health Service (PHS) Act section 2711,[9] to determine which benefits are EHB for purposes of complying with PHS Act section 2711 and its implementing regulations, the Departments of Labor, Treasury, and HHS will 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 is one that is authorized by the Secretary of HHS (including any available benchmark option, supplemented as needed to ensure coverage of all ten statutory categories). Furthermore, the Departments intend to work with those plans that make a good faith effort to apply an authorized definition of EHB to ensure there are no annual or lifetime dollar limits on EHB.

Section 1301(a)(1)(B) of the Affordable Care Act directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the Affordable Care Act, including coverage of the services described in section 1302(b), adhering to the cost-sharing limits described in section 1302(c), and subject to 1302(e), meeting the AV levels established in section 1302(d). Section 2707(a) of the PHS Act extends the coverage of the EHB package to issuers of non-grandfathered individual and small group policies beginning with plan years starting on or after January 1, 2014, irrespective of whether such issuers offer coverage through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost-sharing under the plan does not exceed the limitations described in sections 1302(c)(1) and (2) of the Affordable Care Act.

Section 1302(d)(2) of the Affordable Care Act describes the levels of coverage that section 1302(a)(3) includes in the EHB package: 60 percent for a bronze plan, 70 percent for a silver plan, 80 percent for a gold plan, and 90 percent for a platinum plan. Section 1302(d)(3) directs the Secretary to develop guidelines that allow for de minimis variation in AV calculations.

Section 1311(c)(1)(D)(i) of the Affordable Care Act directs a health plan to ''be accredited with respect to local performance on clinical quality measures * * * by any entity recognized by the Secretary for the accreditation of health insurance issuers or plans (so long as any such entity has transparent and rigorous methodological and scoring criteria).'' Section 1311(c)(1)(D)(ii) requires that QHPs

Available at: *http://cciio.cms.gov/resources/files/Files2/02172012/ehb-faq-508.pdf.*

[6] Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658–42672 (July 20, 2012) (to be codified at 45 CFR part 156).

[7] ''Actuarial Value and Cost-Sharing Reductions Bulletin.'' February 24, 2012. Available at: *http://cciio.cms.gov/resources/files/Files2/02242012/Av-csr-bulletin.pdf.*

[8] We note that the Affordable Care Act uses the terms ''dental'' and ''oral'' interchangeably when referring to the pediatric dental care category of EHB (*see, e.g.,* section 1302(B)(1)(J), referring to pediatric oral care, and section 1311(d)(2)(B)(ii), referring to stand-alone dental benefits). Similarly, we intend for purposes of the EHB rule that these terms be used without distinction.

[9] *See* 75 FR 37188, 37191 (June 28, 2010). The regulations define ''essential health benefits'' by cross-reference to section 1302(b) of the Affordable Care Act and applicable regulations, which had not been issued at the time of publication of the regulations implementing PHS Act section 2711.

''receive such accreditation within a period established by an Exchange * * * ''. In a final rule published on July 20, 2012 (77 FR 42658), because NCQA and URAC already met the statutory requirements, they were recognized as accrediting entities on an interim basis, subject to the submission of documentation required in 45 CFR 156.275(c)(4). This recognition is now effective as indicated in the **Federal Register** notice (77 FR 70163) published on November 23, 2012, titled ''Recognition of Entities for the Accreditation of Qualified Health Plans.''

In this final rule, HHS establishes a process by which accrediting entities that are not already recognized can submit an application to be recognized and a proposed notice and final notice process for recognizing any new accrediting entities. This final rule also sets forth a timeline for the accreditation requirement in a Federally-facilitated Exchange.

B. Stakeholder Consultation and Input

HHS consulted with interested stakeholders on several policies related to EHB, AV, and Exchange functions. HHS held a number of listening sessions with consumers, providers, employers, health plans, and state representatives to gather public input, and released several documents for public review and comment. In addition, HHS consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the process of awarding and monitoring grants for the establishment of Exchanges, Medicaid consultations, and meetings with tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties.

HHS received approximately 11,000 comments in response to the EHB Bulletin. Commenters represented a wide variety of stakeholders, including health insurance issuers, consumers, health providers, states, employers, employees, and Members of Congress. In the proposed rule, we noted that these comments were considered as the policies were developed and were also discussed throughout the preamble of the proposed rule. HHS has consulted with and will continue to consult with federally recognized tribes on the provisions of this rule that impact tribes.

II. Provisions of the Regulation and Analysis of and Responses to Public Comments

The proposed rule, titled ''Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation'' (77 FR 70644), was published in the **Federal Register** on November 26, 2012. In that rule, we proposed to codify regulations in 45 CFR parts 147, 155, and 156. For Part 147, we proposed standards for health insurance issuers in the small group and individual markets related to health insurance reforms. For Part 155, we proposed standards for states seeking to require benefits in addition to those in EHB and outlined the proposed standards for Exchanges related to the QHP accreditation timeline. Additionally, for Part 156, we proposed standards relating to EHB and AV, as well as relating to accreditation of QHP issuers. These standards apply only in the individual and small group markets, and not to Medicaid benchmark or benchmark-equivalent plans. In a proposed rule, released on January 14, 2013, titled ''Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefits Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing,'' [10] CMS proposed EHB applicability to Medicaid.

We received approximately 5,798 public comments including roughly 600 total unique letters on the essential health benefit proposals, including comments from states, health plans, industry experts, health care providers, Members of Congress, consumer groups, and members of the public. Many non-unique comments concerned coverage of lactation services, medical foods, acupuncture services, maternity coverage for dependents, and cost sharing for mental health services. Many commenters expressed concern about the comprehensiveness of the proposed benchmark standard, the balance between affordability and state flexibility, and the length of the public comment period. In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing.

The comments and our responses to general comments are set forth below.

Comment: Several commenters were concerned that the 30-day comment period was not an adequate amount of time to provide sufficient feedback on the proposed regulation. Specifically, many commenters requested a 60-day comment period, but provided no substantive comment.

Response: CMS provided a 30-day comment period, which is consistent with the Administrative Procedure Act and the policy established by the Assistant Secretary for Administration (ASA) and the Office of Management and Budget (OMB). We note that CMS previously allowed for an extended comment period on the EHB Bulletin, which outlined the intended policy in the proposed rule. CMS believes that interested stakeholders had adequate opportunity to provide comment on the policies established in this final rule.

A. Part 147—Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

1. Subpart B—Requirements Relating to Health Care Access

a. Coverage of EHB (§ 147.150)

Section 2707(a) of the PHS Act, as added by the Affordable Care Act, directs health insurance issuers that offer non-grandfathered health insurance coverage in the individual or small group market to ensure that such coverage includes the EHB package, which is defined under section 1302(a) of the Affordable Care Act to include the coverage of EHB, application of cost-sharing limitations, and AV requirements (plans must be a bronze, silver, gold, or platinum plan, or a catastrophic plan).

Section 1255 of the Affordable Care Act provides that this EHB package standard applies starting the first plan year for the small group market or policy year for the individual market beginning on or after January 1, 2014. In 45 CFR 147.150(a), we implement the requirement in section 2707(a) of the PHS Act that a health insurance issuer that offers health insurance coverage in the individual or small group market—inside or outside of the Exchange—ensures that such coverage offers the EHB package.

Section 2707(b) of the PHS Act provides that a group health plan shall ensure that any cost-sharing

[10] Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefits Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 FR 4594 (proposed January 22, 2013) (to be codified at 42 CFR parts 430, 431, 433, 435, 440, 447, and 457 and 45 CFR part 155).

requirements under the plan does not exceed the limitations provided for under section 1302(c)(1), annual limitation on cost-sharing, and (c)(2), annual limitation on deductibles, of the Affordable Care Act. Section 715(a)(1) of the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) of the Internal Revenue Code (the Code) incorporate section 2707(b) of the PHS Act into ERISA and the Code. In the preamble to the proposed rule, HHS, DOL, and the Department of the Treasury state that they read section 2707(b) to apply the deductible limit described in section 1302(c)(2) of the Affordable Care Act only to plans and issuers in the small group market and not to self-insured group health plans, large group health plans, or health insurance issuers offering health insurance coverage in the large group market. However, no rules to implement that interpretation were proposed at that time and we noted that section 147.150(b) would be reserved. The three Departments intend to engage in future rulemaking to implement section 2707(b) but, in light of comments received on the interpretation of section 2707(b), are explaining in more detail here our intended approach to this provision and the application of the section 1302(c)(1) and (2) cost-sharing limits to group health plans. Section 2707(b) provides that ''[a] group health plan shall ensure that any annual cost sharing imposed under the plan does not exceed the limitations provided for under paragraphs (1) and (2) of section 1302(c).'' We recognize the potential ambiguity in this reference to the limitations provided under section 1302(c)(1) and (2) of the Affordable Care Act. As noted below in response to comments, we read section 2707(b) as requiring all group health plans to comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1),[11] annual limitation on cost-sharing. At the same time, consistent with the approach described in the preamble to the proposed rule, we continue to believe that only plans and issuers in the small group market are subject to the deductible limits described in section 1302(c)(2).

We believe there are two alternative reads of the statute that give strong textual support for this interpretation of the relationship between of section 2707(b) and section 1302(c)(2) and lead to effectively the same result. The first interpretation would implement section 2707(b)'s direction that group health plans comply with section 1302(c)(1) and (2) by substituting the term ''group health plan'' from section 2707(b) where the term ''health plan'' appears in section 1302(c)(1) and (2). The annual limitation on cost-sharing in section 1302(c)(1) applies to all ''health plan[s],'' and so under this interpretation that limitation would apply to all ''group health plan[s].'' In contrast, the annual limitation on deductibles in section 1302(c)(2) applies only to ''health plan[s] offered in the small group market,'' and so under this interpretation that limitation would apply only to insured small group market health plans.

Under the second interpretation we see as consistent with the statutory text, section 2707(b) could be read to require all group health plans to comply with both the annual limitation on cost-sharing in section 1302(c)(1) and the annual limitation on deductibles in section 1302(c)(2). Section 1302(c)(2)(C), however, provides that the cap on deductibles shall be applied in such a manner so as not to affect the actuarial value of the plan. If the limitation on deductibles were interpreted to apply to large and self-insured group health plans, the Departments would engage in rulemaking to implement this provision broadly, so as to provide relief to large and self-insured group health plans in cases where complying with the limit on deductibles would affect the actuarial value of those plans. We anticipate that we would develop the applicable parameters in separate rulemaking that would take into consideration the differences in applying the concept of actuarial value to large and self-insured group health plans that do not have to meet the level of coverage requirements that are part of the EHB package.

In addition, section 2707(c) of the PHS Act provides that an issuer offering any level of coverage specified under section 1302(d) of the Affordable Care Act offer coverage in that level as a plan in which the only enrollees are individuals who have not yet attained the age of 21. We codify this standard in 45 CFR 147.150(c).

Comments received regarding § 147.150(a) and (c) are addressed in other sections of this preamble that are more relevant to the substance of the comments. We also received comments addressing the suggested interpretation of section 2707(b) and how the limitations on cost-sharing should apply to all group health plans.

Comment: Some commenters requested that self-insured plans be exempt from the cost sharing limits described in § 156.130(a). Several of these comments indicated operational concerns with applying a single annual limitation on cost sharing to EHB that are administered by separate contractors; in particular, commenters noted the practice of using a pharmacy benefit manager to administer prescription benefits separately from other medical benefits. Other commenters agreed with the legal read that cost sharing limits described in § 156.130(a) apply to all group health plans.

Response: We note that DOL also received correspondence on this issue seeking clarification of how the three Departments would interpret section 2707(b) of the PHS Act and the corresponding provisions in ERISA and the Code. As discussed in more detail above, the three Departments interpret these provisions to mean that large group market and self-insured group health plans must comply with the annual limitation on out-of-pocket maximums described in section 1302(c)(1).

Nevertheless, the Departments are concerned about the operational and timing issues raised by commenters, and find that some transitional relief is appropriate. Accordingly, the three Departments are issuing concurrent sub-regulatory guidance identifying an enforcement safe harbor for large and self-insured group health plans to address those operational concerns.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 147.150 of the proposed rule with two technical edits to paragraph (c) to conform to the underlying statutory authority, including adding to paragraph (c) the following language ''as a plan in which the only enrollees are,'' to clarify that the child-only coverage offered by an issuer under this section must be a plan with only child enrollees.

B. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act State-Required Benefits

Section 1311(d)(3)(B) of the Affordable Care Act explicitly permits a state, at its option, to require QHPs to offer benefits in addition to EHB, but requires the state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional benefits. We proposed that state-required benefits enacted on or before December 31, 2011 (even if not effective

[11] Note that PHS Act section 2707 is not applicable to grandfathered health plans. *See* 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, 45 CFR 147.140.

until a later date) may be considered EHB, which would obviate the requirement for the state to defray costs for these state-required benefits. We also proposed that these state-required benefits that are not included in the benchmark would apply to QHP markets in the same way they apply in the current market. This policy regarding state-required benefits is intended to apply for at least plan years 2014 and 2015. This two year transitional period accommodates current market offerings and limits market disruption in the first years of the Exchanges.

Under the Affordable Care Act, state payment for state-required benefits only applies to QHPs. Since the Exchange is responsible for certifying QHPs, we proposed that the Exchange identify which additional state-required benefits, if any, are in excess of the EHB.

We additionally proposed that the calculations of the cost of additional benefits be made by a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. We also proposed the calculation be done prospectively to allow for the offset of an enrollee's share of premium and for purposes of calculating the premium tax credit and reduced cost sharing.[12]

The comments and our responses to § 155.170 are set forth below.

Comment: Some commenters were concerned that including all state-required benefits enacted before December 31, 2011 in EHB would increase costs for covered individuals. However, most who commented on inclusion of state-required benefits favored this policy.

Response: Research by the HHS Office of the Assistant Secretary for Planning and Evaluation found that the majority of required benefits have a negligible impact on premiums.[13]

Comment: Some commenters suggested that states should make monthly payments to only the issuer on behalf of the enrollee, and that payments to the enrollee directly should not be permitted.

Response: Section 1311(d)(3)(B) of the Affordable Care Act directs the state to make payments either to the individual enrollee or to the issuer, and regulatory language reflects that statutory requirement. We are retaining our proposed approach as final and will permit states to either make payments to individuals or issuers, as applicable.

Comment: Some commenters suggested that we should require the state to defray any cost associated with other types of state requirements, such as rules regarding reimbursement to certain providers, anti-discrimination laws, and rules specific to benefit delivery method.

Response: As we explained in the preamble of the proposed rule, we interpret ''state-required benefits'' to include the care, treatment and services that an issuer must provide to its enrollees. Other state laws that do not relate to specific benefits, including those relating to providers and benefit delivery method, are not addressed in § 155.170.

Comment: In the proposed rule we requested comment on whether the state should make payments based on the statewide average cost of additional state-required benefits that are outside the scope of EHB or make payments based on each QHP issuer's actual cost. Several commenters noted that each QHP issuer's cost may vary due to differences in market share and enrollee pool, and those commenters favored payments based on actual cost. Other commenters recommended that payments should be based on the average benefit cost for the relevant geographic area.

Response: We believe that states may wish to take different approaches, basing payments on either statewide average or each issuer's actual cost. Therefore, we are not establishing a standard in this final rule but permit both options for calculating state payments, at the election of the state.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 155.170 of the proposed rule without modification.

Accreditation Timeline (§ 155.1045)

In § 155.1045, we proposed to redesignate the existing paragraph as paragraph (a) and to add a new paragraph (b) to set forth the timeline for accreditation as a QHP certification requirement in the Federally-facilitated Exchanges (including State Partnership Exchanges). This provision is consistent with § 156.275(a), in which we required that all QHP issuers must be accredited with respect to local performance of their QHPs on the timeline established by the Exchange.

The comments and our responses to § 155.1045 are set forth below.

Comment: Several commenters supported the proposal to phase-in accreditation standards for QHP issuers participating in a Federally-facilitated Exchange. Other commenters did not support this approach and requested that QHP issuer accreditation, as defined in 45 CFR 156.275, be required for QHP issuers beginning in 2013.

Response: HHS is finalizing the accreditation timeline for QHP issuers in the Federally-facilitated Exchanges as proposed. We proposed a phased approach in order to accommodate issuers without existing accreditation and new issuers. We believe that accepting existing accreditation from an issuer's commercial, Medicaid, or Exchange products and phasing in accreditation requirements for issuers without existing accreditation will expand QHP choices available to consumers while ensuring that all QHP issuers commit to delivering high quality care. Creating a phased approach for these requirements also provides issuers and recognized accrediting entities with sufficient time to schedule and conduct accreditation reviews, which can take as long as 18 months.

Comment: Several commenters requested clarification of the requirements specified in proposed § 155.1045(b)(2) and (3) and the meaning of being accredited in accordance with § 156.275.

Response: As stated above, HHS proposed a phased approach to accreditation for the Federally-facilitated Exchanges. In paragraph (b)(2), we proposed that a QHP issuer must be accredited on their policies and procedures that are applicable to their Exchange products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same state in which the issuer is offering Exchange coverage and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP. In paragraph (b)(3), we direct issuers of QHPs to be accredited in accordance with all of the standards specified in § 156.275, including performance measurement reporting required at (a)(1)(i) and (ii) of § 156.275 and the reporting of clinical performance measures and patient experience ratings on a standardized Consumer Assessment of Health Providers and Systems® (CAHPS) survey. We are adopting this phased

[12] Section 36B(b)(3)(D) of the Code specifies that the portion of the premium allocable to required additional benefits shall not be taken into account in determining a premium tax credit. Likewise, section 1402(c) of the Affordable Care Act specifies that cost-sharing reductions do not apply to required additional benefits.

[13] ''Essential Health Benefits: Comparing Benefits in Small Group Products and State and Federal Employee Plans.'' ASPE Research Brief, December 2011. Available at: *http://aspe.hhs.gov/health/reports/2011/marketcomparison/rb.pdf.*

approach to accreditation to align with the earliest possible time that issuers are able to report performance data on their QHP population as part of the accreditation process. We acknowledged in earlier guidance [14] that performance data on an issuer's QHP population will not be available until a full-year of data are available (for example, in 2015 based on the 2014 coverage year).

Comment: One commenter questioned if accreditation at the Exchange product type level would be methodologically sound in 2016 and requested a delay of several years in the requirement at § 155.1045(b)(3) which requires QHP issuers to be accredited in accordance with 45 CFR 156.275 as early as 2016 certification for the 2017 coverage year.

Response: We are requiring performance measurement reporting at the Exchange product type level as part of accreditation required in 2016 to align with the earliest possible time that issuers are able to report performance data on their QHP population. As finalized in 45 CFR 156.275(c)(2)(iii),[15] there is an exception to the Exchange product type level accreditation requirement if the recognized accrediting entity demonstrates that the Exchange product type accreditation is not methodologically sound for a particular issuer.

Comment: One commenter suggested that State-based Exchanges should be encouraged to follow the accreditation timeline set forth for a Federally-facilitated Exchange.

Response: As specified in 45 CFR 155.1045(a), Exchanges must establish a uniform period within which a QHP issuer must become accredited. State-based Exchanges are able to align with the proposed Federally-facilitated Exchange timeline if they choose. This provision was finalized in the Exchange Establishment Final Rule.[16]

Comment: Some commenters urged HHS to take additional steps to monitor and oversee QHP quality, aside from accreditation.

Response: Issuers participating in Exchanges need to meet the range of standards for certification which are included in 45 CFR part 156. As part of plan management functions, Exchanges will be responsible for managing certain types of consumer complaints about QHP issuers, examining potential QHP issuer non-compliance with applicable laws, and ensuring ongoing compliance with the QHP certification standards. We believe these requirements, including processes for issuer recertification and decertification will ensure adequate oversight of issuers participating in a Federally-facilitated Exchange. Additionally, we anticipate future rulemaking on QHP issuer quality reporting requirements, including a QHP-specific quality rating as required by section 1311(c)(3) of the Affordable Care Act.

Comment: Several commenters asked for clarification regarding how HHS will determine if an issuer has existing commercial, Medicaid, or Exchange accreditation. Several commenters noted that Medicaid managed care plans may not be licensed as ''issuers.'' Other commenters questioned if HHS would accept accreditation from a company's Preferred Provider Organization product if it is accredited on a different legal entity than the company's Health Maintenance Organization (HMO) product.

Response: The Exchange Establishment Final Rule, at 45 CFR 155.20, defines ''health insurance issuer or issuer'' by cross-referencing the definition of health insurance issuer as defined in 45 CFR 144.103: A health insurance issuer means ''an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a state and that is subject to state law that regulates insurance (within the meaning of section 514(b)(2) of ERISA).'' This term does not include a group health plan. We consider issuers, as defined above, to have existing accreditation if they are accredited with respect to the product type at issue under the same legal entity as the one that is offering such a product in the Exchange. We plan to issue future guidance as to the process by which issuers may demonstrate how they meet the accreditation standard.

Comment: One commenter asked that HHS clarify that a federally-facilitated Exchange will accept any existing health plan accreditation on issuers' commercial or Medicaid lines of business, in the same state as the Exchange in which the issuer is seeking to offer coverage, at the overall QHP issuer level.

Response: As we stated in a previously issued rule,[17] accreditation at the Exchange product type level balances capturing the QHP experience and enabling the reporting of valid and reliable performance measures. An issuer may offer multiple QHPs under the same product type, in the same Exchange; if the product type for that Exchange is accredited, each of the corresponding QHPs would be considered to be accredited.

Comment: Some commenters questioned whether an issuer would meet the standard in § 155.1045(b) if the recognized accrediting entity that had awarded the accreditation modified its accreditation standards. One commenter specifically asked whether a QHP issuer would meet the similarity standard described in § 155.1045(b)(2) if the recognized accrediting entity loses its recognition.

Response: We view these comments as pertaining to the meaning of being accredited as required in § 156.275. We would consider issuers whose recognized accrediting entity modified its requirements or lost its recognition as being accredited, provided that the accrediting entity was recognized by HHS and accredited as meeting the standards identified in § 156.275 when the accreditation was awarded. These issuers would meet the requirements in § 156.275 and, therefore, the timeliness and similarity standards described in § 155.1045(b). Further, we do not anticipate that phase one recognized accrediting entities are likely to lose their recognition because § 156.275(c)(4)(ii) requires that recognized accrediting entities provide to HHS any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days' notice prior to public notification.[18] Therefore, HHS would have ample time to analyze the entity's changes and assess if the changes should result in the loss of recognition.

Comment: Several commenters requested that HHS exempt certain types of plans or issuers from the accreditation requirements, such as CO–OPs and Medicaid managed care plans,

[14] General Guidance on Federally-facilitated Exchanges, May 16, 2012. Available at *http://cciio.cms.gov/resources/files/ffe-guidance-05-16-2012.pdf.*

[15] Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans,'' 77 FR 42658 (July 20, 2012).

[16] ''Establishment of Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule'' (77 FR 18310 (March 27, 2012)). Available at *http://www.gpo.gov/fdsys/pkg/FR-2012-03-27/pdf/2012-6125.pdf.*

[17] Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658, −42665–42666 (July 20, 2012) (to be codified at 45 CFR 156.275(c)(2)(iii)).

[18] 45 CFR 156.275(c)(2) was finalized in the final rule, Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 42658 (July 20, 2012).

or provide a different accreditation timeline for these issuers.

Response: Under 45 CFR 155.1045(a) Exchanges are responsible for establishing a timeline for which all QHP issuers must be accredited. The timeline for accreditation must be applied consistently across QHP issuers. The phased process was developed in part to accommodate new issuers, including CO–OP, and Medicaid plans without existing accreditation.

Comment: A commenter asked for clarification on the applicability of the accreditation requirements to stand-alone dental plans.

Response: The preamble to the Exchange Establishment Final Rule specifies that to the extent that accreditation standards specific to stand-alone dental plans do not exist, then such plans would not be required to meet the accreditation requirement or the accreditation timeline required by 45 CFR 155.1045.

Comment: Several commenters made recommendations as to when in the QHP certification year a QHP issuer must be accredited in order to be considered to have met the standards proposed in 45 CFR 155.1045(b)(1), (2), and (3). One commenter recommended requiring issuers to crosswalk their existing accredited policies or procedures to their QHP products.

Response: HHS will be issuing forthcoming guidance on how the accreditation requirements will be operationalized as part of the QHP certification process in the Federally-facilitated Exchanges.

Comment: Several commenters submitted comments in regard to the U.S. Office of Personnel Management's (OPM) Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges Notice of Proposed Rulemaking, 77 FR 72582 [19] (December 5, 2012) on accreditation of multi-state plans (MSPs).

Response: HHS has determined that these comments are outside the scope of this rule. As noted in § 155.1045(a), the timeline for accreditation for multi-state plans will be set by OPM.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing § 155.1045 of the proposed rule without modification.

[19] ''Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges'' (77 FR 72582 (December 5, 2012)). Available at: *http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf.*

C. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Subpart A—General Provisions

In § 156.20, we proposed to add the following definitions as follows:

Actuarial Value and Percentage of the Total Allowed Costs of Benefits

We proposed to define ''actuarial value (AV)'' as the percentage paid by a health plan of the total allowed costs of benefits. We proposed to define the ''percentage of the total allowed costs of benefits'' as the anticipated covered medical spending for EHB coverage (as defined in § 156.110 (a)) paid by a health plan for a standard population, computed in accordance with the health plan's cost sharing, divided by the total anticipated allowed charges for EHB coverage provided to the standard population, and expressed as a percentage.

Because section 1302(d)(2) of the Affordable Care Act refers to AV relative to coverage of the EHB for a standard population, we proposed these definitions together in order to provide that AV is the percentage that represents the total allowed costs of benefits paid by the health plan, based on the provision of EHB as defined for that plan according to § 156.115.

Benchmark Plans

Under the benchmark selection and standards proposed in §§ 156.100 and 156.110, we believe it is important to differentiate between the plan selected by a state (or through the default process in § 156.100(c)), which we proposed to call the ''base-benchmark plan,'' and the benchmark standard that EHB plans will need to meet, which we proposed to call the ''EHB-benchmark plan.''

We proposed that ''base-benchmark plan'' means that the plan that is selected by a state from the options described in § 156.100(a), or a default benchmark plan, as described in § 156.100(c), prior to any adjustments made to meet the benchmark standards described in § 156.110.

We proposed that ''EHB-benchmark plan'' means that the standardized set of EHB that must be met by a QHP or other issuer as required by § 147.150.

We proposed that ''Essential health benefits package or EHB package'' means the scope of covered benefits and associated limits of a health plan offered by an issuer, as set forth in section 1302(a) of the Affordable Care Act. The EHB package provides at least the ten statutory categories of benefits, as described in 45 CFR 156.110(a); provides benefits in the manner described in § 156.115; limits cost-sharing for such coverage as described in § 156.130; and subject to offering catastrophic plans as described in section 1302(e) of the Affordable Care Act, provides distinct levels of coverage as described in 45 CFR 156.140.

The comments and our responses to the proposed changes to § 156.20 are set forth below.

Comment: Several commenters urged HHS to provide uniform, standardized definitions for certain terms used throughout the regulation relating to cost sharing.

Response: Terms used throughout the regulation are standard terms of art that are understood in the industry, therefore we will not provide additional definitions.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.20 of the proposed rule, without substantive modifications. We note that we have made technical corrections to clarify that ''EHB package'' and ''essential health benefits package'' are the same.

2. Subpart B—EHB Package

a. State Selection of Benchmark (§ 156.100)

In § 156.100, we proposed to set forth the criteria for the selection process if a state chooses to select a benchmark plan. The EHB-benchmark plan would apply to non-grandfathered health insurance coverage offered in the individual or small group markets. The EHB-benchmark plan would serve as a reference plan, reflecting both the scope of services and limits offered by a typical employer plan in that state. This approach and benchmark selection would apply for at least the 2014 and 2015 benefit years.

Consistent with the approach outlined in the EHB Bulletin, in § 156.100(a) we proposed that the state may select its base-benchmark plan from among the following four types of health plans: (1) The largest plan by enrollment in any of the three largest small group insurance products in the state's small group market as defined in § 155.20; (2) any of the largest three state employee health benefit plans by enrollment; (3) any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by enrollment that are open to Federal employees; or (4) the largest insured commercial non-Medicaid HMO operating in the state. Data from the first quarter two years

prior to the coverage year would be used to determine plan enrollment. HHS also made available benefit data for the single largest Federal Employees Dental and Vision Insurance Program (FEDVIP) dental and vision plans respectively, based on enrollment.

Section 156.100(a)(1) would reflect a typical plan in the state's small group market and provides state flexibility as recommended by the IOM in its report.[20] The remaining proposed benchmark plan options, in § 156.100(a)(2) through (a)(4), would reflect the benchmark approach used in Medicaid, as defined in 42 CFR 440.330, and in the Children's Health Insurance Plan (CHIP), as defined in 42 CFR 457.410 and 457.420.

Because the PHS Act defines ''state'' to include the U.S. territories (Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands), the PHS Act requirements related to EHB, as established by section 1302 of the Affordable Care Act, apply to the territories.

At § 156.100(b), we proposed the standard for approval of a state-selected EHB-benchmark plan.

We proposed that the state's benchmark plan selection in 2012 would be applicable for at least the 2014 and 2015 benefit years and stated that we intend to revisit this policy for subsequent years. This two year transitional period accommodates current market offerings and limits market disruption in the first years of the Exchanges.

In § 156.100(c), we proposed that if a state did not make a benchmark plan selection, the default base-benchmark plan would be the largest plan by enrollment in the largest product by enrollment in the state's small group market. Each state's benchmark is specified in Appendix A with a detailed set of benefits available at *www.cciio.cms.gov.*

The comments and our responses to § 156.100 are set forth below.

Comment: Some commenters preferred a different benchmark plan than the selection proposed in Appendix A of the proposed rule. Commenters suggested that the proposed benchmark was inconsistent with the typical employer plan in the state, and/or the scope of benefits was not sufficiently comprehensive. Several commenters recommended that HHS have a single, uniform federal EHB package because they are concerned that the proposed benchmark options have a large degree of variation in covered benefits which may lead to inconsistent EHB packages from state to state. We also received several comments indicating that the ''top three small group products in each state'' approach to the benchmark selection was not the best option for the default benchmark plan, and that FEHBP would have been a better alternative. Several commenters believed that offering plan benefit packages created for adults or families may not be considered sufficient to meet the requirement to provide child-only coverage and that we should provide child-specific benchmark plans such as states' CHIP plans as a more appropriate child-only plan option.

Response: The benchmark approach for defining EHB sought to balance the statutory ten benefit categories and affordability while providing states—the primary regulators of health insurance markets—with flexibility. The benchmark plan options for each state reflect the scope of benefits and services typically offered in the employer market in that state. This approach meets the statutory requirement that EHB reflect a typical employer plan as well as the recommendation provided by the IOM on the approach to defining EHB. Prior to the release of the proposed rule and during the comment period prior to the release of the final rule, HHS held multiple discussions with states regarding specific details of their EHB-benchmark recommendations and these selections are reflected in the finalized selections available in Appendix A. Furthermore, we believe that our general EHB requirements, along with regulatory prohibitions on benefit discrimination, ensure that plans include an appropriate range of benefits for adults and children. We will monitor these and other benefit packages to ensure regulatory compliance and assess the need for future program changes.

Comment: We received numerous comments that the largest plan in the largest product in the state was not among the options provided by HHS. HHS did not propose the largest plan in the largest product due to technical concerns with the methodology used in determining enrollment data for the list of largest plans in the largest products.

Response: The three largest products in each state's small group market were identified using enrollment data collected by HealthCare.gov. The largest plan for each of the three largest products in the small group market in each state was identified using enrollment data from the plans in each state. We recognize that there are several different methodologies for counting enrollment that we could have chosen, and we selected the one that is most uniform across states and best represents for all states the largest plan in the largest product in the small group market. Prior to the release of the largest three products list, HHS confirmed the methodology with each state.

Comment: We received comments recommending which one of the four types of health plan benchmark options would be the most appropriate default base-benchmark plan for territories. A few commenters recommended that the territories follow the same standard as states for the default base-benchmark plan; however, there was also concern that the territories' markets are too small and unique, compared to those in the states, to use the largest small group market plan. Some commenters recommended using one consistent set of benefits, such as FEHBP, to ensure a comprehensive EHB package. Other commenters discussed that the small group market in Puerto Rico is more similar to the small group markets in the 50 states than to those in the other territories given the much larger size of its population and suggested that Puerto Rico should have the largest small group plan in the market as the default benchmark.

Response: In light of comments received, HHS has selected the largest FEHBP plan as the default base-benchmark plan for all U.S. territories, except for Puerto Rico. Benchmarks for Puerto Rico and the other territories are listed in Appendix A along with the state benchmark plans.

Comment: Several commenters expressed concern over providing enforcement authority to states and recommended a more prescriptive approach to monitoring and enforcement of this regulation. Some requested that the federal government exercise strong oversight of state efforts in monitoring and enforcing this area. Commenters also urged HHS to use 2014 and 2015 as transitional years, during which we would collect data on the plans then use those data to help update EHB annually, starting in 2016. Recommended criteria for review included but were not limited to plan comprehensiveness, affordability, and continuity of coverage. Moreover, commenters recommended that, starting in 2016, HHS adopt a comprehensive, Federal EHB standard.

Response: Enforcement of the requirement to cover EHB is governed by section 2723 of the PHS Act, which looks first to states for enforcement, then to the Secretary where a state has failed to substantially enforce.

[20] Institute of Medicine, ''Essential Health Benefits: Balancing Coverage and Cost'' (2011). Available at: *http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx.*

Therefore, we expect states to enforce the requirement that plans must offer EHB. We are currently reviewing all options for updating EHB in 2016 and anticipate releasing additional guidance in the future on enforcement of EHB requirements and updating EHB.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.100 of the proposed rule, with the following modification: while continuing to be recognized as states, as defined under the PHS Act, the U.S. territories including Guam, American Samoa, the U.S. Virgin Islands and the Northern Mariana Islands, with exception of Puerto Rico, will use the largest FEHBP plan as the default base-benchmark plan. Like the other 50 states and the District of Columbia, Puerto Rico will use the largest plan by enrollment in the largest product by enrollment in its small group market as its default base-benchmark plan. This is reflected in Appendix A.

b. Determination of EHB for Multi-State Plans (§ 156.105)

In § 156.105, we proposed how the EHB determination would be made for Multi-State Plans offered under contract with OPM pursuant to section 1334 of the Affordable Care Act. We proposed that Multi-State Plans must meet benchmark standards set by OPM.[21]

The comments and our responses to § 156.105 are set forth below.

Comment: We received several comments requesting more information on the EHB requirement with respect to Multi-State Plans.

Response: OPM will be releasing regulations and guidance on the application of EHB to Multi-State Plans. Therefore, we are not addressing these comments in this rule.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.105 of the proposed rule without modifications.

c. EHB-Benchmark Plan Standards (§ 156.110)

To clarify the relationship between the 10 statutory EHB categories and the EHB-benchmark plan, in paragraph (a) we proposed that the EHB-benchmark plan provide coverage of at least the following categories of benefits described in section 1302(b)(1) of the Affordable Care Act: (1) Ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care.

We proposed to interpret ''pediatric services'' to mean services for individuals under the age of 19 years. We noted that states have the flexibility to extend pediatric coverage beyond the 19-year age baseline.

For those base-benchmark plan options that would not cover one or more of the 10 statutorily required EHB categories, in paragraph (b), we proposed standards for supplementing. In paragraph (b)(1), we proposed requiring that if a base-benchmark plan option does not cover any items and services within an EHB category, the base-benchmark plan would be supplemented by adding that particular category in its entirety from another base-benchmark plan option. The resulting plan, which would then cover all 10 statutory EHB categories, must also meet standards for non-discrimination and balance defined in paragraphs (d) and (e) of this section. After meeting all of these standards, it would be considered the EHB-benchmark plan.

Proposed paragraphs (b)(2) and (3) discuss two categories of benefits that may not currently be included in some major medical benefit plans but that were included in the EHB as defined in proposed § 156.110(a) and section 1302(b)(1) of the Affordable Care Act. Our review of research on employer-sponsored plan benefits, including small employer products, found that pediatric oral and vision services were not covered under the benefit packages of a number of potential benchmarks, but, rather, were often covered under stand-alone policies. We proposed targeted policy options for each of these benefit categories.

In proposed paragraph (b)(2), we proposed to provide states with two options for supplementing base-benchmark plans that do not include benefits for pediatric oral care coverage. The first option, described in paragraph (b)(2)(i), was to supplement with pediatric coverage included in the FEDVIP dental plan with the largest enrollment. The second option, described in paragraph (b)(2)(ii), was to supplement with the benefits available under that state's separate CHIP program, if one exists, to the eligibility group with the highest enrollment.

Similarly, in proposed paragraph (b)(3), we proposed to provide two options for states to supplement a base-benchmark plan that does not include pediatric vision services. The first option, described in (b)(3)(i), is to supplement with the pediatric vision coverage included in the FEDVIP vision plan with the largest national enrollment offered to federal employees under 5 U.S.C. 8982. The second option, described in (b)(3)(ii), is to supplement pediatric vision coverage with the state's separate CHIP plan, if applicable.

In proposed paragraph (c), we proposed the process by which HHS will supplement a default base-benchmark plan, where necessary. Specifically, HHS would supplement the category of benefits in the default base-benchmark plan with the first of the following options that offers benefits in that particular EHB category: (1) The largest plan by enrollment in the second largest product by enrollment in the state's small group market as defined in § 155.20; (2) the largest plan by enrollment in the third largest product by enrollment in the state's small group market as defined in § 155.20; (3) the largest national FEHBP plan by enrollment across states that is described in and offered to Federal employees under 5 U.S.C. 8903; (4) the plan described in paragraph (b)(2)(i) to cover pediatric oral care benefits; (5) the plan described in (b)(3)(i) to cover pediatric vision care benefits; and (6) habilitative services as described in § 156.110(f) or § 156.115(a)(4).

In proposed paragraph (d), we state that the EHB-benchmark plan must not include discriminatory benefit designs. As set forth in proposed § 156.125, issuers would be prohibited from using benefit designs that discriminate on the basis of an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life or other health condition. Issuers would also have to comply with non-discrimination standards applicable to QHPs under the Exchange rules. These standards would apply both to benefit designs that limit enrollment, and those that prohibit access to care for enrollees.

In proposed paragraph (e), we proposed to implement section 1302(b)(4)(A) of the Affordable Care Act by proposing to require that the EHB-benchmark plan ensure an appropriate

[21] OPM has proposed standards for the Multi-State Plan Program in ''Establishment of the Multi-State Plan Program for the Affordable Insurance Exchanges'' 77 FR 72582 (December 5, 2012). Available at: *http://www.gpo.gov/fdsys/pkg/FR-2012-12-05/pdf/2012-29118.pdf.*

balance among the categories of EHB so that benefits would not be unduly weighted toward any category.

In conducting research on employer-sponsored plan benefits and state-required benefits, HHS found that many health insurance plans do not identify habilitative services as a distinct group of services.[22] Accordingly, our proposed regulation proposed to include a transitional policy for coverage of habilitative services that would provide states with the opportunity to define these benefits if they were not included in the base-benchmark plan. Specifically, in paragraph (f), we proposed that, if the base-benchmark plan did not include coverage of habilitative services, the state would be permitted to determine the services included in the habilitative services category. If states did not define the habilitative services category, plans would be required to provide these benefits as defined in § 156.115(a)(4). HHS intends to carefully monitor coverage of habilitative services across the individual and small group markets, and to use this data to inform future changes to this transitional policy.

The comments and our responses to § 156.110 are set forth below.

Comment: Numerous commenters urged that the 10 EHB categories and individual services or benefits within those categories be defined in more detail. Medicaid was suggested as an appropriate model for defining the habilitation benefit, as well as pediatric dental and vision benefits.

Response: The statute directed the Secretary to define EHB to include at least the 10 identified categories, while ensuring that the scope of EHB is equal to the scope of benefits provided under a typical employer plan. However, typical employer plans differ by state. The Secretary balanced these directives, and minimized market disruption, by directing plans to offer the 10 statutory EHB categories while allowing the state to select the specific details of their EHB coverage by reference to one of a range of popularly selected plans offered in the state or as part of the FEHBP. Accordingly, the states continue to maintain their traditional role in defining the scope of insurance benefits and may exercise that authority by selecting a plan that reflects the benefit priorities of that state. With regard to habilitative and pediatric dental and vision benefits, we appreciate the commenters' recommendation to use Medicaid plans as appropriate models. In order to maintain the states' role in defining required benefits in their markets, we will finalize the regulations to provide for state flexibility in determining how to define habilitation services and to offer other options for supplementing based-benchmark plans that do not include coverage for pediatric dental and vision services. We will continue to monitor this area to assess the need for future regulatory action.

Comment: We received a number of comments recommending that the age limit for the ''pediatric services'' category be raised from 19, as proposed, to 21, to better align with existing Medicaid and CHIP standards for pediatric benefits and help ensure continuity of coverage for those children who will transition between Exchange and public coverage. Commenters further asserted that the higher age limit would improve care for children with chronic or complex conditions such as cystic fibrosis by allowing continued treatment beyond the age of 19 by such children's pediatric provider, who has more expertise in these areas than adult-focused practitioners.

Response: The age of 19 as the upper limit for the definition of pediatric services is consistent with the upper age limit in the Affordable Care Act's prohibition on preexisting conditions for children as well as the age limit for eligibility to enroll in CHIP. In addition, federal Medicaid law requires that states cover children up to age 19 with family incomes up to 100 percent of the federal poverty limit as a mandatory eligibility category. States are permitted to increase this maximum age in defining pediatric services.

Comment: A number of commenters expressed concern with individual state selections for supplementing coverage categories lacking in a chosen benchmark plan, suggested that the regulation allow additional supplementation options, or suggested that states should be required to supplement inadequate coverage of individual service types within a benefit category.

Response: As stated previously, the Secretary structured the EHB regulations to maintain state flexibility in defining benefits within the categorical parameters set out by Congress. Benchmark options derive from the most popular products in each state's small group market, among others. Allowing states to supplement from this range of options allows each state to develop an EHB-benchmark plan that reflects its state benefit priorities.

Comment: Several commenters suggested that we require balance not only across the benefit category but also within each category or across the continuum of care.

Response: The balance provision in § 156.110(e) is consistent with the section 1302(b)(4)(A) of the Affordable Care Act, which it implements. Requiring balance within each category or across the continuum of care could result in plans that are not similar in scope to a typical employer health plan as required by statute.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.110 of the proposed rule with two technical edits. We have added the words ''pediatric oral'' to § 156.110(b)(2) to clarify that supplementation of the pediatric dental services category in the base-benchmark plan would be with the pediatric oral benefits from a benchmark option. We have likewise added the words ''pediatric vision'' to § 156.110(b)(3) in place of the word ''such'' to clarify that supplementation of the pediatric vision services category in the base-benchmark plan would be with the pediatric vision benefits from allowable source plan and have added the words ''by enrollment'' to clarify that the largest product in a state's small group market is determined by enrollment.

d. Provision of EHB (§ 156.115)

In paragraph (a)(1), we proposed that plans may have limitations on coverage that differ from the limitations in the EHB-benchmark plan, but covered benefits and limitations on coverage must remain substantially equal to the benefits in the EHB-benchmark plan.

In paragraph (a)(2), we proposed that in order to satisfy the requirement to offer EHB, mental health and substance use disorder services, including behavioral health treatment services required under § 156.110(a)(5), must be provided in a manner that complies with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA).

In paragraph (a)(3), we further proposed that a plan does not provide EHB unless it meets the standards in 45 CFR 147.130.

In paragraph (a)(4), we proposed that if the EHB-benchmark plan does not include coverage for habilitative services and the state does not determine habilitative benefits, a health

[22] ASPE Research Brief, ''Essential Health Benefits: Comparing Benefits in Small Group Products and State and Federal Employee Plans.'' December 16, 2011. Available at: *http://aspe.hhs.gov/health/reports/2011/MarketComparison/rb.shtml.*

insurance issuer must either: (1) Provide parity by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services; or (2) decide which habilitative services to cover and report on that coverage to HHS.

We proposed the concept of benefit substitution consistent with what HHS outlined in the EHB Bulletin. As outlined in paragraph (b)(1)(i), we proposed that issuers may substitute benefits, or sets of benefits, that are actuarially equivalent to the benefits being replaced. We further proposed in paragraph (b)(1)(ii) that substitution could only occur within benefit categories, not between different benefit categories. In paragraph (b)(1)(iii), we clarify that our proposed benefit substitution policy does not apply to prescription drug benefits. In paragraph (b)(2), we outlined what must be submitted to demonstrate that any substituted benefit, or group thereof, is actuarially equivalent to the original benefit or benefits contained in the EHB-benchmark for that state. Lastly, in paragraph (b)(3), we proposed that actuarial equivalence of benefits be determined based on the value of the service without regard to cost-sharing, as cost sharing will be considered in the actuarial value calculation described in § 156.135. We noted that the resulting plan benefits would be subject to requirements of non-discrimination described in § 156.125. In addition, we note that under this approach, states would have the option to enforce a stricter standard on benefit substitution or prohibit it completely.

In paragraph (c), we proposed to clarify that a plan does not fail to provide EHB solely because it does not offer the services described in § 156.280(d). Here we would apply the statutory provision in section 1303(b)(1)(B)(i) of the Affordable Care Act that allows a QHP to meet the standards for EHB even if it does not offer the services described in 45 CFR § 156.280(d), to health insurance issuers that offer non-grandfathered coverage in the individual or small group market. This provision applies to all services in section 1303(b)(1)(A) of the Affordable Care Act, including pharmacological services.

In paragraph (d), we proposed that an issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, cosmetic orthodontia and long-term/custodial nursing home care benefits as EHB.

The comments and our responses to § 156.115 are set forth below.

Comment: Some commenters asked us to eliminate or provide additional guidance regarding the substantially equal standard.

Response: Based on the rationale we outlined in the proposed rule, we are maintaining the substantially equal standard as written to allow for flexibility of plan design.

Comment: Several commenters requested confirmation that EHB must comply with federal mental health and substance use disorder parity requirements in both the individual and the small group markets. Commenters also asked if states would have to defray the cost of adding benefits in order to comply with parity.

Response: Section 2707 of the PHS Act requires health insurance issuers in the individual and small group health insurance markets to cover the EHB package required under section 1302 of the Affordable Care Act. The Affordable Care Act grants the Secretary broad authority to define EHB. We proposed in § 156.115(a)(2) that plans are required to comply with the parity standards set forth in § 146.136 of this chapter, implementing the requirements under MHPAEA in order to satisfy the requirement to provide EHB. Section 1311(j) of the Affordable Care Act specifies that section 2726 of the PHS Act shall apply to qualified health plans in the same manner and to the same extent as such section applies to health insurance issuers and group health plans. For these reasons, we confirm that plans must comply with the parity standards applicable to mental health and substance use disorder benefits set forth in 45 CFR 146.136 in both the individual and the small group markets in order to satisfy the requirement to cover EHB. Additionally, because compliance with EHB would require compliance with the parity standards, states would not have to defray any costs associated with bringing plans into compliance because any benefits added to ensure parity would be considered part of the EHB package.

Comment: Commenters requested a federal definition of habilitative services. Many recommended that HHS adopt the NAIC definition of habilitation or use the Medicaid statute's definition of habilitation as a reference point, to highlight the importance of maintenance of function. Commenters also asked that HHS eliminate giving issuers the choice of determining their habilitative benefits.

Response: As explained in the EHB Bulletin, habilitative benefits are not well defined in the current commercial market. If habilitative services are not covered by the EHB-benchmark plan, then states have the first opportunity to determine which habilitative benefits must be covered by their benchmark plan. States may choose to use the NAIC or Medicaid definition. If states have not chosen to define habilitative benefits, the issuers' choice remains. This is a transitional policy, and HHS intends to monitor available data regarding coverage of habilitative services.

Comment: Many commenters urged HHS to eliminate the option to substitute benefits, noting concerns that substitution may result in discrimination. Commenters also requested that HHS codify the implied option for states to limit or completely prohibit substitution.

Response: We have retained the discretion we proposed to provide for substitution within categories to provide greater choice to consumers, and promote plan innovation through coverage and design options. We also retained the requirement that any substitution must be actuarially equivalent. As the party responsible for enforcement of EHB, it is up to each state to set criteria for substitution in its state, consistent with paragraph (b) of this Section.

Comment: In the preamble to the proposed rule, we clarified that a plan may not exclude enrollees from coverage in any category except pediatric services. Many commenters recommended that CMS codify this proposal in regulation text.

Response: In response to the comments received, we have modified § 156.115(a)(2) to prohibit an EHB plan from excluding an enrollee from coverage in an EHB category except pediatric services.

Comment: Several commenters urged HHS to remove the provision at § 156.115(c) so that section 1303(b)(1)(A) of the Affordable Care Act would not extend to plans that are not QHPs. Other commenters noted that services under section 1303 of the Affordable Care Act are covered by their state benchmark plan and requested confirmation that other EHB plans will not have to offer such services.

Response: We are finalizing the regulation to include the provision to ensure parity between the Exchange and non-Exchange markets. We note that nothing in the proposed provision impedes an issuer's ability to offer 1303 services. It also does not limit a state's authority to prohibit or require these services under state law.

Comment: While some commenters objected to the exclusion of routine non-pediatric dental services, routine non-pediatric eye exam services, and long term/custodial nursing home care

benefits, from EHB, the majority of commenters agreed with the exclusion of these services because they are not typically included in medical plans offered by a typical employer.

Response: The Affordable Care Act requires EHB to be based on benefits typically offered by a typical employer plan. In contrast with the benefits covered by a typical employer health plan, these particular benefits often qualify as excepted benefits.[23] However, plan offerings are not restricted to EHB, so plans may offer additional benefits.

Comment: We received comments requesting that HHS change the reference to ''cosmetic orthodontia'' and define the excluded service as ''non-medically necessary orthodontia'' to reflect the standard that issuers typically use and to be consistent with the EHB Bulletin.

Response: Based on comments, we have changed the language in § 156.115(d) to refer to non-medically necessary orthodontia and deleted the reference to cosmetic orthodontia.

Summary of Regulatory Changes

We are finalizing the provisions proposed in § 156.115 of the proposed rule, with the following modifications: In paragraph (a) we added subparagraph (2) to clarify that an EHB plan cannot exclude an enrollee from any EHB category except pediatric services. In paragraph (b), we have added regulation text explicitly reflecting our adoption in this final rule of our proposal that states be permitted to limit or prohibit benefit substitutions that would otherwise be permissible under our regulations, and we recodified subparagraph (3) as (2)(iv). We changed the language in § 156.115(d) to use the term ''non-medically necessary'' instead of ''cosmetic'' orthodontia.

e. Prescription Drug Benefits (§ 156.122)

This subsection appeared as § 156.120 in the proposed rule, however, for technical reasons this subsection will be renumbered as § 156.122 in the final rule.

In paragraph (a)(1), we proposed that in order to comply with the requirement to cover EHB, a plan would cover at least the greater of: (1) One drug in every USP category and class; or (2) the same number of drugs in each category and class as the EHB-benchmark plan. In paragraph (a)(2) we proposed that a QHP would have to report its drug list to the Exchange, an EHB plan operating outside of the Exchange must report its drug list to the state, and a multi-state plan must report its drug list to OPM. In paragraph (b) we proposed to clarify that a health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs that are § 156.280(d) services.

We proposed using the most recent version of the United States Pharmacopeia's (USP) Model Guidelines as a common organizational tool for plans to report drug coverage. We stated that we would work with issuers, states and the NAIC to facilitate use of the USP classification system and we would provide a tool for states and issuers to count clinically distinct drugs and categorize them into the USP system.[24]

We also proposed that drugs would be counted toward these requirements if they are chemically distinct.[25] For example, offering two dosage forms or strengths of the same drug would not be offering drugs that are chemically distinct. Similarly, a brand name drug and its generic equivalent are not chemically distinct.

In paragraph (c), we proposed that a plan offering EHB have procedures in place to ensure that enrollees have access to clinically appropriate drugs that are prescribed by a provider but are not included on the plan's drug list, which is generally consistent with private plan practice today.

The comments and our responses to § 156.122 are set forth below.

Comment: Several commenters noted that the proposed rule requires plans to meet a target number of drugs within a specific class without regard to which drugs are covered. Those commenters expressed concern regarding absence of a system to review the adequacy and quality of each plan drug list.

Response: Section 156.125, regarding discrimination, applies to all EHB including prescription drug benefits. Under the prohibition on discrimination regulation we are finalizing at § 156.125 of this part, an issuer's benefit design, or the implementation of its benefit design, may not discriminate based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions. Issuers may continue to use reasonable medical management techniques that are evidence-based in accordance with § 156.125. The states and the Exchanges will be responsible for monitoring drug lists for such compliance as part of their enforcement and certification responsibilities.

Comment: Some commenters noted that the proposed rule does not discuss how plans must address new drugs that come onto the market during the course of a plan year.

Response: While plans must offer at least the greater of one drug for each USP category and class or the number of drugs in the EHB-benchmark plan, plans are permitted to go beyond the number of drugs offered by the benchmark without exceeding EHB.

Comment: Some commenters recommended that HHS should not require coverage of at least one drug in each USP category and class, because such coverage is not similar to a typical employer plan and that certain categories and classes have limited drug options. Some commenters raised concerns about cost and that covering a drug in each USP category and class is arbitrary. Instead, they suggested HHS delete the requirement to match a specific number of drugs per benchmark plan category and class, and allow plans to determine the specific drugs covered.

Response: In response, we internally analyzed and carefully reviewed prescription drug coverage in the EHB-benchmark plans listed in Appendix A, and found that the majority of the benchmark plans already meet the EHB standard or would only have to cover one or two additional drugs to meet the standard. Therefore, we believe that, given current coverage under benchmark plans, the policy of requiring at least one drug per category and class reflects drug coverage in a typical employer plan and will have a negligible effect on premiums. We also note that this section does not require that drugs be covered on a particular tier. Additionally, we are finalizing § 156.122(a)(1) as proposed as a transition policy for the first two plan or policy years beginning in 2014 and will study and take into consideration the effects this policy, if any, have on changing typical drug coverage in the market.

Comment: Many commenters expressed concern over the use of USP as the class and category classification system.

Response: For consistency and to minimize administrative burden and barriers to market entry for health plans, specifically for issuers offering products in multiple states, we believe it is important to use only one classification system. While there was concern among

[23] For more information on excepted benefits, see 26 CFR 54.9831–1, 29 CFR 2590.732, 45 CFR 146.145, and 45 CFR 148.220.

[24] The requirement to use USP classification applies only to submission of formulary for review/certification. Plans may continue to use any classification system they choose in marketing and other plan materials.

[25] The concept of chemically distinct is also described in the Medicare Part D Manual, Chapter 6, Section 30.2.1. More information is available at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads//Chapter6.pdf.*

commenters on the use of USP as the system, there was no universal system identified as a potential alternative. We chose the current version USP Model Guidelines (version 5) because it is publicly available and many pharmacy benefit managers are familiar with it. We believe the USP model best fits the needs for the years 2014 and 2015 during the transitional EHB policy and we have developed a crosswalk tool to count the number of drugs available in each USP category and class. We intend to work with issuers, states and the NAIC to facilitate state use of the USP Model Guidelines Version 5.0 as a classification system and as a comparison tool.

Comment: Several commenters requested additional detail regarding the requirement that that a plan ''must have procedures in place that allow an enrollee to request clinically appropriate drugs not covered by the health plan.''

Response: Additional guidance regarding our expectations for the required exceptions process is forthcoming in sub-regulatory guidance. We note the importance of this option for those whose medical needs require a very narrow range of pharmaceuticals, and emphasize that our research has shown that a large number of plans already offer this option in the market today. It is expected that plans that currently have such a process in place will not be expected to modify their existing process.

Comment: Many commenters suggested that HHS should clarify in § 156.120(c) (as explained above, now renumbered as § 156.122(c)) of the final regulation that plans must have procedures in place that ensure enrollees have access to clinically appropriate drugs, not just allow the enrollee to request such a drug. While the preamble of the proposed rule includes a statement of this standard, the proposed rule does not.

Response: We have added language from the proposed rule preamble to § 156.122(c) directing plans to have procedures to allow an enrollees to gain access to clinically appropriate drugs.

Comment: Commenters urged HHS to provide guidance as to which drugs are covered by § 156.280(d) so that the final rule is clear as to which drugs are actually exempted.

Response: We have revised the language to specify that we are referring to drugs approved by the U.S. Food and Drug Administration (FDA) as a § 156.280(d) service.

Summary of Regulatory Changes

We are finalizing the provisions in § 156.120 of the proposed rule (renumbered as § 156.122 in the final rule), with the following modifications: We have added language to § 156.122(c) based on the proposed rule's preamble text directing plans to have procedures to allow an enrollees to gain access to clinically appropriate drugs. We have revised the language in subparagraph (b) to specify that we are referring to drugs approved by the U.S. Food and Drug Administration (FDA) as a § 156.280(d) service.

f. Prohibition on Discrimination (§ 156.125)

Section 1302(b)(4) of the Affordable Care Act directs the Secretary to address certain standards in defining EHB, including elements related to balance, discrimination, the needs of diverse sections of the population, and denial of benefits. The proposed regulations would provide an approach to addressing discrimination that would allow states to monitor and identify discriminatory benefit designs, or the implementation thereof.

To address potentially discriminatory practices, we proposed in paragraph (a) that an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, or present or predicted disability, degree of medical dependency, quality of life, or other health conditions. In paragraph (b), we proposed that §§ 156.200 and156.225 also apply to all issuers required to provide coverage of EHB, prohibiting discrimination based on factors including but not limited to race, gender, disability, and age as well as marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs.

These provisions would provide a framework and legal standard from which to develop analytic tools to test for discriminatory plan benefits. Such analyses could include evaluations to identify significant deviation from typical plan offerings including such as limitations for benefits with specific characteristics.

The comments and our responses to § 156.125 are set forth below.

Comment: Several commenters indicated their belief that section 1302(b)(4) of the Affordable Care Act does not prohibit discrimination in benefit implementation in the standards for providing EHBs.

Response: Section 1302(b)(4) of the Affordable Care Act specifies that EHB not include ''coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life.'' We believe that this range of prohibited discrimination implicitly encompasses not just the categories of benefits included in the benefit design but also the implementation of that design.

Comment: A number of commenters recommended that we expand this section to prohibit discrimination based on sex, gender identity, sexual orientation, having a particular medical condition, and other factors.

Response: The regulation as written prohibits benefit discrimination on the grounds articulated by Congress in section 1302(b)(4) of the Affordable Care Act, as well as those in 45 CFR 156.200(e), which include race, color, national origin, disability, age, sex, gender identity and sexual orientation.

Comment: Many commenters requested that we add more detail to the regulation regarding standards of nondiscrimination, the framework for monitoring and enforcement, as well as clarification of the roles of the states and the federal government. Several commenters expressed concern that enrollees with certain health conditions might by discriminated against by an issuer's failure to include appropriate specialists in their network.

Response: Enforcement of the PHS Act provisions codified in this rule is governed by section 2723 of the PHS Act, which first looks to states and then to the Secretary where a state has does not substantially enforce. The approach to nondiscrimination will reserve flexibility for both HHS and the states to respond to new developments in benefit structure and implementation and to be responsive to varying circumstances across the states. We agree with the commenters that network adequacy is an important part of plan coverage. Compliance with network adequacy requirements is outside of the scope of this regulation.

Comment: Several commenters expressed concern over state benchmarks that they believed contained discriminatory benefit designs and worried that issuers in those states would be required to copy those designs.

Response: To the extent that a state benchmark plan includes a discriminatory benefit design, non-discrimination regulations at § 156.110(d) and § 156.125 require issuers to meet the benchmark requirements in a nondiscriminatory matter.

Comment: Many commenters expressed concern that § 156.125 would prevent issuers from employing traditional medical management techniques, with some requesting that we revise regulatory text to indicate that evidence-based techniques would not be considered discriminatory. Others expressed ongoing concern that medical management techniques were often used as nuanced mechanisms for discrimination.

Response: As we stated in the preamble to the proposed rule, and consistent with section 1563(d) of the Affordable Care Act, these EHB regulations do not prohibit issuers from applying reasonable medical management techniques. An issuer could use prior authorization, but could not implement prior authorization in a manner that discriminates on the basis of membership in a particular group based on factors such as age, disability, or expected length of life that are not based on nationally recognized, clinically appropriate standards of medical practice evidence or not medically indicated and evidence-based. For example, a reasonable medical management technique would be to require preauthorization for coverage of the zoster (shingles) vaccine in persons under 60 years of age, consistent with the recommendation of the Advisory Committee on Immunization Practices. We are adding a new paragraph (c) in § 156.125, to clarify that nothing in this section shall be construed to prevent an issuer from using reasonable medical management techniques.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.125 of the proposed rule with two modifications. Based on comments addressed below in response to proposed section § 156.130, we have deleted the reference to § 156.225 from paragraph (b) of this section, and, as described in response to the comment above, we have added a new paragraph (c), clarifying that nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

g. Cost-Sharing Requirements (§ 156.130)

The Affordable Care Act provides several standards on cost sharing for certain health plans. Standards in § 156.130 are applicable to QHPs pursuant to section 1301(a)(1)(B), as implemented by 45 CFR 156.200(b)(3) and 45 CFR 156.20, which require QHPs to offer the essential health benefits package described at section 1302(a) of the Affordable Care Act. Similarly, these standards would be applicable to non-grandfathered health insurance coverage offered by health insurance issuers in the individual and small group markets pursuant to section 2707(a) of the PHS Act as implemented by § 147.150(a) of these regulations.

In § 156.130(a), we proposed to codify the Affordable Care Act's limitation on cost sharing for 2014 and in subsequent years. Section 156.130(a)(1) would tie the annual limitation on cost sharing for plan years beginning in 2014, to the enrollee out-of-pocket limit for high-deductible health plans (HDHP), as calculated pursuant to section 223(c)(2)(A)(ii) of Internal Revenue Code of 1986 (the Code) based on section 1302(c)(1)(A) of the Affordable Care Act. Proposed paragraph (a)(1)(i) would address the limitation for self-only coverage and proposed paragraph (a)(1)(ii) would address the limitation for coverage other than self-only coverage; the practical effect for coverage other than self-only coverage would be that the annual limitation would be double the limitation applicable to self-only coverage. For illustrative purposes only, for the year 2013 these amounts will be $6,250 for self-only and $12,500 for non-self only coverage.[26] Amounts for 2014 are expected to be released by the IRS in the spring of 2013. In proposed § 156.130(a)(2)(i), the annual limitation on cost sharing would increase by the premium adjustment percentage, which would be set by HHS as described in § 156.130(e), in years after 2014 for self-only coverage. In proposed § 156.130(a)(2)(ii), the annual limitation on cost sharing in years after 2014 for non-self only coverage is double the annual limitation on cost sharing for self-only coverage for that year.

Sections 1302(c)(2)(A)(i) and 1302(c)(2)(A)(ii) of the Affordable Care Act define and proposed § 156.130(b) codified the annual limitation on deductibles for health plans offered in the small group market as part of the EHB package. This limitation on deductibles is imposed on QHPs by section 1301(a)(1)(B) of the Affordable Care Act and 45 CFR 156.200(b)(3). The limitation is also imposed on non-grandfathered health plans in the individual and small group markets by section 2707(a) of the PHS Act, which we proposed to implement in proposed 45 CFR 147.150(a). In proposed § 156.130(b)(1)(i), we proposed that the annual limitation on deductibles for the year 2014 be $2,000 for self-only coverage and in proposed § 156.160(b)(1)(ii), $4,000 for non self-only coverage. In proposed § 156.130(b)(2), we proposed that in years beyond 2014, the annual deductible limits for self-only plans would increase by the premium adjustment percentage described in paragraph (e) under the authority of section 1302(c)(2)(B) of the Affordable Care Act.

Section 1302(c)(2)(C) of the Affordable Care Act directs that the limit on deductibles described in section 1302(c)(2)(A) for a health plan offered in the small group market be applied so as to not affect the actuarial value of any health plan. We proposed to interpret and implement this provision through our proposal at § 156.130(b)(3) by authorizing a health insurance issuer to make adjustments to its deductible to maintain the specified actuarial value for the applicable level of coverage required under proposed § 156.140. In proposed § 156.130(b)(3), we proposed that a plan may exceed the annual deductible limit if it cannot reasonably reach a given level of coverage (metal tier) without doing so.

Section 1302(c)(2)(A) of the Affordable Care Act permits but does not require, contributions to flexible spending arrangements (FSAs) to be taken into account when determining the deductible maximum. We proposed to standardize the maximum deductible for all health plans in the small group market at $2,000 for self-only coverage and $4,000 for non-self-only coverage, as described in proposed § 156.130(b)(1) and potentially adjusted in proposed § 156.130(b)(3), and not increase the deductible levels by the amount available under the FSA.

In proposed § 156.130(c), we proposed a special rule for network plans. Under our proposal, cost sharing requirements for benefits from a provider outside of a plan's network would not count towards the annual limitation on cost sharing, or the annual limitation on deductibles. We considered an out-of-network provider to be a provider with whom the issuer does not have a contractual arrangement with respect to the applicable plan.

In proposed § 156.130(d), we proposed to codify sections 1302(c)(1)(B) and 1302(c)(2)(B) of the Affordable Care Act by requiring that the annual limitation on cost sharing and the annual limitation on deductibles for a plan year beginning after calendar year 2014 only increase by multiples of $50 and must be

[26] *http://www.irs.gov/pub/irs-drop/rp-12-26.pdf.*

rounded to the next lowest multiple of $50.

In proposed § 156.130(e), we proposed to codify section 1302(c)(4) of the Affordable Care Act, which specifies that the premium adjustment percentage is calculated as the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013.

In proposed § 156.130(f), we proposed to codify section 1302(c)(2)(D) of the Affordable Care Act, which states that the annual deductibles do not apply to preventive care described in § 147.130.

Proposed § 156.130(g) proposed to prohibit discriminatory cost sharing.

Proposed § 156.130(h) proposed to implement the requirements in section 1302(b)(4)(E) of the Affordable Care Act that, as part of coverage of EHB, a QHP must (1) provide coverage for emergency department services provided out-of-network without imposing any requirement under the plan for prior authorization of services or any limitation on coverage for the provision of services that is more restrictive than the requirements or limitations that apply to emergency department services received from network providers, and (2) apply the same cost sharing in the form of a copayment or coinsurance for emergency department services for an out-of-network provider—as would apply to an in-network provider.

The comments and our responses to § 156.130 are set forth below.

Comment: HHS received several comments suggesting a standard definition of the reasonableness exemption in proposed § 156.130(b)(3) for plans in the small group market that can only meet the deductible requirements as well as certain actuarial value requirements such as for a bronze plan for a very narrow range of plan designs.

Response: We intend to provide sub-regulatory guidance outlining options related to plan designs where exceeding the deductible limits described in § 156.130(b) is permissible. We reiterate that § 156.130(b) as finalized here applies only for purposes of defining a cost-sharing limitation application to issuers and QHPs that must offer the EHB package.

Comment: Several commenters expressed concerns about the protection of a health plan's ability to control costs through the use of reasonable medical management, as well as cost and administrative burdens placed on QHP issuers.

Response: We do not believe that the requirements pertaining to cost-sharing would preclude issuers from engaging in reasonable medical management. However, in response to comments about the protection of a health plan's ability to control costs through the use of utilization management and administrative burden, we are not finalizing the policy as paragraph (g) of § 156.130 and we are relabeling the remainder of § 156.130 accordingly.

Comment: HHS received several comments requesting deductible increases for plans in the small group market based on employer FSA contributions. Other commenters preferred our approach, which prohibits these increases, because of the operational complications of determining the FSA contribution in time for plan selection.

Response: The Affordable Care Act provides the option but not the requirement to increase deductibles in the small group market based on FSA contributions. The operational implications of determining which employers are contributing to employee FSAs and matching only those employees to plan options with corresponding increases in deductibles when FSA contributions and plan selection generally occurs simultaneously is operationally infeasible. We are now finalizing our policy due to the operational complications of determining the FSA contribution in time for plan selection, although we will revisit this policy in later years. We believe this will have no impact on enrollment in small group plans for those eligible.

Comment: HHS received several comments discussing the merits of applying the cost-sharing limits to in-network services only rather than applying the annual cost sharing limits defined in § 156.130(a) to all costs including both in-network and out-of-network fees.

Response: Our research has shown that generally, health spending occurs in-network.[27] The IOM in its recommendation [28] focused on the long term balance between affordability and comprehensiveness of coverage, therefore, we have decided to apply cost-sharing limits to in-network visits only to promote health plan affordability. We note that nothing in this proposal explicitly prohibits an issuer from voluntarily establishing a maximum out-of-pocket limit applicable to out-of-network services, or a state from requiring that issuers do so.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.130 of the proposed rule with one modification. We are not finalizing the text proposed as paragraph (g) and are relabeling the provision proposed paragraph (h) as paragraph (g) in this final rule.

h. AV Calculation for Determining Level of Coverage (§ 156.135)

The Affordable Care Act directs issuers offering non-grandfathered health insurance coverage in the individual and small group markets, including QHPs, to ensure that plans meet a level of coverage specified in section 1302(a)(3) of the Affordable Care Act and defined in § 156.140(b). Each level of coverage corresponds to an AV calculated based on the cost-sharing features of the plan. Pursuant to these statutory provisions, in paragraph (a), we proposed that an issuer would use the AV Calculator developed by HHS to determine the health plan's level of coverage as proposed in § 156.140(b), subject to the exception in paragraph (b). As part of this proposal, we solicited comment on both the AV Calculator and a methodology document that includes the logic behind the calculator and a description of the development of the standard population, represented in the calculator as tables of aggregated data called continuance tables.

Consistent with section 1302(d)(2)(A) of the Affordable Care Act that AV be calculated based on the provision of the EHB to a standard population, we proposed that the AV Calculator use one or more sets of national claims data reflecting plans of various levels of generosity as the underlying standard population. In paragraph (b), we proposed options for an issuer whose plan designs do not permit the calculator to provide an accurate summary of plan generosity. Although HHS anticipates that the vast majority of plans will be able to use the calculator in 2014 and beyond, no uniform calculator can accommodate the entire potential universe of plan designs. Therefore, we proposed to provide exceptions for plan designs not compatible with the calculator. Specifically, we proposed in paragraph (b)(1) that plans not using the AV calculator would need to submit documentation in the form of actuarial certification that they have complied with one of the methods described

[27] 26 U.S.C. 223(c)(2)(D)

[28] Institute of Medicine, ''Essential Health Benefits: Balancing Coverage and Cost'' (2011). Available at: *http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx.*

below. We intend for this submission to be made to the appropriate entity (the state, HHS, the Exchange, or OPM) reviewing the health plan for compliance with AV and level of coverage standards.

In paragraph (b)(2), we proposed two options to accommodate plans with benefit designs that cannot be accommodated by the AV Calculator. In paragraph (b)(2)(i), we proposed that a health plan issuer be permitted to decide how to adjust the plan benefit design (for calculation purposes only) to fit the parameters of the calculator and then, pursuant to paragraph (b)(2)(ii), have a member of the American Academy of Actuaries certify that the methodology was fit to the parameters of the AV Calculator in accordance with generally accepted actuarial principles and methodologies. In paragraph (b)(3), we proposed a second option, that the plan may use the calculator for the plan design provisions that correspond to the parameters of the calculator and then have a member of the American Academy of Actuaries calculate appropriate adjustments to the AV as determined by the AV Calculator for plan design features that deviate substantially, in accordance with generally accepted actuarial principles and methodologies. We proposed in paragraph (b)(4) that, to align with the AV Calculator and the rules proposed here for how AV is determined, plans using one of these methods would exclude out-of-network costs when using additional calculation methods.

In paragraph (c), we proposed a standard for the treatment of small group market HDHPs offered with a health savings account (HSA) or a health plan in the small group market integrated with a health reimbursement arrangement (HRA), so that HDHP and HSAs/HRAs are integrated. Recognizing that simply calculating the AV of the HDHP based on the insurance plan alone could understate the value of coverage if the value of the employer contribution to such accounts are not included, and that employer-provided HSAs and HRAs are generally the equivalent of first dollar coverage for any cost-sharing requirements encountered by the enrollee, in paragraph (c)(1), we proposed that the annual employer contributions to HSAs and amounts newly made available under HRAs for the current year count within the plan design.

Section 1302(d)(2)(B) of the Affordable Care Act directs the Secretary to issue regulations under which employer contributions to an HSA (within the meaning of section 223 of the Code) may be taken into account in determining the level of coverage for a plan of the employer and HHS proposed allowing for similar treatment of HRAs.

In paragraphs (c)(2)(i) and (ii), we proposed that the AV Calculator would include any current year HSA contributions or amounts newly made available under integrated HRAs for the current year as an input into the calculator that can be used to determine the AV of an employer-sponsored health benefit plan.

In paragraph (d) we proposed that in years 2015 and after, a state-specific data set may be used as the standard population (that is, in place of the HHS-issued continuance tables) for AV calculations if approved by HHS. Issuers in such a state would still use the AV Calculator logic, but the underlying data used for generating the AV would be specific to the state. In paragraphs (d)(1) through (5), we proposed and solicited comment on criteria, based on a July 2011 American Academy of Actuaries issue brief, for acceptable state claims data and their use.

In paragraph (e), we proposed that the default standard population provided by HHS, which is described in paragraph (f) and represented in the continuance tables incorporated into the regulatory proposal by reference, would be used unless the state submits its own standard population consistent with paragraphs (d) and (e). In paragraph (e), we proposed that the state data set be submitted in a format that can support the AV Calculator described in paragraph (a).

In paragraph (f), we proposed that HHS will develop the standard population to be used to calculate AV in accordance with section 1302(d)(2)(A) of the Affordable Care Act, which requires that AV be calculated using a standard population.

The comments and our responses to § 156.135 are set forth below.

Comment: Some commenters suggested a different version of the AV Calculator including a microsimulation model based calculator, a calculator with greater inputs, or no calculator at all with plans utilizing their own data to calculate an AV. Other commenters supported HHS's decision to develop an AV Calculator based on continuance tables.

Response: We elected to use a continuance table model as a methodology for determining actuarial value because in general this type of model is common, popular, and well understood by the actuarial community. We have no evidence that a microsimulation model would be more precise or would be more successful at parsing plan designs that receive high actuarial values with this continuance table model, but would receive low actuarial values in a microsimulation model. The level of detail of the calculator inputs was thoroughly researched and tested and we concluded that adding detail did not have a material impact on actuarial value.

Comment: HHS received numerous comments in support of the development of an AV Calculator based on a single national standard population. Other commenters suggested the use of standardized plan data instead of a single data set to develop the standard population.

Response: HHS is finalizing its proposed approach to develop an AV Calculator based on a single national standardized dataset. We considered allowing issuers to use standardized plan data to determine AV levels, but in response to comments received to both the AV Bulletin and the proposed regulation, ultimately developed the AV Calculator using a single standardized dataset to best facilitate consumer comparisons so that plans with the same cost-sharing structure would have the same AVs. As described in § 156.135(d), we are also allowing for the use of state-specific standard population data beginning in 2015.

Comment: HHS received several comments urging HHS to allow states to submit their own claims data for use in the AV Calculator starting in 2014 or to account for regional variations in the AV Calculator. Other commenters recommended that HHS wait to allow the use of state data until 2017 or until an update to the AV Calculator is made.

Response: Starting in 2015, states will have the opportunity to submit state-specific claims data for the AV Calculator. In 2014, states and other stakeholders can assess the AV Calculator and determine whether geographic variation or state-specific claims data would be useful modifications starting in 2015.

Comment: Some commenters suggested that the AV Calculator should consider both in and out-of-network utilization. Other commenters supported the inclusion of only in-network utilization for the AV Calculator.

Response: HHS developed the AV Calculator and with regard to exceptions to use of the AV Calculator in § 156.135(b)(4), is finalizing the proposal to consider only in-network utilization based on empirical data indicating that only a small percentage of total costs come from out-of-network

utilization.[29] This approach was supported by the American Academy of Actuaries in its comments on the AV Bulletin.

Comment: Many commenters noted a variety of potential technical issues in the proposed AV Calculator. Other commenters asked HHS to provide additional detail on the development of the standard population and logic and assumptions used to convert the claims data into an AV Calculator, including that HHS provide additional detail on the specific services included in each benefit input in the calculator to facilitate calculation using one of the exceptions, as well as the services included in the unclassified category.

Response: As part of the proposed regulation, HHS released both the AV Calculator tool and a methodology document detailing the development of the standard population and AV Calculator. In developing the final version of the AV Calculator tool, HHS considered all of the technical comments received and made revisions as appropriate. In addition, the revised and final version of the methodology document considers all comments received and provides additional explanation wherever possible. In developing the publicly available methodology document, we described step by step the data and logic that the calculator uses to determine plan AVs and held ourselves to the common practice level of detail present in describing risk adjustment models for CMS as well as academic publications. The final AV Calculator and methodology document are incorporated by reference into this final rule and available at *http://cciio.cms.gov/resources/regulations/index.html#pm.*

Comment: Several commenters asked for additional guidance and clarification on when one of the exceptions in § 156.135(b) may be used to calculate AV.

Response: We intend to interpret this standard as dependent on whether the AV Calculator takes into account or accommodates all material aspects of a plan's cost-sharing structure. For example, we expect that the calculator will not be able to accommodate plan designs with multiple coinsurance rates as different levels of out-of-pocket spending are met or a multi-tier network with substantial amounts of utilization expected in tiers other than the lowest-priced tier. We have also made minor edits to the regulation to clarify that, for a plan that cannot be accommodated by the calculator, an issuer has the option of using either exception method and that both methods require submission of an actuarial certification.

Comment: The majority of commenters noted that the AV Calculator does not address health plans with family cost-sharing features such as deductibles that accrue across members of the same family. Some commenters recommended adjustments or additional guidance for the final AV Calculator to account for these plans.

Response: The AV Calculator standard population was developed using claims data that did not include family cost-sharing information. Therefore, health plans with cost-sharing features that accrue across family members for non-self-only coverage may be treated as unique plan designs, if the family plan design has a material effect on the plan's AV. To address commenters' concerns regarding AV calculation for plans with family cost-sharing features, as a safe harbor, the AV of a plan with a deductible and/or out-of-pocket maximum that accumulates at the family level will be considered the same AV as calculated using the AV Calculator for the corresponding individual plan, so long as the deductible and/or out-of-pocket maximum do not exceed that allowed by a family multiplier set by CMS in future guidance. We note that the out-of-pocket maximum would still be constrained by the maximum permitted by § 156.130(a)(1)(ii).

Comment: Several commenters encouraged HHS to add functionality or additional benefit inputs to the AV Calculator—for example, that the calculator account for more or different benefits as separate cost-sharing inputs and that the calculator take into account service limits.

Response: The AV Calculator was developed to accommodate the vast majority of plan designs and to include as separate cost-sharing inputs those benefits that have a significant impact on a plan's AV. The AV Calculator balances the need to accommodate a wide range of plan designs, with the need to provide a tool that is accessible to the user and contains a manageable number of inputs.

Comment: Several commenters requested that the full amount of HSA and integrated HRA employer contributions be accounted for in the AV Calculator. Some of these commenters also requested that HHS allow employee contributions to count towards a plan's AV.

Response: We clarify here that the AV Calculator implements § 156.135 by treating HSA and amounts newly made available under an integrated HRA that may be used only for cost sharing the same way it treats any other plan benefits. For example, a $1,000 HSA employer contribution is treated in the AV Calculator as if a plan with $1,000 deductible is reduced to $0. The $1,000 HSA contribution does not get counted as $1,000 in the numerator of the AV Calculator because the equation is based on total population expected spending by the total population, rather than by particular individuals. Instead the $1,000 contribution is counted as the average dollar value it would cost to reduce a $1,000 deductible to $0. We note that while the AV Calculator cannot accommodate situations in which the HSA or amounts first made available under integrated HRAs that may be used only for cost sharing, exceeds the deductible, the value of the account can still be accommodated by using the alternative methods for AV calculation allowed under § 156.135(b).

Comment: Some commenters expressed concerns that a health plan issuer would not have access to information on employer contributions to HSAs and HRAs. Other commenters asked HHS to clarify how the provision on HSAs and HRAs would be operationalized.

Response: As finalized in § 156.135(c), employer contributions to an HSA or newly made available through integrated HRAs that may be used only for cost sharing, are taken into account when calculating the AV of a health plan only when the plan is offered with an HSA integrated HRAs that may only be used for cost sharing at the time of purchase. Because it is the issuer that uses the AV Calculator to determine a plan's AV, the HSA employer contribution, or the amount newly made available by the employer under an integrated HRA that may only be used for cost sharing, may be considered part of the AV calculation when the contribution is available and known to the issuer at the time the plan is purchased.

Comment: HHS received numerous comments regarding when and how to update the AV Calculator in future years. In some cases commenters expressed concern that annual updates to the AV Calculator or underlying data would require issuers to make annual updates to plan benefit designs in order to comply with AV standards.

Response: In response to these comments, we are now clarifying that HHS does not anticipate making annual changes to the AV Calculator logic or

[29] AHIP, Center for Policy and Research, ''An Updated Survey of Health Insurance Claims Receipt and Processing Times, 2011'', 2013. *http://www.ahip.org/SurveyHealthCare-January2013.*

underlying standard population. We will consider all comments received and give sufficient notice with regard to updating as we develop a strategy for updating the AV Calculator.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.135 of the proposed rule, with two modifications. First we make minor modifications to paragraph (b) to clarify that the issuer must submit an actuarial certification from an actuary as to the methodology used to determine AV when the plan design is not compatible with the AV Calculator. In paragraph (c) we clarify that, in order to count towards the AV calculation, employer contributions to HSAs and amounts made newly available under integrated HRAs that may only be used for cost sharing must be known to the issuer when the plan is purchased. Whether other types of integrated HRAs might count towards AV is being given further consideration. In this case, guidance on the treatment of HRAs will be issued and this regulation will be amended as necessary.

i. Levels of Coverage (§ 156.140)

This section describes standards for meeting the Affordable Care Act provisions directing that issuers offering QHPs or non-grandfathered health plans in the individual and small group markets offer plans that meet distinct levels of coverage.

In paragraph (a), we proposed the general requirement that the AV of a plan must be calculated according to § 156.135, within de minimis variation, in order to determine a plan's level of coverage. In paragraph (b), we proposed to codify section 1302(d)(1) of the Affordable Care Act, which requires that a bronze plan has an AV of 60 percent; a silver plan, 70 percent; a gold plan, 80 percent; and a platinum plan, 90 percent.

In paragraph (c), we proposed a de minimis variation of +/− 2 percentage points for all non-grandfathered plans. For example, a silver plan could have an AV between 68 and 72 percent.

The comments and our responses to § 156.140 are set forth below.

Comment: Several commenters encouraged HHS to adopt a wider range of de minimis variation to allow for greater variation in plan design and so that more plans are able to maintain their current benefit designs in 2014 or to allow states to define their own de minimis variation. Other commenters requested a narrower range than +/− 2 percentage points.

Response: The proposed de minimis variation of +/− 2 percentage points gives issuers the flexibility to set cost-sharing rates that are simple and competitive while ensuring consumers can easily compare plans of similar generosity. This approach strikes a balance between ensuring comparability of plans within each metal level and allowing plans the flexibility to use convenient cost-sharing metrics. The de minimis range also mitigates the need for annual plan redesign, allowing plans to retain the same plan design year to year and remain at the same metal level.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.140 of the proposed rule without modification.

j. Determination of Minimum Value (§ 156.145)

Section 1302(d)(2)(C) of the Affordable Care Act sets forth the rules for calculating the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage under the PHS Act and the Code by providing that the rule adopted by the Secretary under section 1302(d)(2) include the rules for calculating the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage. Section 36B(c)(2)(C)(ii) of the Code provides that an employer-sponsored plan provides minimum value (MV) if this percentage is no less than 60 percent. For the purpose of determining that a given plan provides MV, we proposed in paragraph (a) that the percentage of the total allowed cost of benefits will be determined using one of the main methodologies as described in Treasury Notice 2012–31, released on May 14, 2012 (''MV Notice'').[30] In paragraph (c), we proposed that MV for employer-sponsored self-insured group health plans and insured large group health plans will be determined using a standard population that is based on self-insured group health plans. We also proposed in the preamble that employer contributions to an HSA and amounts newly made available under an HRA will be taken into account in determining MV in accordance with the principles applied in taking such amounts into account in determining AV.

In applying this approach to determining MV, in paragraph (a)(1), we proposed that employer-sponsored self-insured and insured group plans will be able to use the MV Calculator, which would be made available by HHS and the Internal Revenue Service. We described in preamble to the proposed rule how the MV Calculator is similar in design to the AV Calculator discussed above in connection with § 156.135. Furthermore, section 1302(d)(2)(C) of the Affordable Care Act provides that the percentage of the total allowed costs of benefits provided under a group health plan or health insurance coverage for the purposes of determining whether the plan or insurance provide minimum value will be determined using the rules contained in regulation for determining actuarial value.

As an alternative to using the MV Calculator, we proposed in paragraph (a)(2) that an employer-sponsored plan would be able to use an array of design-based safe-harbors published by HHS and the Internal Revenue Service in the form of checklists to determine whether the plan provides MV.

Third, if an employer-sponsored plan contains non-standard features that are not suitable for the use of the calculator and do not fit the safe harbor checklists, we proposed in paragraph (a)(3) to permit MV to be determined through certification by an actuary without the use of the MV Calculator. The actuary would make this determination based on the plan's benefits and coverage data and the standard population, utilization, and pricing tables available for purposes of the valuation of employer-sponsored plans. As proposed, this final option would be available only when one of the other methodologies is not applicable to the employer-sponsored plan. We proposed that the determination of MV must be made by a member of the American Academy of Actuaries, based on an analysis performed in accordance with generally accepted actuarial principles and methodologies. We intend to issue applicable guidance concerning the actuarial analysis.

In the event that a plan uses the MV Calculator and offers an EHB outside of the parameters of the MV Calculator, we proposed in paragraph (b)(1) that an actuary who is a member of the American Academy of Actuaries will be permitted to determine the value of that benefit and add it to the result derived from the MV Calculator in accordance with the generally accepted actuarial principles and methodologies. For clarity, alignment, and administrative ease, we proposed in paragraph (b)(2),

[30] Internal Revenue Service, ''Minimum value of an employer-sponsored health plan'' (2012). Available at: *http://www.irs.gov/pub/irs-drop/n-12-31.pdf.*

for purposes of determining that a group health plan provides MV, that such plans will be permitted to take into account all benefits provided by the plan that are included in any one of the EHB-benchmarks.

The comments and our responses to § 156.145 are set forth below.

Comment: We received several comments asking why the AV Calculator cannot be used to determine minimum value.

Response: The AV Calculator was designed to reflect a standard population as directed by section 1302(d)(2)(A) of the Affordable Care Act. Because it represents the individual and small group markets, the AV Calculator was designed to include data that is reflective of these anticipated populations. Similarly, the MV Calculator is intended to test whether an employer-sponsored group health plan—which is not in the individual or small group insurance markets—provides minimum value and therefore determine if an employee is eligible for a premium tax credit. Thus, we have developed an MV Calculator with similar functionality to the AV Calculator but based on claims data that better reflects typical employer-sponsored plans. In our sampling, the vast majority of plan designs that are in excess of 60 percent AV are also in excess of 60 percent MV. We are finalizing the rule with added language establishing any plan in the small group market that meets any of the levels of coverage, as described in § 156.140 of this subpart, satisfies minimum value.

Comment: We received numerous comments asking when the MV Calculator and safe-harbor checklists will be available for public use.

Response: The MV Calculator with accompanying continuance tables and the MV methodology are now available at *http://cciio.cms.gov/resources/regulations/index.html#pm* and we look forward to comments on both.

Comment: Several commenters questioned why certain benefits outside EHB would be included in the calculation of MV under paragraph (b).

Response: While employer-sponsored group health plans are not required to offer EHB unless they are health plans offered in the small group market subject to PHS Act section 2707(a), employer-sponsored group health plans that seek to offer minimum value must offer 60 percent of the total allowed cost of benefits. Under section 1302(d)(2) of the Affordable Care Act, this measurement, like AV, is based on the provision of EHB to a standard population. To calculate minimum value, employer-sponsored plans may account for any benefits covered by the employer that are also covered in any one of the EHB-benchmark plan options in any state.

Comment: Commenters recommended using the same de minimis variation of the AV Calculator, +/− 2 percentage points, when using the MV Calculator.

Response: We acknowledge the flexibility in plan design when allowing for a de minimis variation of +/− 2 percentage points in the AV Calculator and the similar functionality of the MV Calculator to the AV Calculator; however, whereas the statute allows for a de minimis range with actuarial value there is no similar provision in section 36B of the Code with regard to MV.

Summary of Regulatory Changes

In general, we are finalizing the provisions of § 156.145 as proposed. To address concerns whether insurance offered in the small group market at a bronze level of coverage provides MV, we have added regulation text at § 156.145(a)(4), to clarify that if a plan in the small group market meets any of the levels of coverage described in § 156.140(b), it meets MV. We have also added § 156.145(d) to reflect the proposed preamble language that employer contributions to an HSA and amounts newly made available under integrated HRAs, specifically HRAs that may be used only for cost sharing, will be taken into account in determining MV. To provide greater clarity, we have modified § 156.145(a) to read that an employer-sponsored plan provides MV if the percentage of the total allowed costs of benefits provided under the plan is no less than 60 percent. An employer-sponsored plan may use one of the methodologies outlined in § 156.145 to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent. Whether other types of integrated HRAs might count towards MV is being given further consideration. In this case, guidance on the treatment of HRAs will be issued and this regulation will be amended as necessary.

k. Application to Stand-alone Dental Plans inside the Exchange (§ 156.150)

In paragraph (a), we proposed that stand-alone dental plans would have a separate annual limitation on cost sharing from QHPs covering the remaining EHBs. While the annual limitation on cost-sharing for a QHP embedding pediatric dental coverage would have to be consistent with § 156.130, the annual limitation on cost sharing for a stand-alone dental plan would be considered in accordance with this section. We proposed that the plan must demonstrate the annual limitation on cost sharing for the stand-alone dental plan is reasonable for coverage of the pediatric dental EHB. The annual limitation on cost sharing would be applicable to in-network services only, consistent with § 156.130(c).

In paragraph (b), we proposed actuarial value standards for stand-alone dental plans. The calculator developed by HHS under proposed § 156.135 would be inappropriate for stand-alone dental plans because the standard population that underlies the HHS-developed calculator could not be reasonably adapted to reflect a pediatric-only population that utilizes dental services. Accordingly, in paragraph (b)(1), we proposed that stand-alone dental plans may not use the HHS-developed AV calculator. Instead, given the unique and narrow focus of the stand-alone dental plan market, we proposed in paragraph (b)(2) that any stand-alone dental plan certified to meet an 75 percent AV, with a de minimis range of +/− 2 percentage points, be considered a ''low'' plan and anything with an AV of 85 percent, with a de minimis range of +/− 2 percentage points, be considered a ''high'' plan. In order to meet this standard we proposed in paragraph (b)(3) that the issuer of a stand-alone plan demonstrate that the plan meets the ''high'' or ''low'' level of coverage as certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

The comments and our responses to § 156.150 are set forth below.

Comment: Several commenters supported our proposal to allow stand-alone dental plan to have a separate out-of-pocket maximum, subject to a standard of ''reasonableness'' and either requested additional guidance on the ''reasonable'' standard or provided suggestions for how best to further define what a ''reasonable'' out-of-pocket maximum would be for a stand-alone dental plan. Other commenters urged HHS to include stand-alone dental plans in the overall out-of-pocket maximum and to find some method to develop a method to track and coordinate the out-of-pocket maximum between issuers.

Response: We agree with comments noting that coordination between medical and dental issuers would be administratively complex and accordingly could result in higher premiums for consumers. We therefore allow for a separate out-of-pocket maximum for stand-alone dental issuers. We clarify that it will be up to the Exchange to decide what constitutes a reasonable out-of-pocket maximum for

stand-alone dental plans and anticipate issuing further interpretive guidance for the federally-facilitated Exchanges in sub-regulatory guidance.

Comment: Several commenters supported the proposed ''high'' and ''low'' approach for the AV calculation of stand-alone dental plans, but urged HHS to decrease the ''low'' option from 75 percent to 70 percent as a more affordable option for consumers and to increase variation between ''high'' and ''low'' plans. Other commenters expressed concerns about the impact of a ''high'' and ''low'' approach on consumers from an affordability standpoint. Lastly, some commenters requested that stand-alone dental plans be held to the same standard as health plans.

Response: A ''high'' and ''low'' approach for the AV calculation of stand-alone dental plans simplifies the comparison between stand-alone dental plans with varying cost-sharing levels, while minimizing market disruption for dental plans. The AV levels for the ''high'' and ''low'' options are high compared to metal levels set in the statute to minimize market disruption. This permits stand-alone dental plans to maintain current benefit designs without adding deductibles or other cost-sharing features that are currently not part of those plans. We agree with commenters that 70 percent as a low level will allow for greater plan variation and are finalizing the regulation with a high/low AV requirement of 70 percent and 85 percent respectively.

Comment: The statute and regulations provide that if an Exchange offers a stand-alone dental plan offering a pediatric dental EHB benefit, medical plans are not required to offer a pediatric dental plan benefit on that Exchange. Several commenters encouraged HHS to extend the ability of a medical insurance plan to not offer the pediatric dental EHB into the non-Exchange market, in cases where a stand-alone dental plan that meet the standards to cover the pediatric dental EHB is offered.

Response: The Affordable Care Act does not provide for the exclusion of a pediatric dental EHB outside of the Exchange as it does in section 1302(b)(4)(F) of the Affordable Care Act for QHPs. Therefore, individuals enrolling in health insurance coverage not offered on an Exchange must be offered the full ten EHB categories, including the pediatric dental benefit. However, in cases in which an individual has purchased stand-alone pediatric dental coverage offered by an Exchange-certified stand-alone dental plan off the Exchange, that individual would already be covered by the same pediatric dental benefit that is a part of EHB. When an issuer is reasonably assured that an individual has obtained such coverage through an Exchange-certified stand-alone dental plan offered outside an Exchange, the issuer would not be found non-compliant with EHB requirements if the issuer offers that individual a policy that, when combined with the Exchange-certified stand-alone dental plan, ensures full coverage of EHB. We note that the stand-alone dental plan would have to be an Exchange-certified stand-alone dental plan to ensure that it covered the pediatric dental EHB, as required for Exchange certification under section 1311(d)(2)(B)(ii) of the Affordable Care Act. However, the Exchange-certified stand-alone dental plan would not need to be purchased through an Exchange. This alternate method of compliance is at the option of the medical plan issuer, and would only apply with respect to individuals for whom the medical plan issuer is reasonably assured have obtained pediatric dental coverage through an Exchange-certified stand-alone dental plan. In addition, this option is only available for the pediatric dental EHB, and not for any other EHB, because of the unique treatment of stand-alone dental plans inside the Exchanges. With respect to other individuals seeking to enroll in the same plan, the issuer would be required to offer the same coverage generally (there would be no exception to guaranteed availability that would apply), but would have to make pediatric dental benefits available to such individuals.

Comment: HHS received comments asking whether childless adults and families with children need to purchase a stand-alone dental plan if the QHP they enroll in through an Exchange has omitted the pediatric dental EHB as allowed under section 1302(b)(4)(F) of the Affordable Care Act.

Response: Section 1302 of the Affordable Care Act outlines the requirements for health plans to cover the ten categories of the essential health benefits. The only exception permitted under 1302 of the Affordable Care Act is for QHPs to exclude coverage of the pediatric dental EHB if there is a stand-alone dental plan offered in the Exchange. Section 1311 of the Affordable Care Act requires all Exchange stand-alone dental plans to cover the pediatric dental EHB. In this way, sections 1302 and 1311 of the Affordable Care Act require that the full set of essential health benefits be offered to people purchasing coverage through the Exchange. However, nothing in this rule requires the purchase of the full set of EHB if the purchase is made through an Exchange. Thus, in an Exchange, someone (with a child or without) can purchase a QHP that does not cover the pediatric dental EHB without purchasing a stand-alone dental plan. As noted above, outside of an Exchange, an individual or family must be offered coverage of all ten categories of EHB, either through one policy, or through a combination of a medical policy and an Exchange-certified stand-alone dental plan, as described above.

Comment: Several commenters asked how the policies in § 156.150 would affect a health insurance plan with an embedded pediatric dental EHB.

Response: In response to these questions, we are now clarifying that the policies in § 156.150 apply only to the pediatric dental EHB when offered by a stand-alone dental plan through an Exchange. When the pediatric dental benefit is embedded in a health insurance plan subject to standards set forth in §§ 156.130 and 156.140, we do not distinguish it from other benefits with respect to AV and cost-sharing requirements.

Comment: Several commenters asked whether stand-alone dental plans in the Exchange can offer family coverage in addition to the pediatric dental EHB benefit.

Response: Pursuant to section 1311(d)(2)(B)(ii) of the Affordable Care Act, a stand-alone dental plan must offer the pediatric dental EHB but may offer additional benefits, which could include non-pediatric coverage. We note that only the pediatric dental benefit, and not any non-pediatric coverage, would be subject to EHB standards, including complying with the requirement to offer benefits that are substantially equal to the benchmark and meeting AV and out-of-pocket limit requirements for stand-alone dental plans.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.150 of the proposed rule, with the following modifications: We clarify in paragraph (a) that the Exchange determines what constitutes a reasonable out-of-pocket maximum for a stand-alone dental plan. Also, in paragraph (b)(2)(i) we are changing the target AV for a ''low'' stand-alone dental plan from 75 percent to 70 percent. In addition, we clarify here that plans outside of the Exchange may offer EHB that exclude pediatric dental benefits if they are ''reasonably

assured'' that such coverage is sold only to individuals who purchase Exchange certified stand-alone dental plans.

3. Subpart C—Accreditation

Accreditation of QHP Issuers (§ 156.275)

Recognition of Accrediting Entity by HHS (§ 156.275(c)(1) and (c)(4))

In § 156.275, we proposed to amend § 156.275(c)(1) to provide an application and review process for the current (''phase one'') recognition process of accrediting entities. This would allow additional accrediting entities the opportunity to apply and demonstrate how they meet the conditions for recognition articulated in 1311(c)(1)(D) of the Affordable Care Act. We also proposed to amend § 156.275(c)(4)(i) to delete the timeframe of submitting the documentation within 60 days of publication of this final rule and require accrediting entities to provide the documentation described in § 156.275(c)(4)(i) with their application for review.

The comments and our responses to § 156.275 are set forth below.

Comment: Commenters generally supported the HHS proposal to establish an application and review process for the recognition of additional accrediting entities as part of the phase one recognition process. Several commenters requested that, to be recognized, accrediting entities be held to the same standards as were used to recognize NCQA and URAC.[31] [32] Other commenters noted specific accrediting entities that should be recognized and asked that issuers seeking QHP certification be able to select the recognized accrediting entity from which to seek accreditation. Commenters also asked HHS to clarify that Exchanges must accept accreditation from any of the recognized accrediting entities.

Response: In our notice titled, ''Recognition of Entities for the Accreditation of Qualified Health Plans'', published on November 23, 2012 (77 FR 70163), we announced NCQA and URAC as recognized accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirements of 45 CFR 156.275 as they have effectively met the conditions listed in § 156.275(c)(2), (c)(3), and (c)(4). Nothing in this final rule changes that recognition. HHS will finalize our regulation text as proposed with slight technical corrections to paragraph (c)(1)(iv) to correct the verb tenses. By finalizing § 156.275(c)(1) and (4) largely as proposed, HHS will implement an application and review process by which additional accrediting entities can be recognized. This process also allows for accrediting entities that apply and are not recognized to reapply, provided that its standards are modified to meet the requirements. We concur with commenters that this process to provide other entities an opportunity to apply would provide expanded choices regarding QHP accreditation for Exchanges, states and issuers. As we stated in the proposed rule, this assessment will be the same as that underlying the recognition of NCQA and URAC. We also confirm that, for the purposes of QHP certification, issuers have the flexibility to seek accreditation from any of the HHS-recognized accrediting entities and that Exchanges must accept accreditation from any of the recognized accrediting entities for the purposes of QHP certification.

Comment: Commenters asked for clarification about when the phase two recognition process would replace phase one.

Response: As stated in the Recognition of Entities for the Accreditation of Qualified Health Plans Final Rule (July 20, 2012 77 FR 42663), the phase one recognition process is effective until it is replaced by the phase two process. HHS has not yet set a timeline for the development and implementation of phase two.

Comment: Several commenters requested that HHS modify the criteria established to evaluate accrediting entities, specified in 45 CFR 156.275, including setting minimum standards for accrediting entities, adding specific clinical measures for accrediting entities to collect as part of accreditation, and adding specific topic areas to the accreditation standards, such as evaluating an issuer's implementation of mental health parity. Other commenters gave suggestions on items for inclusion in the phase two recognition process, including antidiscrimination, network adequacy and essential community provider standards; clinical measures applicable to specific populations, such as children, and specific measurement tools; implementing performance-based accreditation; permitting QHP issuers to have their programs or services accredited; and a process for HHS to update standards over time.

Response: HHS has established criteria for accreditation in 45 CFR 156.275 that correspond to requirements included in section 1311(c)(1)(D) of the Affordable Care Act. We consider these requirements as minimum standards for recognized accrediting entities to review as part of the accreditation of QHPs. These requirements were finalized in 45 CFR 156.275. We will consider the above comments as we develop the phase two recognition process which may establish additional criteria for recognized accrediting entities or for the accreditation to be provided for QHPs.

Comment: Commenters supported the proposal for HHS to review applications from accrediting entities as they are received by HHS. Other commenters asked that HHS modify the proposed process by shortening the timeline to review applications from accrediting entities. Commenters also asked that the documentation required in § 156.275(c)(4) be released to the public.

Response: HHS has established a process to accept accrediting entity applications on a rolling basis in order to allow for any accrediting entity wishing to apply to do so as soon as it meets the requirements established in § 156.275(c). The process also allows for accrediting entities who apply and are not recognized to reapply. HHS maintains that a thorough review of an applicant's documentation supporting the application specified in (c)(1)(i) and the publication of a notice in the **Federal Register** may take up to 60 days from the date of receipt. Further, HHS maintains that a minimum 30-day comment period is necessary to ensure that the public has adequate time to consider the accrediting entities being considered for recognition. HHS further maintains that no time period will be established for when the final notice is published in the **Federal Register**, as HHS must carefully review and consider comments submitted during the comment period before making a determination on whether or not an accrediting entity will be recognized. Lastly, as we proposed in (c)(1)(ii), HHS will publish a notice in the **Federal Register** that will include a summary of HHS's analysis of whether the accrediting entity meets the criteria described in (c)(2) and (3). Other documentation submitted during the application process may be proprietary and will not be made public.

Comment: Several commenters offered suggestions for HHS to consider when implementing future quality reporting requirements for QHP issuers and Exchanges. These suggestions included: Specific quality measures for issuers to report; methods to minimize burden for reporting quality data; elements and attributes to consider in developing the QHP-specific quality

[31] Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658–42672 (July 20, 2012) (to be codified at 45 CFR part 156).

[32] Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 70163 (November 23, 2012).

rating; and consulting with external stakeholders as the quality requirements are developed. Other commenters made recommendations for educating consumers about quality information as well as the types of information that should be displayed to consumers. Finally, we received comments encouraging standardized quality reporting requirements across Exchanges and expressing support for State flexibility in establishing quality requirements.

Response: While HHS appreciates the submission of these comments, they are outside the scope of this rule. We will solicit input on quality reporting requirements as part of future rulemaking.

Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, we are finalizing the provisions proposed in § 156.275(c)(1) and (4) of the proposed rule without substantive modification. We are revising the text at § 156.275(c)(1)(iv) for technical corrections to reflect that the required notice has been published since the proposed rule.

III. Collection of Information

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before an information collection request is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the 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.

Below is a summary of the information collection requirements outlined in this regulation. Throughout this section, we assume that each data collection will occur on an annual basis unless otherwise noted. We used the Bureau of Labor Statistics (BLS) Web site to identify salary data, unless otherwise indicated. Fringe benefit estimates were taken from the BLS March 2011 Employer Costs for Employee Compensation report. These compensation estimates were selected to align with the burden estimates for the data collections described in the final rule that published on March 27, 2012 (77 FR 18310). For purposes of presenting an estimate of paperwork burden, we reflect the operation of an Exchange in fifty states, the U.S. territories, and the District of Columbia. Similarly, we estimate the burden for issuers participating in all 50 states, the territories and the District of Columbia. Therefore, these estimates should be considered an upper bound of burden estimates. These estimates may be adjusted in future information collection requests. We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. ICRs Regarding Additional Required Benefits (§ 155.170(c))

In § 155.170(c), we direct QHP issuers to quantify and report to the Exchange the cost attributable to required benefits in addition to EHB. This is a third-party disclosure requirement. Issuers will use a uniform rate template in a revision to the Rate Increase Disclosure and Review Reporting Requirements information collection request to report this information. The burden associated with meeting this data collection is included in the Rate Review information collection request. A **Federal Register** notice (77 FR 40061),[33] in which we sought comments on this PRA package, was published on July 6, 2012.

As noted in the Rate Review information collection request, we estimate that a total of 2,010 issuers in the individual market and 1,050 issuers in the small group market will offer products and that each issuer will have an average of 2.5 submissions per year. We anticipate that it will take an actuary a total of 11 hours to complete the uniform rate template, at $225 per hour for an actuary. The total annual cost is estimated to be $18,933,750. Of this total amount, only a fraction can be attributable to the portion of the uniform rate template that pertains to benefits in addition to EHB for QHP issuers. We estimate that of the total 11 hours it will take an actuary to complete the uniform rate template, it will take an actuary 1 hour to complete the portion pertaining to benefits in addition to EHB. Therefore, we estimate the cost attributable to the collection of information regarding benefits in addition to EHB to be $1,721,250.

B. ICRs Regarding State Selection of Base-Benchmark (§ 156.100) and EHB-Benchmark Plan Standards (§ 156.110)

In § 156.100, we proposed that a state may select a base-benchmark plan to serve as a reference plan to define EHB in that state. We also proposed that if a state does not select a benchmark plan, its base-benchmark would be the largest plan by enrollment in the largest product in the state's small group market. In § 156.110, we proposed that a state-selected or default benchmark plan must offer coverage in each EHB category, as required by the Affordable Care Act. We proposed that if a base-benchmark plan does not offer coverage in a category, it must be supplemented to include those missing benefit categories.

We do not believe that this is a change to the information collection associated with state selection and submission of a benchmark plan and associated benefits and the data collection to establish default benchmark plans, including any required supplementing, which is already captured in the collection approved under OMB Control Number 0938–1174.

C. ICRs Regarding AV Calculation for Determining Level of Coverage (§ 156.135)

In § 156.135(b), we proposed to create an exception to using the AV calculator for issuers with health plans that are not designed in a way that is compatible with the AV calculator. To take advantage of this exception, issuers must submit an actuarial certification on their alternative method to the state, HHS, the Exchange, or OPM. This is a third-party disclosure requirement when the issuers submit to the state or the Exchange, and this is a reporting requirement when the issuers submit to HHS, OPM, or a Federally-facilitated Exchange. We account for this collection in the Initial Plan Data Collection to Support Qualified Health Plan Certification and Other Financial Management and Exchange Operations information collection request. A **Federal Register** notice (77 FR 40061) regarding this PRA package was published on July 6, 2012. As required by the PRA, we will publish another notice in the **Federal Register** when the aforementioned information collection request is submitted to OMB for review and approval.

In the QHP Certification PRA package, we estimate that 1,200 issuers will each offer 15 potential QHPs, for a total of

[33] ''Agency Information Collection Activities: Proposed Collection; Comment Request; Webinars''. (77 FR 40061) Available at *http://www.gpo.gov/fdsys/pkg/FR-2012-07-06/pdf/2012-16508.pdf.*

18,000 potential QHPs, and that the per-issuer burden will be 175 hours. We estimate the cost per issuer in the first year of operations to be $13,475, which represents an aggregation of several staff, including actuarial staff. This information collection request includes data collections for QHP certification, risk adjustment, and reinsurance. We believe that only 5 percent of issuers will be unable to use the AV calculator, thus use the process proposed in § 156.135(b) and assume that it will take each issuer 8 of the total 175 hours to provide the requested information. We further assume that the 8 hours of work would be performed by an actuary, at $225 per hour. Therefore, we estimate the total cost attributable to § 156.135(b) to be $1,800 per QHP and $1,620,000, per year.

In § 156.135(d), we proposed that beginning in 2015, a state may submit a state-specific standard population, to be used for AV calculations, so long as the criteria described in § 156.135(d)(1) through (6) are met. A state that applies must submit to HHS summary evidence that the requirements described in the proposed rule are met and the dataset is in a format that will support the use of the AV calculator. We expect that for each state choosing this option, the data submission will require 15 hours from a database administrator at $47.70 an hour, 4 hours of actuarial work at $225 an hour, and 1 hour of management review at $75.15 an hour. Therefore, the total cost associated with the reporting requirement for each state choosing this option will be $1,691. We assume that states opting to develop a state-specific standard population will provide new data every three to five years.

D. ICRs Regarding Stand-Alone Dental Plans Inside the Exchange (§ 156.150(a))

In § 156.150(a), we proposed that stand-alone dental plans covering the pediatric dental EHB under § 155.1065 must demonstrate to the Exchange that they have a reasonable annual limitation on cost sharing. This is a third-party disclosure requirement.

We account for this collection in the QHP Certification information collection request discussed earlier in this section, where we estimate that 40 issuers will each offer a stand-alone dental plan, and that the burden for certification will be 6 hours per issuer, at a total hourly billing rate of $77, for a total cost of $462 per issuer. We estimate that of those 6 hours, 1 will be attributable to demonstrating that the annual limitation on cost sharing is reasonable, at a cost of $77 per plan. Therefore, across 40 plans, we estimate the total annual cost to be $3,080.

E. ICRs Regarding Accreditation (§ 156.275)

As part of the proposed rule, titled ''Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation'' (77 FR 70644), published in the **Federal Register** on November 26, 2012, we also issued a 60-day **Federal Register** notice seeking comments on these ICRs. The 60-day comment period closed on January 26, 2013. We will submit a revised information collection request to OMB, under OMB Control Number 0938–1176, to account for the adjustment in the number of respondents and the corresponding adjustment to the burden. At that time, as required by the PRA, we will publish another notice in the **Federal Register** when the aforementioned information collection request is submitted to OMB for review and approval.

The comments and our responses are set forth below.

Comment: One commenter noted that the data collection proposed under the information collection request entitled ''Recognized Accrediting Entities Data Collection'' [34] requires the submission of significant amounts of sensitive, proprietary, or confidential data and may be overly burdensome to issuers.

Response: HHS disagrees that the data submission requirements for recognized accrediting entities and accrediting entities seeking recognition from HHS for the purpose of § 156.275(a) will be overly burdensome to issuers. We describe minimal data submission requirements for issuers. Issuer burden for the accreditation requirement is accounted for in the QHP Application information collection request.[35] All other data requirements described in the information collection request regarding accreditation will be met by recognized accrediting entities and entities applying to be recognized by HHS.

Comment: One commenter offered specific feedback on the content areas that were proposed for data collection, including what accreditation survey data is collected, how accreditation data from different accrediting entities may vary, and requesting that only specific CAHPS survey questions be required for submission by QHP issuers.

Response: The purpose of the ICRs regarding accreditation is to solicit feedback from stakeholders on the estimated burden associated with the proposed data collection on recognized accrediting entities. Comments in regard to specific content areas of the data collection are therefore outside of the scope. We finalized the accreditation documentation submission requirements in a final rule published on July 20, 2012.[36]

IV. Regulatory Impact Analysis

HHS has examined the impacts of this proposed regulation under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993) and Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011).

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 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866—emphasizing the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by the Office of Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action.'' In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget as an economically significant regulatory action.

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. HHS will submit a

[34] Available at: *http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10449.html.*

[35] Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, Final Rule, 77 FR 42658–42672 (July 20, 2012) (to be codified at 45 CFR part 156).

[36] Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans (CMS–9965–F), 77 FR 42,658 (July 20, 2012).

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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective April 26, 2013, sixty days after date of publication in the **Federal Register**.

A. Summary

This final rule will implement the requirements related to EHB and AV levels of coverage, and establish the timeline according to which QHP issuers participating in Federally-facilitated Exchanges must be accredited. We note that the Exchange regulation (45 CFR 156.200) established that QHPs will cover essential health benefits, as defined by the Secretary, and that QHPs be accredited on the basis of local performance. The cost to health plans of obtaining QHP certification and participating in Exchanges is already accounted for in the regulatory impact analysis that accompanies that regulation.[37] Therefore, this analysis describes the incremental costs, benefits, and transfers associated with provisions in this proposed rule, for example that health plans cover the essential health benefits as specifically defined herein, and that health plans use the HHS-developed AV calculator.

This final rule also contains details relating to the establishment of a timeline by which QHPs seeking certification by Federally-facilitated Exchanges must be accredited. We do not believe that this results in incremental benefits, costs, or transfers.

HHS has finalized this regulation to implement the protections intended by the Congress in an economically efficient manner. In accordance with OMB Circular A–4, HHS has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this proposed regulation.

B. Overview of Key Provisions in the Proposed Rule

The Affordable Care Act directs the Secretary to define EHB such that EHB includes at least and reflects an appropriate balance among 10 benefit categories, and is equal in scope to benefits offered by a typical employer plan. Non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges, including multi-state plans, Medicaid benchmark and benchmark-equivalent, and Basic Health Programs, if applicable, must cover EHB beginning in 2014. This final rule establishes how the Secretary will define EHB based on a state-specific benchmark plan and lays out standards for the EHB-benchmark plan and for issuers that cover EHB.

In addition, the Affordable Care Act directs issuers offering non-grandfathered health plans in the individual and small group markets to ensure that any offered plan meets specific AVs. The final rule outlines a process for computing plan AV using an HHS-developed AV calculator, as well as standards and flexibility for issuers in meeting the metal tiers.

C. Need for Regulatory Action

This rule finalizes standards related to EHB and AV consistent with the Affordable Care Act. HHS believes that the provisions that are included in this final rule are necessary to fulfill the Secretary's obligations under sections 1302 and 1311 of the Affordable Care Act. Establishing specific approaches for defining EHB and calculating AV will bring needed clarity for states, issuers, and other stakeholders. Absent the provisions outlined in this proposed rule, states, issuers, and consumers would face significant uncertainty about how coverage of EHB should be defined and evaluated. Similarly, failing to specify a method for calculating AV could result in significant inconsistency across states and issuers, and significant confusion for consumers. Finally, establishing a clear timeline for potential QHPs to become accredited is essential to successful issuer participation in Federally-facilitated Exchanges.

D. Summary of Impacts and Accounting Table

In accordance with OMB Circular A–4, Table IV.1 below depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

HHS anticipates that the provisions of this final rule will assure consumers that they will have health insurance coverage for EHB, and significantly increase consumers' ability to compare health plans, make an informed selection by promoting consistency across covered benefits and levels of coverage, and more efficiently purchase coverage. This final rule ensures that consumers can shop on the basis of issues that are important to them such as price, network physicians, and benefits offered, and be confident that the plan they choose does not include unexpected coverage gaps, like hidden benefit exclusions. It also allows for flexibility for plans to promote innovation in benefit design.

Insurance contracts are extremely complicated documents; therefore, many consumers may not understand the content of the contracts they purchase.[38] This complexity has two undesirable results. First, consumers may unknowingly purchase a product that does not meet their basic needs—the product may not cover benefits to restore or maintain good health, or may result in more financial exposure than the consumer anticipated. Second, complexity may deter consumers from market transactions, whereas a small number of meaningful choices may increase consumers' willingness to purchase coverage.[39]

The specific approach to defining EHB in this final rule realizes the benefits of simplicity and transparency by allowing each state to choose a benchmark from a set of plans that are typical of the benefits offered by employers in that state. The final rule allows that EHB in each state reflect the choices made by employers and employees in that state today, and minimizes disruption in existing coverage in the small group market. In addition, the provisions addressing specific benefit categories, such as habilitative services and pediatric dental and vision services, will improve access to care for consumers who require these benefits.

The approach to defining AV in this final rule uses standard assumptions about utilization and prices, and, for most products, directs issuers to use an AV calculator created by the Department to compute AV. This approach will ensure that two plans with the same cost-sharing parameters

[37] ''Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, Exchange Standards for Employers (CMS–9989–FWP) and Standards Related to Reinsurance, Risk Corridors and Risk Adjustment (CMS–9975–F): Regulatory Impact Analysis.'' Centers for Medicare & Medicaid Services. Available at: *http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf.*

[38] Consumers Union. (2012). ''What's Behind the Door: Consumers' Difficulties Selecting Health Plans.'' Available at: *http://www.consumersunion.org/pub/pdf/Consumer%20Difficulties%20Selecting%20Health%20Plans%20Jan%202012.pdf.*

[39] Iyengar, Sheena S.; Lepper, Mark R. Journal of Personality and Social Psychology, Vol 79(6), Dec 2000, 995–1006.

(that is, deductibles, copayments, and coinsurance features) will have the same AVs. This approach is intended to lower consumer information costs and drive competition in the market by enabling consumers to easily compare the relative generosity of plans, knowing that the AV of each plan has been calculated in the same manner.

In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

TABLE IV.1—ACCOUNTING TABLE

Category	Estimates	Units		
		Year dollar	Discount rate	Period covered
Benefits				
Annualized Monetized ($millions/year)	Not Estimated Not Estimated	2011 2011	7% 3%	2013–2016 2013–2016
Qualitative	(1) Improved coverage in benefit categories less typically available. Expanded access to coverage of benefits, particularly in the individual market, including maternity and prescription drug coverage. (2) Alignment with current consumer and employer choices. Flexibility for states; limited market disruption; allowance for health plan innovation (e.g., substitution within benefit categories; de minimis variation for AV). (3) Efficiency due to greater transparency. Increased transparency and consumer ability to compare coverage.			
Costs				
Annualized Monetized ($millions/year)	$3.4* $3.1*	2011 2011	7% 3%	2013–2016 2013–2016
Qualitative	(1) Administrative costs. Insurers will incur administrative costs associated with altering benefit packages to ensure compliance with the definition of EHB established in this proposed rule. Issuers may also incur minor administrative costs related to computing AV.			
	(2) Costs due to higher service utilization. As consumers gain additional coverage for benefits that previously did not meet the standards outlined in this proposed rule (for example, pediatric dental or vision coverage), utilization, and thus costs, may increase. A portion of this increased utilization and costs may be economically inefficient.			
Transfers				
Federal Annualized Monetized ($millions/year)	Not Estimated Not Estimated	2011 2011	7% 3%	2013–2016 2013–2016

***Note:** Administrative costs include costs associated with Information Collection Requirements as described in section III of this final rule. These costs are annualized over the analysis period of 2013–2016.

E. Methods and Limitations of Analysis

There are many provisions of the Affordable Care Act that are integral to the goal of expanding access to affordable insurance coverage, including the provisions of this proposed rule relating to EHB and AV. Because it is often difficult to isolate the effects associated with each particular provision of the Affordable Care Act, we discuss the evidence relating to the provisions of this proposed rule, as well as related provisions of the Affordable Care Act, in this regulatory impact analysis. We present quantitative evidence where it is possible and supplement with qualitative discussion.

F. Estimated Number of Affected Entities

As discussed elsewhere in the preamble, standards relating to EHB and AV will apply to all health insurance issuers offering non-grandfathered coverage in the individual and small group markets—both inside and outside of the Exchanges. The following sections summarize HHS's estimates of the number of entities that will be affected by this proposed regulation.

a. Issuers

For purposes of the regulatory impact analysis, we have estimated the total number of health insurance issuers that will be affected by this proposed

regulation at the company level because this is the level at which issuers currently submit their annual financial reports to the National Association of Insurance Commissioners (NAIC). Table IV.2 shows the estimated distribution of issuers offering comprehensive major medical coverage in the individual and small group markets based on data submitted on the National Association of Insurance Commissioners' 2011 Supplemental Health Care Exhibit (SHCE).[40] Additionally, because many issuers are licensed in more than one state, we have also included data by ''licensed entity'' (company/state combination) for each market.

TABLE IV.2—ESTIMATED NUMBER OF ISSUERS AND LICENSED ENTITIES AFFECTED BY THE EHB AND AV REQUIREMENTS BY MARKET, 2011

Description	Issuers [1] offering comprehensive major medical coverage		Licensed entities [2] offering comprehensive major medical coverage	
	Number	% of Total	Number	% of Total
Total Issuers Offering Comprehensive Major Medical Coverage [3]	446	100.0	2,107	100.0
By Market: [4]				
Individual Market	355	79.6	1,663	78.9
Small Group Market [5]	366	82.1	1,039	49.3
Large Group Market	375	84.1	922	43.8
Individual and/or Small Group Markets [6]	427	95.7	1,993	94.6
Individual Market Only	82	18.4	904	42.9
Small Group Market Only	39	8.7	117	5.6
Individual & Small Group Markets Only	29	6.5	164	7.8
All Three Markets	279	62.6	545	25.9

Notes: [1] Issuers represents companies (for example, NAIC company codes).
[2] Licensed Entities represents company/state combinations.
[3] Total issuers excludes data for companies that are regulated by the California Department of Managed Health Care.
[4] To be counted as offering coverage in a particular comprehensive major medical market, the issuer must have reported non-zero premiums and claims and had at least $1,000 in total premiums per life year for at least one state.
[5] Small group is defined based on the current definition in the PHS Act.
[6] Subcategories do not add to the total because other categories are not shown separately such as those entities in the large group and small group markets, but not in the individual market.
Source: ASPE analysis of 2011 NAIC Supplemental Health Care Exhibit data.

b. Individuals

Persons enrolled in non-grandfathered individual or small group market coverage inside or outside of the Exchanges beginning in 2014 will be affected by the provisions of this final rule.[41]

In July 2012, CBO estimated that there will be approximately 24 million enrollees in Exchange coverage by 2016.[42] Participation rates among potential enrollees are expected to be lower in the first few years of Exchange availability as employers and individuals adjust to the features of the Exchanges.[43] Additionally, the EHB and AV provisions of this final rule will also affect enrollees in non-grandfathered individual and small group coverage outside of the Exchanges.

G. Anticipated Benefits

The Affordable Care Act ensures non-grandfathered health plans offered in the individual and small group markets offer a basic package of items and services. The benefits of health insurance coverage are well documented and discussed at length in previous RIAs,[44] including improvement in clinical outcomes and financial security.[45] [46] This final rule applies a definition to EHB and finalizes other standards that are required of health plans, as directed under the statute.

In the market today, it is difficult for consumers to make well-informed choices when selecting from among competing health plans. The benefits offered are complicated and can vary widely across plans, making it difficult for consumers to understand which benefits are covered.[47] Further, wide variation in deductibles, coinsurance,

[40] The most complete source of data on the number of entities offering fully insured, private comprehensive major medical coverage in the individual and group markets is the National Association of Insurance Commissioners (NAIC) Annual Financial Statements and Policy Experience Exhibits database. These data contain information that issuers submit to the NAIC through State insurance regulators on four different financial exhibits (the Health, Life, Property & Casualty, and Fraternal ''Blanks''). The 2011 SHCE captures data on individual, small group and large group comprehensive major medical coverage at the State level in a consistent manner across all Blanks, providing more extensive information about this market than was previously available. We note that issuers electing not to offer non-grandfathered individual or small group market policies would not be affected by the proposed rule.

[41] The provisions in this proposed regulation could also potentially affect some enrollees with non-grandfathered large group market coverage in States that choose to give larger employers the option of purchasing coverage through the Exchange starting in 2017. However, the Congressional Budget Office (CBO) and Joint Committee on Taxation (JCT) ''expect that few large firms would take [advantage of] that option if offered because their administrative costs would generally be lower than those of nongroup policies that would be available in the exchanges.'' (For more information, see Congressional Budget Office, ''Letter to the Honorable Evan Bayh: An Analysis of Health Insurance Premiums under the Patient Protection and Affordable Care Act,'' Washington, DC, 2009.)

[42] ''CBO's February 2013 Estimate of the Effects of the Affordable Care Act on Health Insurance Coverage,'' Congressional Budget Office, February 2013. Available at *http://www.cbo.gov/sites/default/files/cbofiles/attachments/43900_ACAInsuranceCoverageEffects.pdf.*

[43] Congressional Budget Office, ''Letter to the Honorable Evan Bayh: An Analysis of Health Insurance Premiums under the Patient Protection and Affordable Care Act,'' Washington, DC 20009.

[44] Available at: *http://cciio.cms.gov/resources/files/Files2/03162012/hie3r-ria-032012.pdf.*

[45] Institute of Medicine (2001). *Coverage Matters: Insurance and Health Care.* National Academies Press: Washington, DC. Burstin HR, Swartz K, O'Neil AC, Orav EJ, Brennan TA. 1999. The effect of change of health insurance on access to care. *Inquiry; 35:* 389–97. Finkelstein A et al. 2011. The Oregon health insurance experiment: Evidence from the first year. NBER Working Paper No. 17190.

[46] Institute of Medicine (2002). *Care without coverage: too little, too late.* National Academies Press. Ayanian J, et al. ''Unmet Health Needs of Uninsured Adults in the United States.'' *JAMA.* 284(16). 2000:2061–9. 27; Roetzheim R, et al. ''Effects of Health Insurance and Race on Colorectal Cancer Treatments and Outcomes.'' *American Journal of Public Health* 90(11). 2000: 1746–54; Wilper, et al. ''Health Insurance and Mortality in US Adults.'' *American Journal of Public Health.* 99(12). 2009: 2289–2295.

[47] Garnick, D.W. et al. (1993). ''How well do Americans understand their health coverage?'' *Health Affairs,* 12(3); 204–212.

and other cost sharing features make it difficult for consumers to understand the relative levels of financial protection they will receive under competing plans.[48] [49]

Under the provisions in this final rule, the EHB-benchmark plan will reflect both the scope of services and any limits offered by a ''typical employer plan'' in that state. This approach, applying for at least the 2014 and 2015 benefit years, will allow states to build on coverage that is already widely available, minimize market disruption, and provide consumers with familiar products. This should heighten consumer understanding of plan options and may facilitate consumers' abilities to make choices that better suit their needs. In addition, by ensuring that all plans cover a core set of benefits and services that will be compared against other plans that offer the same financial protection to the consumer, this final rule is expected to improve the quality and value of the coverage that is available for EHB.

Information on AV is expected to be used by consumers to compare non-grandfathered individual and small group market plans, and provides a method for consumers to understand relative plan value. Proposing standard pricing and utilization assumptions for AV calculations for QHPs and non-grandfathered health plans in the individual and small group markets will promote transparency and simplicity in the consumer shopping experience, as well as offer issuers the flexibility to set cost-sharing rates that are simple and competitive. Without this approach, plans with the same cost-sharing provisions could have different AVs making it difficult for consumers to compare and choose among health plans. It also fosters plan competition based on price, quality, and service—rather than variations in benefit design.

H. Anticipated Costs and Transfers

In addition to the administrative costs described in the Information Collection Requirements section of this proposed rule, HHS anticipates that the provisions of this final rule could result in increased costs related to increased utilization of health care services by people receiving coverage for previously uncovered or unaffordable benefits.

States have primary enforcement authority over health insurance issuers and this proposed rule extends this primary enforcement authority for compliance with EHB and AV requirements defined in this rule. In addition, states must defray the cost of any state-required benefits in excess of the EHB that apply to QHPs and multi-state plans offered through Exchanges. As stated earlier, we expect that this will rarely occur, if at all, in 2014 and 2015, the period coverage by the benchmark policy.

The anticipated effects on enrollees in the individual market are expected to be larger than the effects on enrollees in the small group market. Coverage in the small group market is much more likely to include EHB already and, in fact, is included in the choice of benchmark plans.[50] Second, almost all products in the group market have AV above 60 percent,[51] while there are likely to be changes to products in the individual market due to the provisions of this proposed rule.

Impact on Issuers

Commonly purchased products in the small group market, state employee plans, and the FEHBP Blue Cross Blue Shield (BCBS) Standard and Basic Options and Government Employees Health Association (GEHA) plans do not differ significantly in the range of services they cover.[52] Because one of these plans will be chosen as the reference plan for EHB, most small group plans will provide benefits that are similar to EHB, and changes in benefits offered to comply with EHB provisions will be relatively minor.

Notwithstanding this general conclusion, there are four types of benefits where changes are expected in the small group market: Mental health and substance use disorder, habilitative services, pediatric dental care, and pediatric vision services. In addition, individual health plans are less likely than small group health plans to cover all of the 10 statutory EHB categories. Below we discuss two categories of benefits and services that are less likely to be covered in the market today: mental health and substance use disorder services, and habilitative services.

Coverage of additional benefits results in a transfer from out-of-pocket payments to premium payments. Increased access to insurance coverage for previously excluded benefits will make medical care for those benefit categories more affordable for consumers by covering a portion of the costs of those services. While out-of-pocket costs would decline, consumers could purchase benefits and services inefficiently—that is, purchase more than the efficient amount of the previously excluded benefits and services. However, studies of the Medicare program suggest that the costs of this inefficiency are likely more than offset by the benefits of risk reduction.[53] The introduction of the Medicare program resulted largely in changes from uninsured to insured—research suggests that only 25 percent of seniors had private hospital insurance before the introduction of the program.[54] In contrast, this final rule will likely result in incremental gains in access, rather than changes in status from uninsured to insured. Accordingly, CMS expects that the tradeoff between the costs of inefficiency and the benefits of risk reduction will be as or more favorable as the results observed in studies of the Medicare program. As discussed previously, many other provisions of the Affordable Care Act, including healthier risk pools, greater administrative efficiencies, premium tax credits, and the transitional reinsurance program will lower premiums in the individual market and Exchanges.

[48] Consumers Union. (2012). ''What's Behind the Door: Consumers' Difficulties Selecting Health Plans.'' Available at: *http://www.consumersunion.org/pub/pdf/Consumer%20Difficulties%20Selecting%20Health%20Plans%20Jan%202012.pdf.*

[49] Isaacs, S.L. (2006). Consumer's information needs: results of a national survey. *Health Affairs,* 15(4): 31–41.

[50] A study conducted by the Assistant Secretary for Planning and Evaluation (ASPE) found that commonly purchased products in the small group market, state employee plans, and federal employee plans do not differ significantly in the range of services they cover. Because one of these plans will be chosen as the reference plan for EHB, most small group plans will provide benefits that are similar to EHB. (ASPE Issue Brief (2011). ''EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans,'' U.S. Department of Health & Human Services.) In contrast, another ASPE study found that many current subscribers in the individual market lack coverage for some EHB benefits and services, such as maternity care and prescription drugs. (ASPE Research Brief (2011). ''EHB: Individual Market Coverage'' U.S. Department of Health & Human Services.)

[51] ASPE Research Brief (2011). ''AV and Employer Sponsored Insurance,'' available at: *http://aspe.hhs.gov/health/reports/2011/AV-ESI/rb.pdf.* Similar results were found in a recent study by Gabel and colleagues. Jon R. Gabel, Ryan Lore, Roland D. McDevitt, Jeremy D. Pickreign, Heidi Whitmore, Michael Slover and Ethan Levy-Forsythe, ''More Than Half Of Individual Health Plans Offer Coverage That Falls Short Of What Can Be Sold Through Exchanges As Of 2014,'' Health Affairs, (2012), available at: *http://content.healthaffairs.org/content/early/2012/05/22/hlthaff.2011.1082.full.pdf+html.*

[52] ASPE Issue Brief (2011). ''EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans,'' U.S. Department of Health & Human Services (2011).

[53] Finkelstein A, McKnight R: ''What Did Medicare Do (And Was It Worth It)?'' Journal of Public Economics 2008, 92:1644–1669; and Finkelstein, A, ''The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare,'' National Bureau of Economic Research. Working Paper No. 11619, Sept, 2005.

[54] Finkelstein, A, ''The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare,'' National Bureau of Economic Research. Working Paper No. 11619, Sept, 2005.

The statute requires that all plans covering EHB offer mental health and substance use disorder service benefits, including behavioral health treatment and services. The preamble of this rule provides that coverage of EHB must provide parity in treatment limitations between medical and surgical benefits and the mental health and substance use disorder benefits required to be covered as EHB in both the individual and small group markets. Many states [55] [56] have already added some form of mental health parity in some or all insured markets.[57] About 95 percent of those with coverage through the three largest small group products in each state had substance use disorder and mental health benefits.[58] Additionally, a study of implementation of parity in the FEHBP plans [59] as well as research into state-passed mental health parity laws [60] have shown little or no increase in utilization of mental health services, but found that parity reduced out-of-pocket spending among those who used mental health and substance abuse services.

As indicated in the preamble, many health insurance plans do not identify habilitative services as a distinct group of services.[61] By implementing a transitional policy for coverage of habilitative services, this rule allows issuers time for review and development of policy in this area, and to gain experience to define these benefits. To the extent that states exercise the option to define habilitative services, small group market issuers may incur administrative and contracting costs associated with bringing their products into compliance with a state's definition. However, because it is not yet clear which states will exercise this option or how any such states will define habilitative services, HHS cannot estimate these costs at this time.

With respect to AV and MV, research indicates that the overwhelming majority of employer-sponsored health plans meets and exceeds an AV of 60 percent.[62] Combining both small group and large group, an estimated 1.6 percent to 2.0 percent of people covered by employer-sponsored insurance are enrolled in plans with an AV of less than 60 percent.

To keep premium costs low, the Affordable Care Act allows certain individuals (adults under age 30 and people who otherwise have unaffordable coverage) to purchase catastrophic coverage, which still guarantees first dollar coverage of preventive services and primary care check-ups but has higher deductibles and lower AVs.

Costs to States

State governments are generally responsible for health insurance enforcement in the individual and small group markets, with the federal government assuming that role in connection with federal law requirements if a state does not do so. While HHS expects that states may need additional resources to enforce the requirements that non-grandfathered plans in the individual and small group market provide EHB, and that these plans offer coverage with an AV equal to one of the four metal levels, these costs will be relatively minor.

If a state requires issuers to cover benefits in excess of EHB, the Affordable Care Act directs the state to defray the costs of these benefits in QHPs. States may include as part of their benchmark plan state benefit requirements that were enacted before December 31, 2011, avoiding costs associated with these provisions.

Costs to Health Insurance Issuers

Issuers will incur administrative costs to modify existing offerings to meet EHB and AV standards as defined in this final rule. For example, issuers that do not currently meet the standards for prescription drug coverage will incur contracting and one-time administrative costs to bring their pharmacy benefits into compliance. Issuers may also incur minor administrative costs related to AV standards and computing AV. However, because EHB will be based on a benchmark plan that is typical of what is offered in the market in each state currently, the modifications in benefits are expected to be relatively minor for most issuers. Further, issuers have extensive experience in offering products with various levels of cost sharing, and HHS expects that following the process for computing AV outlined in this proposed rule will not demand many additional resources.

I. Regulatory Alternatives

In addition to the regulatory approach outlined in the Essential Health Bulletin issued on December 16, 2011, HHS considered several alternatives when developing policy around defining EHBs and calculating AV.

Definition of EHBs

At the request of some commenters, HHS considered one national definition of EHB that would have applicable issuers offer a uniform list of benefits. However, this approach would not allow for state flexibility and issuer innovation in benefit design, would require a burdensome overhaul for issuers, and would disrupt the market.

HHS also considered codifying the 10 statutorily required categories without additional definition and allowing issuers to adjust their benefit packages accordingly. However, this approach would have allowed extremely wide variation across plans in the benefits offered, would not have assured consumers that they would have coverage for basic benefits, and would not have improved the ability of consumers to make comparisons among plans.

HHS believes the benchmark approach best strikes the balance between comprehensiveness, affordability, and state flexibility. Additionally, HHS believes that the benchmark approach, supplemented when necessary, best addresses the statutory requirements that EHBs reflect a typical employer plan and encompass at least the 10 statutory EHB categories of items and services outlined in the statute.

[55] Kaiser State Health Facts. *State mandated benefits in small group private health insurance: Mandated coverage in mental health, as of January 2010.* Available at: *http://www.statehealthfacts.org/comparereport.jsp?rep=2&cat=7.*

[56] Health Insurance Mandates in the States 2010, Council for Affordable Health Insurance, available at: *http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010ExecSummary.pdf.*

[57] Health Insurance Mandates in the States 2010, Council for Affordable Health Insurance, available at: *http://www.cahi.org/cahi_contents/resources/pdf/MandatesintheStates2010ExecSummary.pdf.*

[58] ASPE Issue Brief, ''EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans, U.S. Department of Health & Human Services (2011).

[59] Goldman HH, et al. 2006. Behavioral health insurance parity for federal employees. New Engl J Med;354 1378–86.

[60] Barry CL, Busch SH. 2007. Effects of state parity laws on the family financial burden of children with mental health care needs. *Health Serv Res; 42:* 1061–84. Ma CA, McGuire TG. 1998. Cost and incentives in a behavioral health carve-out. *Health Affairs;17:* 56–67.

[61] ASPE Research Brief (2011). ''EHB: Comparing Benefits in Small Group Products and State and Federal Employee Plans.'' Available at: *http://aspe.hhs.gov/health/reports/2011/MarketComparison/rb.shtml.*

[62] ASPE Research Brief (2011). ''AV and Employer Sponsored Insurance,'' available at: *http://aspe.hhs.gov/health/reports/2011/AV-ESI/rb.pdf.* Similar results were found in a recent study by Gabel and colleagues. Jon R. Gabel, Ryan Lore, Roland D. McDevitt, Jeremy D. Pickreign, Heidi Whitmore, Michael Slover and Ethan Levy-Forsythe, ''More Than Half Of Individual Health Plans Offer Coverage That Falls Short Of What Can Be Sold Through Exchanges As Of 2014,'' Health Affairs, (2012), available at: *http://content.healthaffairs.org/content/early/2012/05/22/hlthaff.2011.1082.full.pdf+html.*

Calculation of AV

In the calculation of AV, the statute specifies the use of a standard population. As described in the AV/CSR Bulletin, HHS considered allowing issuers to use their own utilization and pricing data in connection with an HHS-defined standard population (that is, HHS-set demographics for the standard population) to calculate a standard population. However, this would not have allowed for consumer transparency and would not have increased competition. The approach in this final rule instead reduces issuer burden while allowing consumers to compare more easily among plans.

The comments and our responses to the RIA are set forth below.

Comment: A few commenters stated that the RIA included in the proposed rule was insufficiently quantitative; failed to address specific potential impacts of the regulation, such as access to previously uncovered benefits and premium costs associated with induced utilization; and did not adequately describe other regulatory alternatives considered by HHS.

Response: HHS published the Establishment of Exchanges Final Rule on March 27, 2012. In the regulatory impact analysis associated with that final rule, HHS codified standards related to coverage of EHB, compliance with AV levels, and accreditation of QHPs. The costs, benefits, and other impacts associated with those standards are described in the RIA associated with CMS–9989–F. This final rule builds upon CMS–9989–F by establishing a specific definition of EHB and AV, and detailing a timeline for issuers to obtain accreditation. Accordingly, the RIA associated with this final rule assesses only the costs and benefits of applying that specific definition and timeline (that is, adopting a benchmark-based approach to defining EHB and a calculator-based approach to computing AV). HHS provided quantitative estimates of the costs and benefits associated with the specific provisions of this regulation where possible, and supplemented those estimates with qualitative discussion. HHS and OMB reviewed the RIA to confirm that it addressed all critical components required by Executive Orders 12866 and 13563, including a description of regulatory alternatives that HHS considered.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to analyze options for regulatory relief of small businesses if a proposed rule has a significant impact on a substantial number of small entities. The Act generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit 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.'') HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

This final rule is necessary to implement standards related to the EHB, AV, cost-sharing limitations, and quality, as authorized by the Affordable Care Act. For purposes of the Regulatory Flexibility Analysis, we expect the following types of entities to be affected by this final rule: (1) Issuers; (2) employers; and (3) providers.

We believe that health insurers would be classified under the North American Industry Classification System (NAICS) Code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $7 million or less would be considered small entities for this NAICS code. Health issuers could possibly also be classified in NAICS Code 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $10 million or less.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis we determined that there were few, if any, insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for ''small'' business established by the SBA (currently $7 million in annual receipts for health insurers, based on North American Industry Classification System Code 524114).[63]

In the proposed rule, we noted that HHS used 2011 National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and small group markets. HHS used total Accident and Health (A&H) earned premiums as a proxy for annual receipts. Table IV.3 shows that HHS estimates that there were 35 small entities with less than $7 million in accident and health earned premiums offering individual or small group comprehensive major medical (CMM) coverage; however, this estimate may overstate the actual number of small health insurance issuers offering such coverage, since it does not include receipts from these companies' other lines of business.

HHS estimates that 83 percent of these small issuers are subsidiaries of larger carriers, and 71 percent also offer large group or other types of A&H coverage. On average, HHS estimates that individual and small group CMM coverage accounts for approximately 45 percent of total A&H earned premiums for these small issuers. HHS estimates that 75 percent of these small issuers only offer individual and small group CMM coverage in a single state. Additionally, HHS estimates that approximately a third (11) of these small issuers only offer individual market CMM coverage.

[63] ''Table of Size Standards Matched to North American Industry Classification System Codes,'' effective November 5, 2010, U.S. Small Business Administration, available at *http://www.sba.gov.*

TABLE IV.3—DESCRIPTION OF ISSUERS OFFERING INDIVIDUAL OR SMALL GROUP COMPREHENSIVE MAJOR MEDICAL (CMM) COVERAGE BY SIZE, 2011

Total earned premiums for accident and health coverage	Total issuers offering individual or small group market CMM coverage	Percent of issuers that are part of larger carriers	Average number of States in which individual or small group CMM coverage is offered	Percent of issuers only offering individual or small group CMM coverage in a single State	Individual & small group CMM premiums as a percent of total A&H premiums	Percent of issuers also offering large group CMM or other A&H coverage	Number of issuers only offering individual market CMM coverage
Less Than $7 Million	35	82.9	2.3	74.3	45.0	71.4	11
$7 million to $99 million	93	68.8	4.5	62.4	37.2	66.7	6
$100 million to $999 million	184	87.0	5.2	65.8	27.0	84.8	11
$1 billion or more	115	87.8	4.8	69.6	24.0	93.9	1
Total	427	82.9	4.7	66.7	24.5	82.2	29

Notes: (1) Issuers represents companies (for example, NAIC company codes). (2) Licensed Entities represents company/state combinations. (3) Total issuers excludes data for companies that are regulated by the California Department of Managed Health Care. (4) To be counted as offering coverage in a particular comprehensive major medical market, the issuer must have reported positive premiums, non-zero claims and had at least $1,000 in total premiums per life year for at least one state. (5) Small group is defined based on the current definition in the PHS Act.
Sources: ASPE analysis of 2011 NAIC Supplemental Health Care Exhibit data.

This rule finalizes standards related to EHB, AV, and accreditation of QHPs (specifically, by establishing a timeline for accreditation for QHPs seeking certification in Federally-facilitated Exchanges and recognition of accrediting entities). These standards may impose some additional costs on issuers offering coverage that is affected by these provisions. For example, as discussed earlier, issuers are likely to experience some administrative costs associated with reconfiguring existing non-grandfathered plans to meet EHB and AV metal level standards as defined in this final rule. However, these costs will vary depending on a number of factors, including the extent to which an issuer offers coverage in multiple states or is a subsidiary of a larger carrier, and the variation between these standards and current practice. Further, some of the changes that standardize coverage may reduce administrative costs.

As discussed in the regulatory impact analysis for the Establishment of Exchanges Final Rule, the cost of participating in an Exchange is an investment for QHP issuers, with benefits expected to accrue to QHP issuers because of access to new markets where consumers may receive tax credits to purchase insurance.

This final rule also establishes standards that will affect employers participating in the small group market, including those that choose to participate in a SHOP. As discussed in the Summary of Regulatory Impact Analysis for the Establishment of Exchanges Final Rule, the SHOP is limited by statute to employers with at least one but not more than 100 employees. For this reason, we expect that many affected employers would meet the SBA standard for small entities. However, the standards outlined in this proposed rule apply to issuers of small group market health insurance coverage, and not to any small employers that elect to purchase such coverage on behalf of their employees (that is, the final rule impacts what coverage is available to be purchased). We anticipate that the essential health benefits, coupled with the ability to compare plans based on metal level, will lead to greater transparency and reduce transaction costs for small employers.

HHS anticipates that the provisions in this proposed rule will have a positive effect on providers—particularly those offering services in areas where many individual market enrollees previously did not have coverage for these services, and those who serve a substantial share of the low-income population. HHS anticipates that small providers will also experience positive effects relating to the provisions of this proposed rule.

Therefore, the Secretary certifies that this final rule will not have a significant impact on a substantial number of small entities. We welcomed comments on the analysis described in this section and on HHS's conclusion.

VII. Unfunded Mandates

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 early 2013, that threshold level is approximately $139 million.

UMRA does not address the total cost of a final rule. Rather, it focuses on certain categories of cost, mainly those ''Federal mandate'' costs resulting from: (1) Imposing enforceable duties on state, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, state, local, or tribal governments under entitlement programs.

Because states are not required to set up an Exchange, and because grants are available for funding of the establishment of an Exchange by a state, we anticipate that this final rule would not impose costs above that threshold on state, local, or Tribal governments. In addition, because states largely already collect information on plan rates and benefits to license them, we believe that the burden on states is limited. However, because these costs have not been estimated, HHS sought comments on any additional burdens.

Under the final rule, issuers will provide coverage of certain benefits. While some issuers may not currently offer benefit packages that meet the standards outlined in the final rule, we anticipate that the administrative costs associated with compliance will fall below the threshold. We anticipate that such administrative costs will be concentrated in the initial year, with costs significantly tapering off during subsequent years.

The benchmark-based approach to defining EHB ensures that EHB will reflect the scope of services offered by a ''typical employer plan.'' Accordingly, we anticipate that many small group market plans meet or are close to meeting the coverage requirements for EHB and will not need to incur significant administrative costs to bring

currently available plans into compliance. Individual market plans are somewhat less likely to cover all statutorily required benefits and services as described in this final rule; however, many such plans are offered by issuers with diverse portfolios that may include small and large group products or other individual market products that do include the required services. Accordingly, we do not anticipate that the provisions related to the EHB package outlined in the final rule impose costs greater than $139 million on the private sector.

Consistent with policy embodied in UMRA, this final rule has been designed to be a low-burden alternative for state, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

VIII. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications.

States regulate health insurance coverage. States would continue to apply state laws regarding health insurance coverage. However, if any state law or requirement prevents the application of a federal standard, then that particular state law or requirement would be preempted. State requirements that are more stringent than the federal requirements would not be preempted by this proposed rule unless such requirements prevent the application of federal law. Accordingly, states have significant latitude to impose requirements with respect to health insurance coverage that are more consumer-protective than the Federal law.

In the view of HHS, this final rule does not impose substantial direct costs on state and local governments. However, we believe that this final rule has federalism implications due to direct effects on the distribution of power and responsibilities among the state and Federal governments relating to determining standards for health insurance coverage that is offered in the individual and small group markets. Each state would adhere to the federal standards outlined in this final rule for purposes of determining whether non-grandfathered individual and small group market health insurance coverage includes the EHB package, or have HHS enforce these policies.

HHS expects that the federalism implications, if any, are substantially mitigated for a number of reasons. First, the final rule affords discretion to states to select an EHB-benchmark plan. States also can choose to be responsible for evaluating the selected benchmark and making adjustments as needed, and for determining whether non-grandfathered individual and small group market health insurance coverage meets the standards outlined in this final rule. While this final rule establishes new federal standards for certain health insurance coverage, states will retain their traditional regulatory roles. Further, if a state elects not to substantially enforce the standards outlined in the final rule, the federal government will assume responsibility for these standards.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of the states, HHS has made efforts to consult with and work cooperatively with states as evidenced by continued communication through weekly calls and listening sessions.

HHS initiated weekly calls with key stakeholders from states in April 2010 as a way for HHS and states to have a regular means of communication about the Affordable Care Act. The audience for the call is ''State Government Implementers of the Affordable Care Act'' which often includes Governors' office staff, state Medicaid Directors' staff, Insurance Commissioners' staff, state high risk pool staff, Exchange grantees, health reform coordinators, and other state staff. National intergovernmental organizations are also invited to participate. Regular participants also include representatives from the following intergovernmental organizations:

- National Governors Association
- National Conference of State Legislatures
- National Association of Medicaid Directors
- National Association of Insurance Commissioners
- American Public Human Services Association
- The Council of State Governments
- National Academy for State Health Policy
- National Association of Counties

These calls, in addition to listening sessions specifically related to EHB, have helped HHS understand states' major questions about implementation of the Affordable Care Act. Ongoing communication with states allowed HHS to develop policy that addressed two central issues: Flexibility and state-required benefits. The benchmark approach allows states to select a benchmark option that offer benefit packages that reflect the needs of their populations and maintain state-required benefits that were enacted before December 31, 2011. This approach minimizes state burden while increasing access to quality health care.

List of Subjects

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance, Women, and Youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory Committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, Safety, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

Department of Health and Human Services

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 147, 155, and 156 as set forth below:

Subchapter B—Requirements Relating to Health Care Access

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. 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 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Section 147.150 is added to read as follows:

§ 147.150 Coverage of essential health benefits.

(a) *Requirement to cover the essential health benefits package.* A health insurance issuer offering health insurance coverage in the individual or small group market must ensure that such coverage includes the essential health benefits package as defined in section 1302(a) of the Affordable Care Act effective for plan or policy years beginning on or after January 1, 2014.

(b) *Cost-sharing under group health plans.* [Reserved.]

(c) *Child-only plans.* If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 1302(d)(1) of the Affordable Care Act, the issuer must offer coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 3. The authority citation for part 155 is revised to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1402, 1411, 1412, 1413, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 4. Section 155.170 is added to subpart B to read as follows:

§ 155.170 Additional required benefits.

(a) *Additional required benefits.* (1) A State may require a QHP to offer benefits in addition to the essential health benefits.

(2) A State-required benefit enacted on or before December 31, 2011 is not considered in addition to the essential health benefits.

(3) The Exchange shall identify which state-required benefits are in excess of EHB.

(b) *Payments.* The State must make payments to defray the cost of additional required benefits specified in paragraph (a) of this section to one of the following:

(1) To an enrollee, as defined in § 155.20 of this subchapter; or

(2) Directly to the QHP issuer on behalf of the individual described in paragraph (b)(1) of this section.

(c) *Cost of additional required benefits.* (1) Each QHP issuer in the State shall quantify cost attributable to each additional required benefit specified in paragraph (a) of this section.

(2) A QHP issuer's calculation shall be:

(i) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(ii) Conducted by a member of the American Academy of Actuaries; and

(iii) Reported to the Exchange.

■ 5. Revise § 155.1045 to read as follows:

§ 155.1045 Accreditation timeline.

(a) *Timeline.* The Exchange must establish a uniform period following certification of a QHP within which a QHP issuer that is not already accredited must become accredited as required by § 156.275 of this subchapter, except for multi-state plans. The U.S. Office of Personnel Management will establish the accreditation period for multi-state plans.

(b) *Federally-facilitated Exchange.* The accreditation timeline used in federally-facilitated Exchanges follows:

(1) During certification for an issuer's initial year of QHP certification (for example, in 2013 for the 2014 coverage year), a QHP issuer without existing commercial, Medicaid, or Exchange health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is applying to offer coverage must have scheduled or plan to schedule a review of QHP policies and procedures of the applying QHP issuer with a recognized accrediting entity.

(2) Prior to a QHP issuer's second year and third year of QHP certification (for example, in 2014 for the 2015 coverage year and 2015 for the 2016 coverage year), a QHP issuer must be accredited by a recognized accrediting entity on the policies and procedures that are applicable to their Exchange products, or a QHP issuer must have commercial or Medicaid health plan accreditation granted by a recognized accrediting entity for the same State in which the issuer is offering Exchange coverage and the administrative policies and procedures underlying that accreditation must be the same or similar to the administrative policies and procedures used in connection with the QHP.

(3) Prior to the QHP issuer's fourth year of QHP certification and in every subsequent year of certification (for example, in 2016 for the 2017 coverage year and forward), a QHP issuer must be accredited in accordance with § 156.275 of this subchapter.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 6. The authority citation for part 156 is revised to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, and 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, and 26 U.S.C. 36B).

■ 7. Section 156.20 is amended by adding new definitions for ''Actuarial value (AV),'' ''Base-benchmark plan,'' ''EHB-benchmark plan,'' ''Essential health benefits package or EHB package,'' and ''Percentage of the total allowed costs of benefits'' in alphabetical order to read as follows:

§ 156.20 Definitions.

Actuarial value (AV) means the percentage paid by a health plan of the percentage of the total allowed costs of benefits.

* * * * *

Base-benchmark plan means the plan that is selected by a State from the options described in § 156.100(a) of this subchapter, or a default benchmark plan, as described in § 156.100(c) of this subchapter, prior to any adjustments made pursuant to the benchmark standards described in § 156.110 of this subchapter.

* * * * *

EHB-benchmark plan means the standardized set of essential health benefits that must be met by a QHP, as defined in § 155.20 of this section, or other issuer as required by § 147.150 of this subchapter.

Essential health benefits package or EHB package means the scope of covered benefits and associated limits of a health plan offered by an issuer that provides at least the ten statutory categories of benefits, as described in § 156.110(a) of this subchapter; provides the benefits in the manner described in § 156.115 of this subchapter; limits cost sharing for such coverage as described in § 156.130; and subject to offering catastrophic plans as described in section 1302(e) of the Affordable Care Act, provides distinct levels of coverage as described in § 156.140 of this subchapter.

* * * * *

Percentage of the total allowed costs of benefits means the anticipated

covered medical spending for EHB coverage (as defined in § 156.110(a) of this subchapter) paid by a health plan for a standard population, computed in accordance with the plan's cost-sharing, divided by the total anticipated allowed charges for EHB coverage provided to a standard population, and expressed as a percentage.

* * * * *

■ 8. Subpart B is revised to read as follows:

Subpart B—Essential Health Benefits Package

Sec.

156.100 State selection of benchmark.
156.105 Determination of EHB for multi-state plans.
156.110 EHB-benchmark plan standards.
156.115 Provision of EHB.
156.122 Prescription drug benefits.
156.125 Prohibition on discrimination.
156.130 Cost-sharing requirements.
156.135 AV calculation for determining level of coverage.
156.140 Levels of coverage.
156.145 Determination of minimum value.
156.150 Application to stand-alone dental plans inside the Exchange.

Subpart B—Essential Health Benefits Package

§ 156.100 State selection of benchmark.

Each State may identify a single EHB-benchmark plan according to the selection criteria described below:

(a) *State selection of base-benchmark plan.* The options from which a base-benchmark plan may be selected by the State are the following:

(1) *Small group market health plan.* The largest health plan by enrollment in any of the three largest small group insurance products by enrollment, as defined in § 159.110 of this subpart, in the State's small group market as defined in § 155.20 of this subchapter.

(2) *State employee health benefit plan.* Any of the largest three employee health benefit plan options by enrollment offered and generally available to State employees in the State involved.

(3) *FEHBP plan.* Any of the largest three national Federal Employees Health Benefits Program (FEHBP) plan options by aggregate enrollment that is offered to all health-benefits-eligible federal employees under 5 USC 8903.

(4) *HMO.* The coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

(b) *EHB-benchmark selection standards.* In order to become an EHB-benchmark plan as defined in § 156.20 of this subchapter, a state-selected base-benchmark plan must meet the requirements for coverage of benefits and limits described in § 156.110 of this subpart; and

(c) *Default base-benchmark plan.* If a State does not make a selection using the process defined in § 156.100 of this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market. If Guam, the U.S. Virgin Islands, American Samoa, or the Northern Marianna Islands do not make a benchmark selection, the default base-benchmark plan will be the largest FEHBP plan by enrollment.

§ 156.105 Determination of EHB for multi-state plans.

A multi-state plan must meet benchmark standards set by the U.S. Office of Personnel Management.

§ 156.110 EHB-benchmark plan standards.

An EHB-benchmark plan must meet the following standards:

(a) *EHB coverage.* Provide coverage of at least the following categories of benefits:

(1) Ambulatory patient services.

(2) Emergency services.

(3) Hospitalization.

(4) Maternity and newborn care.

(5) Mental health and substance use disorder services, including behavioral health treatment.

(6) Prescription drugs.

(7) Rehabilitative and habilitative services and devices.

(8) Laboratory services.

(9) Preventive and wellness services and chronic disease management.

(10) Pediatric services, including oral and vision care.

(b) *Coverage in each benefit category.* A base-benchmark plan not providing any coverage in one or more of the categories described in paragraph (a) of this section, must be supplemented as follows:

(1) *General supplementation methodology.* A base-benchmark plan that does not include items or services within one or more of the categories described in paragraph (a) of this section must be supplemented by the addition of the entire category of such benefits offered under any other benchmark plan option described in § 156.100(a) of this subpart unless otherwise described in this subsection.

(2) *Supplementing pediatric oral services.* A base-benchmark plan lacking the category of pediatric oral services must be supplemented by the addition of the entire category of pediatric oral benefits from one of the following:

(i) The FEDVIP dental plan with the largest national enrollment that is described in and offered to federal employees under 5 U.S.C. 8952; or

(ii) The benefits available under that State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(3) *Supplementing pediatric vision services.* A base-benchmark plan lacking the category of pediatric vision services must be supplemented by the addition of the entire category of pediatric vision benefits from one of the following:

(i) The FEDVIP vision plan with the largest national enrollment that is offered to federal employees under 5 USC 8982; or

(ii) The benefits available under the State's separate CHIP plan, if a separate CHIP plan exists, to the eligibility group with the highest enrollment.

(c) *Supplementing the default base-benchmark plan.* A default base-benchmark plan as defined in § 156.100(c) of this subpart that lacks any categories of essential health benefits will be supplemented by HHS in the following order, to the extent that any of the plans offer benefits in the missing EHB category:

(1) The largest plan by enrollment in the second largest product by enrollment in the State's small group market, as defined in § 155.20 of this subchapter (except for pediatric oral and vision benefits);

(2) The largest plan by enrollment in the third largest product by enrollment in the State's small group market, as defined in § 155.20 of this subchapter (except for pediatric oral and vision benefits);

(3) The largest national FEHBP plan by enrollment across States that is offered to federal employees under 5 USC 8903 (except for pediatric oral and vision benefits);

(4) The plan described in paragraph (b)(2)(i) of this section with respect to pediatric oral care benefits;

(5) The plan described in paragraph (b)(3)(i) of this section with respect to pediatric vision care benefits; and

(6) A habilitative benefit determined by the plan as described in § 156.115(a)(5) of this subpart or by the State as described in paragraph (f) of this section.

(d) *Non-discrimination.* Not include discriminatory benefit designs that contravene the non-discrimination standards defined in § 156.125 of this subpart.

(e) *Balance.* Ensure an appropriate balance among the EHB categories to ensure that benefits are not unduly weighted toward any category.

(f) *Determining habilitative services.* If the base-benchmark plan does not include coverage for habilitative

services, the State may determine which services are included in that category.

§ 156.115 Provision of EHB.

(a) Provision of EHB means that a health plan provides benefits that—

(1) Are substantially equal to the EHB-benchmark plan including:

(i) Covered benefits;

(ii) Limitations on coverage including coverage of benefit amount, duration, and scope; and

(iii) Prescription drug benefits that meet the requirements of § 156.122 of this subpart;

(2) With the exception of the EHB category of coverage for pediatric services, do not exclude an enrollee from coverage in an EHB category.

(3) With respect to the mental health and substance use disorder services, including behavioral health treatment services, required under § 156.110(a)(5) of this subpart, comply with the requirements of § 146.136 of this subchapter.

(4) Include preventive health services described in § 147.130 of this subchapter.

(5) If the EHB-benchmark plan does not include coverage for habilitative services, as described in § 156.110(f) of this subpart, include habilitative services in a manner that meets one of the following—

(i) Provides parity by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services; or

(ii) Is determined by the issuer and reported to HHS.

(b) Unless prohibited by applicable State requirements, an issuer of a plan offering EHB may substitute benefits if the issuer meets the following conditions—

(1) Substitutes a benefit that:

(i) Is actuarially equivalent to the benefit that is being replaced as determined in paragraph (b)(2) of this section;

(ii) Is made only within the same essential health benefit category; and

(iii) Is not a prescription drug benefit.

(2) Submits evidence of actuarial equivalence that is:

(i) Certified by a member of the American Academy of Actuaries;

(ii) Based on an analysis performed in accordance with generally accepted actuarial principles and methodologies;

(iii) Based on a standardized plan population; and

(iv) Determined regardless of cost-sharing.

(c) A health plan does not fail to provide EHB solely because it does not offer the services described in § 156.280(d) of this subchapter.

(d) An issuer of a plan offering EHB may not include routine non-pediatric dental services, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB.

§ 156.122 Prescription drug benefits.

(a) A health plan does not provide essential health benefits unless it:

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan; and

(2) Submits its drug list to the Exchange, the State, or OPM.

(b) A health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs approved by the Food and Drug Administration as a service described in § 156.280(d) of this subchapter.

(c) A health plan providing essential health benefits must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the health plan.

§ 156.125 Prohibition on discrimination.

(a) An issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.

(b) An issuer providing EHB must comply with the requirements of § 156.200(e) of this subchapter; and

(c) Nothing in this section shall be construed to prevent an issuer from appropriately utilizing reasonable medical management techniques.

§ 156.130 Cost-sharing requirements.

(a) *Annual limitation on cost sharing.* (1) For a plan year beginning in the calendar year 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the annual dollar limit as described in section 223(c)(2)(A)(ii)(I) of the Internal Revenue Code of 1986 as amended, for self-only coverage that that is in effect for 2014; or

(ii) For other than self-only coverage—the annual dollar limit in section 223(c)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 as amended, for non-self-only coverage that is in effect for 2014.

(2) For a plan year beginning in a calendar year after 2014, cost sharing may not exceed the following:

(i) For self-only coverage—the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage, as defined in paragraph (e) of this section.

(ii) For other than self-only coverage—twice the dollar limit for self-only coverage described in paragraph (a)(2)(i) of this section.

(b) *Annual limitation on deductibles for plans in the small group market.* (1) For a plan year beginning in calendar year 2014, the annual deductible for a health plan in the small group market may not exceed the following:

(i) For self-only coverage—$2,000; or

(ii) For coverage other than self-only—$4,000.

(2) For a plan year beginning in a calendar year after 2014, the annual deductible for a health plan in the small group market may not exceed the following:

(i) For self-only coverage—the annual limitation on deductibles for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage as defined in paragraph (e) of this section; and

(ii) For other than self-only coverage—twice the annual deductible limit for self-only coverage described in paragraph (b)(2)(i) of this section.

(3) A health plan's annual deductible may exceed the annual deductible limit if that plan may not reasonably reach the actuarial value of a given level of coverage as defined in § 156.140 of this subpart without exceeding the annual deductible limit.

(c) *Special rule for network plans.* In the case of a plan using a network of providers, cost-sharing paid by, or on behalf of, an enrollee for benefits provided outside of such network shall not count towards the annual limitation on cost-sharing (as defined in paragraph (a) of this section), or the annual limitation on deductibles (as defined in paragraph (b) of this section).

(d) *Increase annual dollar limits in multiples of 50.* For a plan year beginning in a calendar year after 2014, any increase in the annual dollar limits described in paragraphs (a) and (b) of this section that do not result in a multiple of 50 dollars must be rounded to the next lowest multiple of 50 dollars.

(e) *Premium adjustment percentage.* The premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. HHS will publish the annual premium adjustment percentage in the

annual HHS notice of benefits and payment parameters.

(f) *Coordination with preventive limits.* Nothing in this subpart is in derogation of the requirements of § 147.130 of this subchapter.

(g) *Coverage of emergency department services.* Emergency department services must be provided as follows:

(1) Without imposing any requirement under the plan for prior authorization of services or any limitation on coverage where the provider of services is out of network that is more restrictive than the requirements or limitations that apply to emergency department services received in network; and

(2) If such services are provided out-of-network, cost-sharing must be limited as provided in § 147.138(b)(3) of this subchapter.

§ 156.135 AV calculation for determining level of coverage.

(a) *Calculation of AV.* Subject to paragraph (b) of this section, to calculate the AV of a health plan, the issuer must use the AV Calculator developed and made available by HHS.

(b) *Exception to the use of the AV Calculator.* If a health plan's design is not compatible with the AV Calculator, the issuer must meet the following:

(1) Submit the actuarial certification from an actuary, who is a member of the American Academy of Actuaries, on the chosen methodology identified in paragraphs (b)(2) and (b)(3) of this section:

(2) Calculate the plan's AV by:

(i) Estimating a fit of its plan design into the parameters of the AV Calculator; and

(ii) Having an actuary, who is a member of the American Academy of Actuaries, certify that the plan design was fit appropriately in accordance with generally accepted actuarial principles and methodologies; or

(3) Use the AV Calculator to determine the AV for the plan provisions that fit within the calculator parameters and have an actuary, who is a member of the American Academy of Actuaries calculate and certify, in accordance with generally accepted actuarial principles and methodologies, appropriate adjustments to the AV identified by the calculator, for plan design features that deviate substantially from the parameters of the AV Calculator.

(4) The calculation methods described in paragraphs (b)(2) and (3) of this section may include only in-network cost-sharing, including multi-tier networks.

(c) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For plans other than those in the individual market that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

(d) *Use of state-specific standard population for the calculation of AV.* Beginning in 2015, if submitted by the State and approved by HHS, a state-specific data set will be used as the standard population to calculate AV in accordance with paragraph (a) of this section. The data set may be approved by HHS if it is submitted in accordance with paragraph (e) of this section and:

(1) Supports the calculation of AVs for the full range of health plans available in the market;

(2) Is derived from a non-elderly population and estimates those likely to be covered by private health plans on or after January 1, 2014;

(3) Is large enough that: (i) The demographic and spending patterns are stable over time; and (ii) Includes a substantial majority of the State's insured population, subject to the requirement in paragraph (d)(2) of this section;

(4) Is a statistically reliable and stable basis for area-specific calculations; and (5) Contains claims data on health care services typically offered in the then-current market.

(e) *Submission of state-specific data.* AV will be calculated using the default standard population described in paragraph (f) of this section, unless a data set in a format specified by HHS that can support the use of the AV Calculator as described in paragraph (a) of this section is submitted by a State and approved by HHS consistent with paragraph (d) of this section by a date specified by HHS.

(f) *Default standard population.* The default standard population for AV calculation will be developed and summary statistics, such as in continuance tables, will be provided by HHS in a format that supports the calculation of AV as described in paragraph (a) of this section.

§ 156.140 Levels of coverage.

(a) *General requirement for levels of coverage.* AV, calculated as described in § 156.135 of this subpart, and within a de minimis variation as defined in paragraph (c) of this section, determines whether a health plan offers a bronze, silver, gold, or platinum level of coverage.

(b) *The levels of coverage* are:

(1) *A bronze health plan* is a health plan that has an AV of 60 percent.

(2) *A silver health plan* is a health plan that has an AV of 70 percent.

(3) *A gold health plan* is a health plan that has an AV of 80 percent.

(4) *A platinum health plan* is a health plan that has as an AV of 90 percent.

(c) *De minimis variation.* The allowable variation in the AV of a health plan that does not result in a material difference in the true dollar value of the health plan is +/− 2 percentage points.

§ 156.145 Determination of minimum value.

(a) *Acceptable methods for determining MV.* An employer-sponsored plan provides minimum value (MV) if the percentage of the total allowed costs of benefits provided under the plan is no less than 60 percent. An employer-sponsored plan may use one of the following methods to determine whether the percentage of the total allowed costs of benefits provided under the plan is not less than 60 percent.

(1) The MV Calculator to be made available by HHS and the Internal Revenue Service. The result derived from the calculator may be modified under the rules in paragraph (b) of this section.

(2) Any safe harbor established by HHS and the Internal Revenue Service.

(3) A group health plan may seek certification by an actuary to determine MV if the plan contains non-standard features that are not suitable for either of the methods described in paragraphs (a)(1) or (2) of this section. The determination of MV must be made by a member of the American Academy of Actuaries, based on an analysis performed in accordance with generally accepted actuarial principles and methodologies.

(4) Any plan in the small group market that meets any of the levels of coverage, as described in § 156.140 of this subpart, satisfies minimum value.

(b) *Benefits that may be counted towards the determination of MV.* (1) In the event that a group health plan uses the MV Calculator and offers an EHB

outside of the parameters of the MV Calculator, the plan may seek an actuary, who is a member of the American Academy of Actuaries, to determine the value of that benefit and adjust the result derived from the MV Calculator to reflect that value.

(2) For the purposes of applying the options described in paragraph (a) of this section in determining MV, a group health plan will be permitted to take into account all benefits provided by the plan that are included in any one of the EHB-benchmarks.

(c) *Standard population.* The standard population for MV determinations described in paragraph (a) of this section is the standard population developed by HHS for such use and described through summary statistics issued by HHS. The standard population for MV must reflect the population covered by self-insured group health plans.

(d) *Employer contributions to health savings accounts and amounts made available under certain health reimbursement arrangements.* For employer-sponsored self-insured group health plans and insured group health plans that at the time of purchase are offered in conjunction with an HSA or with integrated HRAs that may be used only for cost-sharing, annual employer contributions to HSAs and amounts newly made available under such HRAs for the current year are:

(1) Counted towards the total anticipated medical spending of the standard population that is paid by the health plan; and

(2) Adjusted to reflect the expected spending for health care costs in a benefit year so that:

(i) Any current year HSA contributions are accounted for; and

(ii) The amounts newly made available under such integrated HRAs for the current year are accounted for.

§ 156.150 Application to stand-alone dental plans inside the Exchange.

(a) *Annual limitation on cost-sharing.* A stand-alone dental plan covering the pediatric dental EHB under § 155.1065 of this subchapter must demonstrate that it has a reasonable annual limitation on cost-sharing as determined by the Exchange. Such annual limit is calculated without regard to EHBs provided by the QHP and without regard to out-of-network services.

(b) *Calculation of AV.* A stand-alone dental plan:

(1) May not use the AV calculator in § 156.135 of this subpart;

(2) Must demonstrate that the stand-alone dental plan offers the pediatric dental essential health benefit at either:

(i) A low level of coverage with an AV of 70 percent; or

(ii) A high level of coverage with an AV of 85 percent; and

(iii) Within a de minimis variation of +/− 2 percentage points of the level of coverage in paragraphs (b)(2)(i) or (ii) of this section.

(3) The level of coverage as defined in paragraph (b)(2) of this section must be certified by a member of the American Academy of Actuaries using generally accepted actuarial principles.

■ 9. Section 156.275 is amended by revising paragraphs (c)(1), (c)(4) introductory text, and (c)(4)(i) to read as follows:

§ 156.275 Accreditation of QHP issuers.

* * * * *

(c) * * *

(1) *Recognition of accrediting entity by HHS*—(i) *Application.* An accrediting entity may apply to HHS for recognition. An application must include the documentation described in paragraph (c)(4) of this section and demonstrate, in a concise and organized fashion how the accrediting entity meets the requirements of paragraphs (c)(2) and (3) of this section.

(ii) *Proposed notice.* Within 60 days of receiving a complete application as described in paragraph (c)(1)(i) of this section, HHS will publish a notice in the **Federal Register** identifying the accrediting entity making the request, summarizing HHS's analysis of whether the accrediting entity meets the criteria described in paragraphs (c)(2) and (3) of this section, and providing no less than a 30-day public comment period about whether HHS should recognize the accrediting entity.

(iii) *Final notice.* After the close of the comment period described in paragraph (c)(1)(ii) of this section, HHS will notify the public in the **Federal Register** of the names of the accrediting entities recognized and those not recognized as accrediting entities by the Secretary of HHS to provide accreditation of QHPs.

(iv) *Other recognition.* Upon completion of conditions listed in paragraphs (c)(2), (3), and (4) of this section, HHS recognized, and provided notice to the public in the **Federal Register**, the National Committee for Quality Assurance (NCQA) and URAC as accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirement of this section.

* * * * *

(4) *Documentation.* An accrediting entity applying to be recognized under the process described in (c)(1) of this section must provide the following documentation:

(i) To be recognized, an accrediting entity must provide current accreditation standards and requirements, processes and measure specifications for performance measures to demonstrate that it meets the conditions described in paragraphs (c)(2) and (3) of this section to HHS.

* * * * *

Dated: February 12, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 14, 2013.

Kathleen Sebelius,

Secretary.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendix A: List of Essential Health Benefits Benchmarks

The purpose of this appendix is to list the EHB-benchmark plans for the 50 States, the U.S. territories (Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands) and the District of Columbia. As described in § 156.100 of this regulation, each State may select a benchmark plan to serve as the standard for plans required to offer EHB in the State.[64] HHS has also stated that the default base-benchmark plan for States, Puerto Rico and the District of Columbia that do not exercise the option to select a benchmark health plan would be the largest plan by enrollment in the largest product by enrollment in the State's small group market. The default base-benchmark plan for the territories other than Puerto Rico is the largest FEHBP plan by enrollment. As described in § 156.110, an EHB-benchmark plan must offer coverage in each of the 10 statutory benefit categories. In the summary table that follows, we list the EHB-benchmark plans. Additional information on the specific benefits, limits, and prescription drug categories and classes covered by the EHB-benchmark plans, and state-required benefits, is provided on the Center for Consumer Information and Insurance Oversight (CCIIO) Web site (*http://cciio.cms.gov/resources/data/ehb.html*).

[64] Non-grandfathered plans in the individual and small group markets both inside and outside of the Exchanges along with certain other types of plans must cover EHBs beginning in 2014. Self-insured group health plans, health insurance coverage offered in the large group market, and grandfathered health plans are not required to cover the essential health benefits.

State	Plan type	Issuer and plan name	Supplemented categories	Supplementary plan type	Habilitative services
Alabama	Largest small group product.	Blue Cross Blue Shield of Alabama PPO 320 Plan.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Alaska	Largest small group product.	Premera Blue Cross Blue Shield of Alaska Heritage Select Envoy PPO.	Mental health and substance use disorder services, including behavioral health treatment. Pediatric oral Pediatric vision	Largest FEHBP. O='xl'≤ FEDVIP.. FEDVIP.	Yes.
American Samoa	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Arizona	Largest State employee plan.	Arizona Benefit Options EPO Plan, administered by United HealthCare.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
Arkansas	Plan from third largest small group product.	HMO Partners, Inc. Open Access POS, 13262 AR001.	Mental health and substance use disorder services, including behavioral health treatment. Pediatric oral Pediatric vision	2nd Largest FEHBP. CHIP. CHIP.	No.
California	Plan from largest small group product.	Kaiser Foundation Health Plan, Inc. Small Group HMO 30 ID 40513CA035.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
Colorado	Plan from largest small group product.	Kaiser Foundation Health Plan of Colorado Ded HMO 1200D.	Pediatric oral	CHIP	No.
Connecticut	Largest State non-Medicaid HMO.	ConnectiCare HMO	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Delaware	Plan from second largest small group product.	Highmark Blue Cross Blue Shield Delaware Simply Blue EPO 100 500.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
District of Columbia	Plan from largest small group product.	Group Hospitalization and Medical Services, Inc. BluePreferred PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Florida	Plan from largest small group product.	Blue Cross Blue Shield of Florida, Inc. BlueOptions PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
Georgia	Plan from largest small group product.	Blue Cross Blue Shield of Georgia HMO Urgent Care 60 Copay.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Guam	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Hawaii	Plan from largest small group product.	Hawaii Medical Service Association Preferred Provider Plan 2010.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Idaho	Plan from largest small group product.	Blue Cross of Idaho Health Service, Inc. Preferred Blue PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Illinois	Plan from largest small group product.	Blue Cross and Blue Shield of Illinois BlueAdvantage PPO.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
Indiana	Plan from largest small group product.	Anthem Blue Cross and Blue Shield of Indiana Blue 5 Blue Access PPO Medical Option 6 Rx Option G.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Iowa	Plan from largest small group product.	Wellmark Inc. Alliance Select Copayment Plus PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Kansas	Plan from largest small group product.	Blue Cross and Blue Shield of Kansas Comprehensive Major Medical Blue Choice PPO GF 500 deductible with Blue Rx card.	Pediatric oral Pediatric vision	CHIP CHIP.	No.
Kentucky	Plan from largest small group product.	Anthem Health Plans of Kentucky, Inc. PPO.	Pediatric oral Pediatric vision	CHIP CHIP.	Yes.
Louisiana	Plan from largest small group product.	Blue Cross and Blue Shield of Louisiana GroupCare PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.

State	Plan type	Issuer and plan name	Supplemented categories	Supplementary plan type	Habilitative services
Maine	Plan from largest small group product.	Anthem Health Plans of Maine Blue Choice 20 PPO with RX 10 30 50 50.	Pediatric oral	FEDVIP	Yes.
Maryland	Plan from largest small group product.	BlueChoice 20 with RX 10 30 50 50.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
Massachusetts	Plan from largest small group product.	Blue Cross Blue Shield of Massachusetts, Inc. HMO Blue 2000 Deductible.	Pediatric oral	CHIP	Yes.
Michigan	Largest State non-Medicaid HMO.	Priority Health PriorityHMO 100 Percent Hospital Services Plan.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Minnesota	Plan from largest small group product.	HealthPartners 500 25 Open Access PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Mississippi	Plan from largest small group product.	Blue Cross and Blue Shield of Mississippi Network Blue PPO.	Pediatric oral Pediatric vision	CHIP CHIP.	Yes.
Missouri	Plan from largest small group product.	Healthy Alliance Life Insurance Co. (Anthem BCBS) Blue 5 Blue Access PPO Medical Option 4 Rx Option D.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Montana	Plan from largest small group product.	Blue Cross and Blue Shield of Montana Blue Dimensions PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Nebraska	Plan from largest small group product.	Blue Cross and Blue Shield of Nebraska BluePride PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Nevada	Plan from largest small group product.	HPN POS Group 1 c XV 500 HCR.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
New Hampshire	Plan from second largest small group product.	Matthew Thornton Health Plan (Anthem BCBS) HMO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
New Jersey	Plan from largest small group product.	Horizon HMO Access HSA Compatible.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
New Mexico	Plan from largest small group product.	Lovelace Insurance Company Classic PPO.	Pediatric oral Pediatric vision	CHIP CHIP.	Yes.
New York	Plan from largest small group product.	Oxford Health Insurance, Inc. Oxford EPO.	Pediatric oral Pediatric vision	CHIP CHIP.	No.
North Carolina	Plan from largest small group product.	Blue Cross and Blue Shield of North Carolina Blue Options PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
North Dakota	Largest State non-Medicaid HMO.	Sanford Health Plan HMO	Pediatric oral Pediatric vision	CHIP CHIP.	No.
Northern Mariana Islands	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Ohio	Plan from largest small group product.	Community Insurance Company (Anthem BCBS) Blue 6 Blue Access PPO Medical Option D4 Rx Option G.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
Oklahoma	Plan from largest small group product.	Blue Cross and Blue Shield of Oklahoma BlueOptions PPO RYB05.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
Oregon	Plan from third largest small group product.	PacificSource Health Plans PPO Preferred CoDeduct Value 3000 35 70.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Pennsylvania	Plan from largest small group product.	Aetna Health, Inc. PA POS Cost Sharing 34 1500 Ded.	Pediatric oral	FEDVIP	No.
Puerto Rico	Plan from largest small group product.	Triple-S Salud, Inc. Óptimo Plus (Plan de Salud PG–OP 2008).	Pediatric vision	FEDVIP	No.
Rhode Island	Plan from largest small group product.	Blue Cross and Blue Shield of Rhode Island Vantage Blue PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
South Carolina	Plan from largest small group product.	Blue Cross Blue Shield of South Carolina Business Blue Complete PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
South Dakota	Plan from largest small group product.	Wellmark of South Dakota Blue Select PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Tennessee	Plan from largest small group product.	Blue Cross Blue Shield of Tennessee PPO.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.

State	Plan type	Issuer and plan name	Supplemented categories	Supplementary plan type	Habilitative services
Texas	Plan from largest small group product.	Blue Cross Blue Shield of Texas BestChoice PPO RS26.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Utah	Plan from third largest State employee plan.	Public Employee's Health Program Utah Basic Plus.	None	None	Yes.
Vermont	Plan from largest small group product.	The Vermont Health Plan, LLC, CDHP–HMO.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Virginia	Plan from largest small group product.	Anthem Health Plans of VA PPO KeyCare 30 with KC30 Rx plan 10 30 50 OR 20.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	Yes.
Virgin Islands	Largest National FEHBP	Blue Cross Blue Shield Standard Option PPO.	Pediatric vision	FEDVIP	Yes.
Washington	Plan from largest small group product.	Regence BlueShield non-grandfathered small group product.	Pediatric oral Pediatric vision	CHIP FEDVIP.	Yes.
West Virginia	Plan from largest small group product.	Highmark Blue Cross Blue Shield West Virginia Super Blue PPO Plus 2000 1000 Ded.	Pediatric oral Pediatric vision	CHIP FEDVIP.	No.
Wisconsin	Plan from largest small group product.	UnitedHealthcare Insurance Company Choice Plus Definity HSA Plan A92NS.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.
Wyoming	Plan from largest small group product.	Blue Cross Blue Shield of Wyoming Blue Choice Business 1000 80 20.	Pediatric oral Pediatric vision	FEDVIP FEDVIP.	No.

Appendix B: Largest FEDVIP Dental and Vision Plan Options, as of March 31, 2012

Section 156.110(b)(2)–(3) directs States to supplement base-benchmark plans that lack pediatric oral or vision services with benefits drawn from either the Federal Employees Dental and Vision Program (FEDVIP) or a State's separate CHIP program. Specifically, States may select benefits from either: (1) The FEDVIP dental or vision plans with the largest national enrollments, or (2) the State's separate CHIP program's dental or vision benefits, where they exist, which offer benefits to the eligibility group with the highest enrollment. To assist States with this process, we collected information about the benefits provided in the FEDVIP dental and vision plans with the highest national enrollments, as issued by MetLife and FED Blue, respectively. Below, we provide a chart with a summary of the benefits offered by these plans.

LARGEST FEDVIP DENTAL AND VISION PLAN OPTIONS, AS OF MARCH 31, 2012 *

Issuer name	Plan name	Additional information
MetLife (dental)	MetLife Federal Dental Plan—High	2012 Plan Benefit Brochure: *http://www.opm.gov/insure/health/planinfo/2012/brochures/MetLife.pdf*
BCBS Association (vision)	FEP BlueVision—High	2012 Plan Benefit Brochure: *http://www.opm.gov/insure/health/planinfo/2012/brochures/FEPBlueVi.pdf*

Source: U.S. Office of Personnel Management.
**Please note that this information will be updated with the latest data when released.*

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Part III

Department of Justice

Antitrust Division

United States v. Apple, Inc., Hachette Book Group, Inc., Harpercollins Publishers L.L.C., Verlagsgruppe Georg Von Holtzbrinck GMBH, Holtzbrinck Publishers, LLC d/b/a Macmillan, The Penguin Group, A Division of Pearson PLC, Penguin Group (USA), Inc., and Simon & Schuster, Inc.; Proposed Final Judgment and Competitive Impact Statement; Notice

DEPARTMENT OF JUSTICE

Antitrust Division

United States v. Apple, Inc., Hachette Book Group, Inc., Harpercollins Publishers L.L.C., Verlagsgruppe Georg Von Holtzbrinck GMBH, Holtzbrinck Publishers, LLC d/b/a Macmillan, The Penguin Group, A Division of Pearson PLC, Penguin Group (USA), Inc., and Simon & Schuster, Inc.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Southern District of New York in *United States of America* v. *Apple, Inc. et al.,* Civil Action No. 12–CV–2826. On April 11, 2012, the United States filed a Complaint alleging that the defendants agreed to raise the retail price of e-books, in violation of Section 1 of the Sherman Act, 15 U.S.C. 1. On February 8, 2013, the United States filed a proposed Final Judgment as to defendants Verlagsgruppe Georg von Holtzbrinck GmbH and Holtzbrinck Publishers, LLC d/b/a Macmillan (collectively, ''Macmillan'') to return pricing discretion to e-book retailers and comply with other obligations designed to end the anticompetitive effects of the conspiracy. Previously, on September 6, 2012, a Final Judgment as to defendants Hachette Book Group, Inc., HarperCollins Publishers L.L.C., and Simon & Schuster, Inc. was entered by the United States District Court for the Southern District of New York. On December 18, 2012, the United States filed a proposed Final Judgment as to defendants Penguin Group (USA), Inc. and The Penguin Group, a division of Pearson plc; that proposed Final Judgment is currently subject to a public comment period that expires on March 5, 2013.

Copies of the Complaint, proposed Final Judgment as to Macmillan, and Competitive Impact Statement are available for inspection at the Department of Justice, Antitrust Division, Antitrust Documents Group, 450 Fifth Street NW., DC 20530 Suite 1010 (telephone: 202–514–2481), on the Department of Justice's Web site at *http://www.justice.gov/atr*, and at the Office of the Clerk of the United States District Court for the Southern District of New York. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment on the proposed Final Judgment as to Macmillan is invited within 60 days of the date of this notice. Such comments will be filed with the Court and will either be published in the **Federal Register** or, with the permission of the Court, be posted electronically on the Department of Justice's Web site. Comments should be directed to John R. Read, Chief, Litigation III Section, Antitrust Division, Department of Justice, 450 Fifth Street NW., Suite 4000, Washington, DC 20530 (telephone: 202–307–0468).

Patricia A. Brink,

Director of Civil Enforcement.

United States District Court for the Southern District of New York

United States of America, Plaintiff, v. *Apple, Inc., Hachette Book Group, Inc., Harpercollins Publishers L.L.C., Verlagsgruppe Georg Von Holtzbrinck Gmbh, Holtzbrinck Publishers, LLC D/B/A Macmillan, The Penguin Group, A Division of Pearson Plc, Penguin Group (USA), Inc.*, and *Simon & Schuster, Inc.,* Defendants.

Civil Action No. 12–CV–2826.

Complaint

The United States of America, acting under the direction of the Attorney General of the United States, brings this civil antitrust action against Defendants Apple, Inc. (''Apple''); Hachette Book Group, Inc. (''Hachette''); HarperCollins Publishers L.L.C. (''HarperCollins''); Verlagsgruppe Georg von Holtzbrinck GmbH and Holtzbrinck Publishers, LLC d/b/a Macmillan (collectively, ''Macmillan''); The Penguin Group, a division of Pearson plc and Penguin Group (USA), Inc. (collectively, ''Penguin''); and Simon & Schuster, Inc. (''Simon & Schuster''; collectively with Hachette, HarperCollins, Macmillan, and Penguin, ''Publisher Defendants'') to obtain equitable relief to prevent and remedy violations of Section 1 of the Sherman Act, 15 U.S.C. 1.

Plaintiff alleges:

I. Introduction

1. Technology has brought revolutionary change to the business of publishing and selling books, including the dramatic explosion in sales of ''e-books''—that is, books sold to consumers in electronic form and read on a variety of electronic devices, including dedicated e-readers (such as the Kindle or the Nook), multipurpose tablets, smartphones and personal computers. Consumers reap a variety of benefits from e-books, including 24-hour access to product with near-instant delivery, easier portability and storage, and adjustable font size. E-books also are considerably cheaper to produce and distribute than physical (or ''print'') books.

2. E-book sales have been increasing rapidly ever since Amazon released its first Kindle device in November of 2007. In developing and then mass marketing its Kindle e-reader and associated e-book content, Amazon substantially increased the retail market for e-books. One of Amazon's most successful marketing strategies was to lower substantially the price of newly released and bestselling e-books to $9.99.

3. Publishers saw the rise in e-books, and particularly Amazon's price discounting, as a substantial challenge to their traditional business model. The Publisher Defendants feared that lower retail prices for e-books might lead eventually to lower wholesale prices for e-books, lower prices for print books, or other consequences the publishers hoped to avoid. Each Publisher Defendant desired higher retail e-book prices across the industry before ''$9.99'' became an entrenched consumer expectation. By the end of 2009, however, the Publisher Defendants had concluded that unilateral efforts to move Amazon away from its practice of offering low retail prices would not work, and they thereafter conspired to raise retail e-book prices and to otherwise limit competition in the sale of e-books. To effectuate their conspiracy, the Publisher Defendants teamed up with Defendant Apple, which shared the same goal of restraining retail price competition in the sale of e-books.

4. The Defendants' conspiracy to limit e-book price competition came together as the Publisher Defendants were jointly devising schemes to limit Amazon's ability to discount e-books and Defendant Apple was preparing to launch its electronic tablet, the iPad, and considering whether it should sell e-books that could be read on the new device. Apple had long believed it would be able to ''trounce Amazon by opening up [its] own ebook store,'' but the intense price competition that prevailed among e-book retailers in late 2009 had driven the retail price of popular e-books to $9.99 and had reduced retailer margins on e-books to levels that Apple found unattractive. As a result of discussions with the Publisher Defendants, Apple learned that the Publisher Defendants shared a common objective with Apple to limit e-book retail price competition, and that the Publisher Defendants also desired to have popular e-book retail prices stabilize at levels significantly higher

than $9.99. Together, Apple and the Publisher Defendants reached an agreement whereby retail price competition would cease (which all the conspirators desired), retail e-book prices would increase significantly (which the Publisher Defendants desired), and Apple would be guaranteed a 30 percent ''commission'' on each e-book it sold (which Apple desired).

5. To accomplish the goal of raising e-book prices and otherwise limiting retail competition for e-books, Apple and the Publisher Defendants jointly agreed to alter the business model governing the relationship between publishers and retailers. Prior to the conspiracy, both print books and e-books were sold under the longstanding ''wholesale model.'' Under this model, publishers sold books to retailers, and retailers, as the owners of the books, had the freedom to establish retail prices. Defendants were determined to end the robust retail price competition in e-books that prevailed, to the benefit of consumers, under the wholesale model. They therefore agreed jointly to replace the wholesale model for selling e-books with an ''agency model.'' Under the agency model, publishers would take control of retail pricing by appointing retailers as ''agents'' who would have no power to alter the retail prices set by the publishers. As a result, the publishers could end price competition among retailers and raise the prices consumers pay for e-books through the adoption of identical pricing tiers. This change in business model would not have occurred without the conspiracy among the Defendants.

6. Apple facilitated the Publisher Defendants' collective effort to end retail price competition by coordinating their transition to an agency model across all retailers. Apple clearly understood that its participation in this scheme would result in higher prices to consumers. As Apple CEO Steve Jobs described his company's strategy for negotiating with the Publisher Defendants, ''We'll go to [an] agency model, where you set the price, and we get our 30%, and yes, the customer pays a little more, but that's what you want anyway.'' Apple was perfectly willing to help the Publisher Defendants obtain their objective of higher prices for consumers by ending Amazon's ''$9.99'' price program as long as Apple was guaranteed its 30 percent margin and could avoid retail price competition from Amazon.

7. The plan—what Apple proudly described as an ''aikido move''—worked. Over three days in January 2010, each Publisher Defendant entered into a functionally identical agency contract with Apple that would go into effect simultaneously in April 2010 and ''chang[e] the industry permanently.'' These ''Apple Agency Agreements'' conferred on the Publisher Defendants the power to set Apple's retail prices for e-books, while granting Apple the assurance that the Publisher Defendants would raise retail e-book prices at all other e-book outlets, too. Instead of $9.99, electronic versions of bestsellers and newly released titles would be priced according to a set of price tiers contained in each of the Apple Agency Agreements that determined de facto retail e-book prices as a function of the title's hardcover list price. All bestselling and newly released titles bearing a hardcover list price between $25.01 and $35.00, for example, would be priced at $12.99, $14.99, or $16.99, with the retail e-book price increasing in relation to the hardcover list price.

8. After executing the Apple Agency Agreements, the Publisher Defendants all then quickly acted to complete the scheme by imposing agency agreements on all their other retailers. As a direct result, those retailers lost their ability to compete on price, including their ability to sell the most popular e-books for $9.99 or for other low prices. Once in control of retail prices, the Publisher Defendants limited retail price competition among themselves. Millions of e-books that would have sold at retail for $9.99 or for other low prices instead sold for the prices indicated by the price schedules included in the Apple Agency Agreements—generally, $12.99 or $14.99. Other price and non-price competition among e-book publishers and among e-book retailers also was unlawfully eliminated to the detriment of U.S. consumers.

9. The purpose of this lawsuit is to enjoin the Publisher Defendants and Apple from further violations of the nation's antitrust laws and to restore the competition that has been lost due to the Publisher Defendants' and Apple's illegal acts.

10. Defendants' ongoing conspiracy and agreement have caused e-book consumers to pay tens of millions of dollars more for e-books than they otherwise would have paid.

11. The United States, through this suit, asks this Court to declare Defendants' conduct illegal and to enter injunctive relief to prevent further injury to consumers in the United States.

II. Defendants

12. Apple, Inc. has its principal place of business at 1 Infinite Loop, Cupertino, CA 95014. Among many other businesses, Apple, Inc. distributes e-books through its iBookstore.

13. Hachette Book Group, Inc. has its principal place of business at 237 Park Avenue, New York, NY 10017. It publishes e-books and print books through publishers such as Little, Brown, and Company and Grand Central Publishing.

14. HarperCollins Publishers L.L.C. has its principal place of business at 10 E. 53rd Street, New York, NY 10022. It publishes e-books and print books through publishers such as Harper and William Morrow.

15. Holtzbrinck Publishers, LLC d/b/a Macmillan has its principal place of business at 175 Fifth Avenue, New York, NY 10010. It publishes e-books and print books through publishers such as Farrar, Straus and Giroux and St. Martin's Press. Verlagsgruppe Georg von Holtzbrinck GmbH owns Holtzbrinck Publishers, LLC d/b/a Macmillan and has its principal place of business at Gänsheidestraße 26, Stuttgart 70184, Germany.

16. Penguin Group (USA), Inc. has its principal place of business at 375 Hudson Street, New York, NY 10014. It publishes e-books and print books through publishers such as The Viking Press and Gotham Books. Penguin Group (USA), Inc. is the United States affiliate of The Penguin Group, a division of Pearson plc, which has its principal place of business at 80 Strand, London WC2R 0RL, United Kingdom.

17. Simon & Schuster, Inc. has its principal place of business at 1230 Avenue of the Americas, New York, NY 10020. It publishes e-books and print books through publishers such as Free Press and Touchstone.

III. Jurisdiction, Venue, and Interstate Commerce

18. Plaintiff United States of America brings this action pursuant to Section 4 of the Sherman Act, 15 U.S.C. 4, to obtain equitable relief and other relief to prevent and restrain Defendants' violations of Section 1 of the Sherman Act, 15 U.S.C 1.

19. This Court has subject matter jurisdiction over this action under Section 4 of the Sherman Act, 15 U.S.C. 4, and 28 U.S.C. 1331, 1337(a), and 1345.

20. This Court has personal jurisdiction over each Defendant and venue is proper in the Southern District of New York under Section 12 of the Clayton Act, 15 U.S.C. 22, and 28 U.S.C. 1391, because each Defendant transacts business and is found within the Southern District of New York. The U.S. component of each Publisher Defendant

is headquartered in the Southern District of New York, and acts in furtherance of the conspiracy occurred in this District. Many thousands of the Publisher Defendants' e-books are and have been sold in this District, including through Defendant Apple's iBookstore.

21. Defendants are engaged in, and their activities substantially affect, interstate trade and commerce. The Publisher Defendants sell e-books throughout the United States. Their e-books represent a substantial amount of interstate commerce. In 2010, United States consumers paid more than $300 million for the Publisher Defendants' e-books, including more than $40 million for e-books licensed through Defendant Apple's iBookstore.

IV. Co-Conspirators

22. Various persons, who are known and unknown to Plaintiff, and not named as defendants in this action, including senior executives of the Publisher Defendants and Apple, have participated as co-conspirators with Defendants in the offense alleged and have performed acts and made statements in furtherance of the conspiracy.

V. The Publishing Industry and Background of the Conspiracy

A. Print Books

23. Authors submit books to publishers in manuscript form. Publishers edit manuscripts, print and bind books, provide advertising and related marketing services, decide when a book should be released for sale, and distribute books to wholesalers and retailers. Publishers also determine the cover price or ''list price'' of a book, and typically that price appears on the book's cover.

24. Retailers purchase print books directly from publishers, or through wholesale distributors, and resell them to consumers. Retailers typically purchase print books under the ''wholesale model.'' Under that model, retailers pay publishers approximately one-half of the list price of books, take ownership of the books, then resell them to consumers at prices of the retailer's choice. Publishers have sold print books to retailers through the wholesale model for over 100 years and continue to do so today.

B. E-books

25. E-books are books published in electronic formats. E-book publishers avoid some of the expenses incurred in producing and distributing print books, including most manufacturing expenses, warehousing expenses, distribution expenses, and costs of dealing with unsold stock.

26. Consumers purchase e-books through Web sites of e-book retailers or through applications loaded onto their reading devices. Such electronic distribution allows e-book retailers to avoid certain expenses they incur when they sell print books, including most warehousing expenses and distribution expenses.

27. From its very small base in 2007 at the time of Amazon's Kindle launch, the e-book market has exploded, registering triple-digit sales growth each year. E-books now constitute at least ten percent of general interest fiction and non-fiction books (commonly known as ''trade'' books [1]) sold in the United States and are widely predicted to reach at least 25 percent of U.S. trade books sales within two to three years.

D. Publisher Defendants and ''The $9.99 Problem''

28. The Publisher Defendants compete against each other for sales of trade e-books to consumers. Publishers bid against one another for print- and electronic-publishing rights to content that they expect will be most successful in the market. They also compete against each other in bringing those books to market. For example, in addition to price-setting, they create cover art and other on-book sales inducements, and also engage in advertising campaigns for some titles.

29. The Publisher Defendants are five of the six largest publishers of trade books in the United States. They publish the vast majority of their newly released titles as both print books and e-books. Publisher Defendants compete against each other in the sales of both trade print books and trade e-books.

30. When Amazon launched its Kindle device, it offered newly released and bestselling e-books to consumers for $9.99. At that time, Publisher Defendants routinely wholesaled those e-books for about that same price, which typically was less than the wholesale price of the hardcover versions of the same titles, reflecting publisher cost savings associated with the electronic format. From the time of its launch, Amazon's e-book distribution business has been consistently profitable, even when substantially discounting some newly released and bestselling titles.

31. To compete with Amazon, other e-book retailers often matched or approached Amazon's $9.99-or-less prices for e-book versions of new releases and *New York Times* bestsellers. As a result of that competition, consumers benefited from Amazon's $9.99-or-less e-book prices even if they purchased e-books from competing e-book retailers.

32. The Publisher Defendants feared that $9.99 would become the standard price for newly released and bestselling e-books. For example, one Publisher Defendant's CEO bemoaned the ''wretched $9.99 price point'' and Penguin USA CEO David Shanks worried that e-book pricing ''can't be $9.99 for hardcovers.''

33. The Publisher Defendants believed the low prices for newly released and bestselling e-books were disrupting the industry. The Amazon-led $9.99 retail price point for the most popular e-books troubled the Publisher Defendants because, at $9.99, most of these e-book titles were priced substantially lower than hardcover versions of the same title. The Publisher Defendants were concerned these lower e-book prices would lead to the ''deflation'' of hardcover book prices, with accompanying declining revenues for publishers. The Publisher Defendants also worried that if $9.99 solidified as the consumers' expected retail price for e-books, Amazon and other retailers would demand that publishers lower their wholesale prices, further compressing publisher profit margins.

34. The Publisher Defendants also feared that the $9.99 price point would make e-books so popular that digital publishers could achieve sufficient scale to challenge the major incumbent publishers' basic business model. The Publisher Defendants were especially concerned that Amazon was well positioned to enter the digital publishing business and thereby supplant publishers as intermediaries between authors and consumers. Amazon had, in fact, taken steps to do so, contracting directly with authors to publish their works as e-books—at a higher royalty rate than the Publisher Defendants offered. Amazon's move threatened the Publisher Defendants' traditional positions as the gate-keepers of the publishing world. The Publisher Defendants also feared that other competitive advantages they held as a result of years of investments in their print book businesses would erode and, eventually, become irrelevant, as e-book sales continued to grow.

[1] Non-trade e-books include electronic versions of children's picture books and academic textbooks, reference materials, and other specialized texts that typically are published by separate imprints from trade books, often are sold through separate channels, and are not reasonably substitutable for trade e-books.

E. Publisher Defendants Recognize They Cannot Solve ''The $9.99 Problem'' Alone

35. Each Publisher Defendant knew that, acting alone, it could not compel Amazon to raise e-book prices and that it was not in its economic self-interest to attempt unilaterally to raise retail e-book prices. Each Publisher Defendant relied on Amazon to market and distribute its e-books, and each Publisher Defendant believed Amazon would leverage its position as a large retailer to preserve its ability to compete and would resist any individual publisher's attempt to raise the prices at which Amazon sold that publisher's e-books. As one Publisher Defendant executive acknowledged Amazon's bargaining strength, ''we've always known that unless other publishers follow us, there's no chance of success in getting Amazon to change its pricing practices.'' In the same email, the executive wrote, ''without a critical mass behind us Amazon won't 'negotiate,' so we need to be more confident of how our fellow publishers will react * * * .''

36. Each Publisher Defendant also recognized that it would lose sales if retail prices increased for only its e-books while the other Publisher Defendants' e-books remained competitively priced. In addition, higher prices for just one publisher's e-books would not change consumer perceptions enough to slow the erosion of consumer-perceived value of books that all the Publisher Defendants feared would result from Amazon's $9.99 pricing policy.

VI. Defendants' Unlawful Activities

37. Beginning no later than September 2008, the Publisher Defendants' senior executives engaged in a series of meetings, telephone conversations and other communications in which they jointly acknowledged to each other the threat posed by Amazon's pricing strategy and the need to work collectively to end that strategy. By the end of the summer of 2009, the Publisher Defendants had agreed to act collectively to force up Amazon's retail prices and thereafter considered and implemented various means to accomplish that goal, including moving under the guise of a joint venture. Ultimately, in late 2009, Apple and the Publisher Defendants settled on the strategy that worked—replacing the wholesale model with an agency model that gave the Publisher Defendants the power to raise retail e-book prices themselves.

38. The evidence showing conspiracy is substantial and includes:

• *Practices facilitating a horizontal conspiracy.* The Publisher Defendants regularly communicated with each other in private conversations, both in person and on the telephone, and in emails to each other to exchange sensitive information and assurances of solidarity to advance the ends of the conspiracy.

• *Direct evidence of a conspiracy.* The Publisher Defendants directly discussed, agreed to, and encouraged each other to collective action to force Amazon to raise its retail e-book prices.

• *Recognition of illicit nature of communications.* Publisher Defendants took steps to conceal their communications with one another, including instructions to ''double delete'' email and taking other measures to avoid leaving a paper trail.

• *Acts contrary to economic interests.* It would have been contrary to the economic interests of any Publisher Defendant acting alone to attempt to impose agency on all of its retailers and then raise its retail e-book prices. For example, Penguin Group CEO John Makinson reported to his parent company board of directors that ''the industry needs to develop a common strategy'' to address the threat ''from digital companies whose objective may be to disintermediate traditional publishers altogether'' because it ''will not be possible for any individual publisher to mount an effective response,'' and Penguin later admitted that it would have been economically disadvantaged if it ''was the only publisher dealing with Apple under the new business model.''

• *Motive to enter the conspiracy, including knowledge or assurances that competitors also will enter.* The Publisher Defendants were motivated by a desire to maintain both the perceived value of their books and their own position in the industry. They received assurances from both each other and Apple that they all would move together to raise retail e-book prices. Apple was motivated to ensure that it would not face competition from Amazon's low-price retail strategy.

• *Abrupt, contemporaneous shift from past behavior.* Prior to January 23, 2010, all Publisher Defendants sold their e-books under the traditional wholesale model; by January 25, 2010, all Publisher Defendants had irrevocably committed to transition all of their retailers to the agency model (and Apple had committed to sell e-books on a model inconsistent with the way it sells the vast bulk of the digital media it offers in its iTunes store). On April 3, 2010, as soon as the Apple Agency Agreements simultaneously became effective, all Publisher Defendants immediately used their new retail pricing authority to raise the retail prices of their newly released and bestselling e-books to the common ostensible maximum prices contained in their Apple Agency Agreements.

A. The Publisher Defendants Recognize a Common Threat

39. Starting no later than September of 2008 and continuing for at least one year, the Publisher Defendants' CEOs (at times joined by one non-defendant publisher's CEO) met privately as a group approximately once per quarter. These meetings took place in private dining rooms of upscale Manhattan restaurants and were used to discuss confidential business and competitive matters, including Amazon's e-book retailing practices. No legal counsel was present at any of these meetings.

40. In September 2008, Penguin Group CEO John Makinson was joined by Macmillan CEO John Sargent and the CEOs of the other four large publishers at a dinner meeting in ''The Chef's Wine Cellar,'' a private room at Picholene. One of the CEOs reported that business matters were discussed.

41. In January 2009, the CEO of one Publisher Defendant, a United States subsidiary of a European corporation, promised his corporate superior, the CEO of the parent company, that he would raise the future of e-books and Amazon's potential role in that future at an upcoming meeting of publisher CEOs. Later that month, at a dinner meeting hosted by Penguin Group CEO John Makinson, again in ''The Chef's Wine Cellar'' at Picholene, the same group of publisher CEOs met once more.

42. On or about June 16, 2009, Mr. Makinson again met privately with other Publisher Defendant CEOs and discussed, *inter alia,* the growth of e-books and Amazon's role in that growth.

43. On or about September 10, 2009, Mr. Makinson once again met privately with other Publisher Defendant CEOs and the CEO of one non-defendant publisher in a private room of a different Manhattan restaurant, Alto. They discussed the growth of e-books and complained about Amazon's role in that growth.

44. In addition to the CEO dinner meetings, Publisher Defendants' CEOs and other executives met in-person, one-on-one to communicate about e-books multiple times over the course of 2009 and into 2010. Similar meetings took place in Europe, including meetings in the fall of 2009 between executives of Macmillan parent company Verlagsgruppe Georg von

Holtzbrinck GmbH and executives of another Publisher Defendant's parent company. Macmillan CEO John Sargent joined at least one of these parent company meetings.

45. These private meetings provided the Publisher Defendants' CEOs the opportunity to discuss how they collectively could solve ''the $9.99 problem.''

B. Publisher Defendants Conspire To Raise Retail E-book Prices Under the Guise of Joint Venture Discussions

46. While each Publisher Defendant recognized that it could not solve ''the $9.99 problem'' by itself, collectively the Publisher Defendants accounted for nearly half of Amazon's e-book revenues, and by refusing to compete with one another for Amazon's business, the Publisher Defendants could force Amazon to accept the Publisher Defendants' new contract terms and to change its pricing practices.

47. The Publisher Defendants thus conspired to act collectively, initially in the guise of joint ventures. These ostensible joint ventures were not meant to enhance competition by bringing to market products or services that the publishers could not offer unilaterally, but rather were designed as anticompetitive measures to raise prices.

48. All five Publisher Defendants agreed in 2009 at the latest to act collectively to raise retail prices for the most popular e-books above $9.99. One CEO of a Publisher Defendant's parent company explained to his corporate superior in a July 29, 2009 email message that ''[i]n the USA and the UK, but also in Spain and France to a lesser degree, the 'top publishers' are in discussions to create an alternative platform to Amazon for e-books. The goal is less to compete with Amazon as to force it to accept a price level higher than 9.99. * * * I am in NY this week to promote these ideas and the movement is positive with [the other four Publisher Defendants].'' (Translated from French).

49. Less than a week later, in an August 4, 2009 strategy memo for the board of directors of Penguin's ultimate parent company, Penguin Group CEO John Makinson conveyed the same message:

> Competition for the attention of readers will be most intense from digital companies whose objective may be to disintermediate traditional publishers altogether. This is not a new threat but we do appear to be on a collision course with Amazon, and possibly Google as well. It will not be possible for any individual publisher to mount an effective response, because of both the resources necessary and the risk of retribution, so the industry needs to develop a common strategy. This is the context for the development of the Project Z initiatives [joint ventures] in London and New York.

C. Defendants Agree To Increase and Stabilize Retail E-Book Prices by Collectively Adopting an Agency Model

50. To raise e-book prices, the Publisher Defendants also began to consider in late 2009 selling e-books under an ''agency model'' that would take away Amazon's ability to set low retail prices. As one CEO of a Publisher Defendant's parent company explained in a December 6, 2009 email message, ''[o]ur goal is to force Amazon to return to acceptable sales prices through the establishment of agency contracts in the USA. * * * To succeed our colleagues must know that we entered the fray and follow us.'' (Translated from French).

51. Apple's entry into the e-book business provided a perfect opportunity for collective action to implement the agency model and use it to raise retail e-book prices. Apple was in the process of developing a strategy to sell e-books on its new iPad device. Apple initially contemplated selling e-books through the existing wholesale model, which was similar to the manner in which Apple sold the vast majority of the digital media it offered in its iTunes store. On February 19, 2009, Apple Vice President of Internet Services Eddy Cue explained to Apple CEO Steve Jobs in an email, ''[a]t this point, it would be very easy for us to compete and I think trounce Amazon by opening up our own ebook store.'' In addition to considering competitive entry at that time, though, Apple also contemplated illegally dividing the digital content world with Amazon, allowing each to ''own the category'' of its choice—audio/video to Apple and e-books to Amazon.

52. Apple soon concluded, though, that competition from other retailers—especially Amazon—would prevent Apple from earning its desired 30 percent margins on e-book sales. Ultimately, Apple, together with the Publisher Defendants, set in motion a plan that would compel all non-Apple e-book retailers also to sign onto agency or else, as Apple's CEO put it, the Publisher Defendants all would say, ''we're not going to give you the books.''

53. The executive in charge of Apple's inchoate e-books business, Eddy Cue, telephoned each Publisher Defendant and Random House on or around December 8, 2009 to schedule exploratory meetings in New York City on December 15 and December 16. Hachette and HarperCollins took the lead in working with Apple to capitalize on this golden opportunity for the Publisher Defendants to achieve their goal of raising and stabilizing retail e-book prices above $9.99 by collectively imposing the agency model on the industry.

54. It appears that Hachette and HarperCollins communicated with each other about moving to an agency model during the brief window between Mr. Cue's first telephone calls to the Publisher Defendants and his visit to meet with their CEOs. On the morning of December 10, 2009, a HarperCollins executive added to his calendar an appointment to call a Hachette executive at 10:50 a.m. At 11:01 a.m., the Hachette executive returned the phone call, and the two spoke for six minutes. Then, less than a week later in New York, both Hachette and HarperCollins executives told Mr. Cue in their initial meetings with him that they wanted to sell e-books under an agency model, a dramatic departure from the way books had been sold for over a century.

55. The other Publisher Defendants also made clear to Apple that they ''certainly'' did not want to continue ''the existing way that they were doing business,'' *i.e.,* with Amazon promoting their most popular e-books for $9.99 under a wholesale model.

56. Apple saw a way to turn the agency scheme into a highly profitable model for itself. Apple determined to give the Publisher Defendants what they wanted while shielding itself from retail price competition and realizing margins far in excess of what e-book retailers then averaged on each newly released or bestselling e-book sold. Apple realized that, as a result of the scheme, ''the customer'' would ''pay[] a little more.''

57. On December 16, 2009, the day after both companies' initial meetings with Apple, Penguin Group CEO John Makinson had a breakfast meeting at a London hotel with the CEO of another Publisher Defendant's parent company. Consistent with the Publisher Defendants' other efforts to conceal their activities, Mr. Makinson's breakfast companion wrote to his U.S. subordinate that he would recount portions of his discussion with Mr. Makinson only by telephone.

58. By the time Apple arrived for a second round of meetings during the week of December 21, 2009, the agency model had become the focus of its discussions with all of the Publisher Defendants. In these discussions, Apple proposed that the Publisher Defendants require *all* retailers of their e-books to accept the agency model. Apple thereby sought to ensure that it would not have

to compete on retail prices. The proposal appealed to the Publisher Defendants because wresting pricing control from Amazon and other e-book retailers would advance their collusive plan to raise retail e-book prices.

59. The Publisher Defendants acknowledged to Apple their common objective to end Amazon's $9.99 pricing. As Mr. Cue reported in an email message to Apple's CEO Steve Jobs, the three publishers with whom he had met saw the ''plus'' of Apple's position as ''solv[ing the] Amazon problem.'' The ''negative'' was that Apple's proposed retail prices—topping out at $12.99 for newly released and bestselling e-books—were a ''little less than [the publishers] would like.'' Likewise, Mr. Jobs later informed an executive of one of the Publisher Defendant's corporate parents that ''[a]ll major publishers'' had told Apple that ''Amazon's $9.99 price for new releases is eroding the value perception of their products in customer's minds, and they do not want this practice to continue for new releases.''

60. As perhaps the only company that could facilitate their goal of raising retail e-book prices across the industry, Apple knew that it had significant leverage in negotiations with Publisher Defendants. Apple exercised this leverage to demand a thirty percent commission—a margin significantly above the prevailing competitive margins for e-book retailers. The Publisher Defendants worried that the combination of paying Apple a higher commission than they would have liked and pricing their e-books lower than they wanted might be too much to bear in exchange for Apple's facilitation of their agreement to raise retail e-book prices. Ultimately, though, they convinced Apple to allow them to raise prices high enough to make the deal palatable to them.

61. As it negotiated with the Publisher Defendants in December 2009 and January 2010, Apple kept each Publisher Defendant informed of the status of its negotiations with the other Publisher Defendants. Apple also assured the Publisher Defendants that its proposals were the same to each and that no deal Apple agreed to with one publisher would be materially different from any deal it agreed to with another publisher. Apple thus knowingly served as a critical conspiracy participant by allowing the Publisher Defendants to signal to one another both (a) which agency terms would comprise an acceptable means of achieving their ultimate goal of raising and stabilizing retail e-book prices, and (b) that they could lock themselves into this particular means of collectively achieving that goal by all signing their Apple Agency Agreement.

62. Apple's Mr. Cue emailed each Publisher Defendant between January 4, 2010, and January 6, 2010 an outline of what he tabbed ''the best approach for e-books.'' He reassured Penguin USA CEO David Shanks and other Publisher Defendant CEOs that Apple adopted the approach ''[a]fter talking to all the other publishers.'' Mr. Cue sent substantively identical email messages and proposals to each Publisher Defendant.

63. The outlined proposal that Apple circulated after consulting with each Publisher Defendant contained several key features. First, as Hachette and HarperCollins had initially suggested to Apple, the publisher would be the principal and Apple would be the agent for e-book sales. Consumer pricing authority would be transferred from retailers to publishers. Second, Apple's proposal mandated that every other retailer of each publisher's e-books—Apple's direct competitors—be forced to accept the agency model as well. As Mr. Cue wrote, ''all resellers of new titles need to be in agency model.'' Third, Apple would receive a 30 percent commission for each e-book sale. And fourth, each Publisher Defendant would have identical pricing tiers for e-books sold through Apple's iBookstore.

64. On January 11, 2010, Apple emailed its proposed e-book distribution agreement to all the Publisher Defendants. As with the outlined proposals Apple sent earlier in January, the proposed e-book distribution agreements were substantially the same. Also on January 11, 2010, Apple separately emailed to Penguin and two other Publisher Defendants charts showing how the Publisher Defendant's bestselling e-books would be priced at $12.99—the ostensibly maximum price under Apple's then-current price tier proposal—in the iBookstore.

65. The proposed e-book distribution agreement mainly incorporated the principles Apple set out in its email messages of January 4 through January 6, with two notable changes. First, Apple demanded that the Publisher Defendants provide Apple their complete e-book catalogs and that they not delay the electronic release of any title behind its print release. Second, and more important, Apple replaced the express requirement that each publisher adopt the agency model with each of its retailers with an unusual most favored nation (''MFN'') pricing provision. That provision was not structured like a standard MFN in favor of a retailer, ensuring Apple that it would receive the best available wholesale price. Nor did the MFN ensure Apple that the Publisher Defendants would not set a higher retail price on the iBookstore than they set on other Web sites where they controlled retail prices. Instead, the MFN here required each publisher to guarantee that it would lower the retail price of each e-book in Apple's iBookstore to match the lowest price offered by any other retailer, even if the Publisher Defendant did not control that other retailer's ultimate consumer price. That is, instead of an MFN designed to protect Apple's ability to compete, this MFN was designed to protect Apple from having to compete on price at all, while still maintaining Apple's 30 percent margin.

66. The purpose of these provisions was to work in concert to enforce the Defendants' agreement to raise and stabilize retail e-book prices. Apple and the Publisher Defendants recognized that coupling Apple's right to all of their e-books with its right to demand that those e-books not be priced higher on the iBookstore than on any other Web site effectively required that each Publisher Defendant take away retail pricing control from all other e-book retailers, including stripping them of any ability to discount or otherwise price promote e-books out of the retailer's own margins. Otherwise, the retail price MFN would cause Apple's iBookstore prices to drop to match the best available retail price of each e-book, and the Publisher Defendants would receive only 70 percent of those reduced retail prices. Price competition by other retailers, if allowed to continue, thus likely would reduce e-book revenues to levels the Publisher Defendants could not control or predict.

67. In negotiating the retail price MFN with Apple, ''some of [the Publisher Defendants]'' asserted that Apple did not need the provision ''because they would be moving to an agency model with [the other e-book retailers,]'' regardless. Ultimately, though, all Defendants agreed to include the MFN commitment mechanism.

68. On January 16, 2010, Apple, via Mr. Cue, offered revised terms to the Publisher Defendants that again were identical in substance. Apple modified its earlier proposal in two significant ways. First, in response to publisher requests, it added new maximum pricing tiers that increased permissible e-book prices to $16.99 or $19.99, depending on the book's hardcover list price. Second, Apple's new proposal mitigated these price increases somewhat by adding special pricing tiers for e-book versions of books on the *New York Times* fiction and non-fiction bestseller lists. For e-book versions of

bestsellers bearing list prices of $30 or less, Publisher Defendants could set a price up to $12.99; for bestsellers bearing list prices between $30 and $35, the e-book price cap would be $14.99. In conjunction with the revised proposal, Mr. Cue set up meetings for the next week to finalize agreements with the Publisher Defendants.

69. Each Publisher Defendant required assurances that it would not be the only publisher to sign an agreement with Apple that would compel it either to take pricing authority from Amazon or to pull its e-books from Amazon. The Publisher Defendants continued to fear that Amazon would act to protect its ability to price e-books at $9.99 or less if any one of them acted alone. Individual Publisher Defendants also feared punishment in the marketplace if only its e-books suddenly became more expensive at retail while other publishers continued to allow retailers to compete on price. As Mr. Cue noted, ''all of them were very concerned about being the only ones to sign a deal with us.'' Penguin explicitly communicated to Apple that it would sign an e-book distribution agreement with Apple only if at least three of the other ''major[]'' publishers did as well. Apple supplied the needed assurances.

70. While the Publisher Defendants were discussing e-book distribution terms with Apple during the week of January 18, 2010, Amazon met in New York City with a number of prominent authors and agents to unveil a new program under which copyright holders could take their e-books directly to Amazon—cutting out the publisher—and Amazon would pay royalties of up to 70 percent, far in excess of what publishers offered. This announcement further highlighted the direct competitive threat Amazon posed to the Publisher Defendants' business model. The Publisher Defendants reacted immediately. For example, Penguin USA CEO David Shanks reported being ''really angry'' after ''hav[ing] read [Amazon's] announcement.'' After thinking about it for a day, Mr. Shanks concluded, ''[o]n Apple I am now more convinced that we need a viable alternative to Amazon or this nonsense will continue and get much worse.'' Another decisionmaker stated he was ''p****d'' at Amazon for starting to compete directly against the publishers and expressed his desire ''to screw Amazon.''

71. To persuade one of the Publisher Defendants to stay with the others and sign an agreement, Apple CEO Steve Jobs wrote to an executive of the Publisher Defendant's corporate parent that the publisher had only two choices apart from signing the Apple Agency Agreement: (i) accept the status quo (''Keep going with Amazon at $9.99''); or (ii) continue with a losing policy of delaying the release of electronic versions of new titles (''Hold back your books from Amazon''). According to Jobs, the Apple deal offered the Publisher Defendants a superior alternative path to the higher retail e-book prices they sought: ''Throw in with Apple and see if we can all make a go of this to create a real mainstream e-books market at $12.99 and $14.99.''

72. In addition to passing information through Apple and during their private dinners and other in-person meetings, the Publisher Defendants frequently communicated by telephone to exchange assurances of common action in attempting to raise the retail price of e-books. These telephone communications increased significantly during the two-month period in which the Publisher Defendants considered and entered the Apple Agency Agreements. During December 2009 and January 2010, the Publisher Defendants' U.S. CEOs placed at least 56 phone calls to one another. Each CEO, including Penguin's Shanks and Macmillan's Sargent, placed at least seven such phone calls.

73. The timing, frequency, duration, and content of the Publisher Defendant CEOs' phone calls demonstrate that the Publisher Defendants used them to seek and exchange assurances of common strategies and business plans regarding the Apple Agency Agreements. For example, in addition to the telephone calls already described in this complaint:

- Near the time Apple first presented the agency model, one Publisher Defendant's CEO used a telephone call—ostensibly made to discuss a marketing joint venture—to tell Penguin USA CEO David Shanks that ''everyone is in the same place with Apple.''
- After receiving Apple's January 16, 2010 revised proposal, executives of several Publisher Defendants responded to the revised proposal and meetings by, again, seeking and exchanging confidential information. For example, on Sunday, January 17, one Publisher Defendant's CEO used his mobile phone to call another Publisher Defendant's CEO and talk for approximately ten minutes. And on the morning of January 19, Penguin USA CEO David Shanks had an extended telephone conversation with the CEO of another Publisher Defendant.
- On January 21, 2010, the CEO of one Publisher Defendant's parent company instructed his U.S. subordinate via email to find out Apple's progress in agency negotiations with other publishers. Four minutes after that email was sent, the U.S. executive called another Publisher Defendant's CEO, and the two spoke for over eleven minutes.
- On January 22, 2010, at 9:30 a.m., Apple's Cue met with one Publisher Defendant's CEO to make what Cue hoped would be a ''final go/no-go decision'' about whether the Publisher Defendant would sign an agreement with Apple. Less than an hour later, the Publisher Defendant's CEO made phone calls, two minutes apart, to two other Publisher Defendants' CEOs, including Macmillan's Sargent. The CEO who placed the calls admitted under oath to placing them specifically to learn if the other two Publisher Defendants would sign with Apple prior to Apple's iPad launch.
- On the evening of Saturday, January 23, 2010, Apple's Cue emailed his boss, Steve Jobs, and noted that Penguin USA CEO David Shanks ''want[ed] an assurance that he is 1 of 4 before signing.'' The following Monday morning, at 9:46 a.m., Mr. Shanks called another Publisher Defendant's CEO and the two talked for approximately four minutes. Both Penguin and the other Publisher Defendant signed their Apple Agency Agreements later that day.

74. On January 24, 2010, Hachette signed an e-book distribution agreement with Apple. Over the next two days, Simon & Schuster, Macmillan, Penguin, and HarperCollins all followed suit and signed e-book distribution agreements with Apple. Within these three days, the Publisher Defendants agreed with Apple to abandon the longstanding wholesale model for selling e-books. The Apple Agency Agreements took effect simultaneously on April 3, 2010 with the release of Apple's new iPad.

75. The final version of the pricing tiers in the Apple Agency Agreements contained the $12.99 and $14.99 price points for bestsellers, discussed earlier, and also established prices for all other newly released titles based on the hardcover list price of the same title. Although couched as maximum retail prices, the price tiers in fact established the retail e-book prices to be charged by Publisher Defendants.

76. By entering the Apple Agency Agreements, each Publisher Defendant effectively agreed to require all of their e-book retailers to accept the agency model. Both Apple and the Publisher Defendants understood the Agreements would compel the Publisher Defendants to take pricing authority from all non-Apple e-book retailers. A February 10, 2010 presentation by one Publisher Defendant applauded this result

(emphasis in original): ''The Apple agency model deal means that we will have to shift to an agency model with Amazon which [will] strengthen our control over pricing.''

77. Apple understood that the final Apple Agency Agreements ensured that the Publisher Defendants would raise their retail e-book prices to the ostensible limits set by the Apple price tiers not only in Apple's forthcoming iBookstore, but on Amazon.com and all other consumer sites as well. When asked by a *Wall Street Journal* reporter at the January 27, 2010 iPad unveiling event, ''Why should she buy a book for * * * $14.99 from your device when she could buy one for $9.99 from Amazon on the Kindle or from Barnes & Noble on the Nook?'' Apple CEO Steve Jobs responded, ''that won't be the case * * * the prices will be the same.''

78. Apple understood that the retail price MFN was the key commitment mechanism to keep the Publisher Defendants advancing their conspiracy in lockstep. Regarding the effect of the MFN, Apple executive Pete Alcorn remarked in the context of the European roll-out of the agency model in the spring of 2010:

> I told [Apple executive Keith Moerer] that I think he and Eddy [Cue] made it at least halfway to changing the industry permanently, and we should keep the pads on and keep fighting for it. I might regret that later, but right now I feel like it's a giant win to keep pushing the MFN and forcing people off the [A]mazon model and onto ours. If anything, the place to give is the pricing—long run, the mfn is more important. The interesting insight in the meeting was Eddy's explanation that it doesn't have to be that broad—any decent MFN forces the model.

79. Within the four months following the signing of the Apple Agency Agreements, and over Amazon's objections, each Publisher Defendant had transformed its business relationship with all of the major e-book retailers from a wholesale model to an agency model and imposed flat prohibitions against e-book discounting or other price competition on all non-Apple e-book retailers.

80. For example, after it signed its Apple Agency Agreement, Macmillan presented Amazon a choice: adopt the agency model or lose the ability to sell e-book versions of new hardcover titles for the first seven months of their release. Amazon rejected Macmillan's ultimatum and sought to preserve its ability to sell e-book versions of newly released hardcover titles for $9.99. To resist Macmillan's efforts to force it to accept either the agency model or delayed electronic availability, Amazon effectively stopped selling Macmillan's print books and e-books.

81. When Amazon stopped selling Macmillan titles, other Publisher Defendants did not view the situation as an opportunity to gain market share from a weakened competitor. Instead, they rallied to support Macmillan. For example, the CEO of one Publisher Defendant's parent company instructed the Publisher Defendant's CEO that ''[Macmillan CEO] John Sargent needs our help!'' The parent company CEO explained, ''M[acm]illan have been brave, but they are small. We need to move the lines. And I am thrilled to know how A[mazon] will react against 3 or 4 of the big guys.''

82. The CEO of one Publisher Defendant's parent company assured Macmillan CEO John Sargent of his company's support in a January 31, 2010 email: ''I can ensure you that you are not going to find your company alone in the battle.'' The same parent company CEO also assured the head of Macmillan's corporate parent in a February 1 email that ''others will enter the battle field!'' Overall, Macmillan received ''hugely supportive'' correspondence from the publishing industry during Macmillan's effort to force Amazon to accept the agency model.

83. As its battle with Amazon continued, Macmillan knew that, because the other Publisher Defendants, via the Apple Agency Agreements, had locked themselves into forcing agency on Amazon to advance their conspiratorial goals, Amazon soon would face similar edicts from a united front of Publisher Defendants. And Amazon could not delist the books of all five Publisher Defendants because they together accounted for nearly half of Amazon's e-book business. Macmillan CEO John Sargent explained the company's reasoning: ''we believed whatever was happening, whatever Amazon was doing here, they were going to face—they're going to have more of the same in the future one way or another.'' Another Publisher Defendant similarly recognized that Macmillan was not acting unilaterally but rather was ''leading the charge on moving Amazon to the agency model.''

84. Amazon quickly came to fully appreciate that not just Macmillan but all five Publisher Defendants had irrevocably committed themselves to the agency model across all retailers, including taking control of retail pricing and thereby stripping away any opportunity for e-book retailers to compete on price. Just two days after it stopped selling Macmillan titles, Amazon capitulated and publicly announced that it had no choice but to accept the agency model, and it soon resumed selling Macmillan's e-book and print book titles.

D. Defendants Further the Conspiracy by Pressuring Another Publisher To Adopt the Agency Model

85. When a company takes a pro-competitive action by introducing a new product, lowering its prices, or even adopting a new business model that helps it sell more product at better prices, it typically does not want its competitors to copy its action, but prefers to maintain a first-mover or competitive advantage. In contrast, when companies jointly take collusive action, such as instituting a coordinated price increase, they typically want the rest of their competitors to join them in that action. Because collusive actions are not pro-competitive or consumer friendly, any competitor that does not go along with the conspirators can take more consumer friendly actions and see its market share rise at the expense of the conspirators. Here, the Defendants acted consistently with a collusive arrangement, and inconsistently with a pro-competitive arrangement, as they sought to pressure another publisher (whose market share was growing at the Publisher Defendants' expense after the Apple Agency Contracts became effective) to join them.

86. Penguin appears to have taken the lead in these efforts. Its U.S. CEO, David Shanks, twice directly told the executives of the holdout major publisher about his displeasure with their decision to continue selling e-books on the wholesale model. Mr. Shanks tried to justify the actions of the conspiracy as an effort to save brick-and-mortar bookstores and criticized the other publisher for ''not helping'' the group. The executives of the other publisher responded to Mr. Shanks's complaints by explaining their objections to the agency model.

87. Mr. Shanks also encouraged a large print book and e-book retailer to punish the other publisher for not joining Defendants' conspiracy. In March 2010, Mr. Shanks sent an email message to an executive of the retailer complaining that the publisher ''has chosen to stay on their current model and will allow retailers to sell at whatever price they wish.'' Mr. Shanks argued that ''[s]ince Penguin is looking out for [your] welfare at what appears to be great costs to us, I would hope that [you] would be equally brutal to Publishers who have thrown in with your competition with obvious disdain for your welfare. . . . I hope you make

[the publisher] hurt like Amazon is doing to [the Publisher Defendants].''

88. When the third-party retailer continued to promote the non-defendant publisher's books, Mr. Shanks applied more pressure. In a June 22, 2010 email to the retailer's CEO, Mr. Shanks claimed to be ''baffled'' as to why the retailer would promote that publisher's books instead of just those published by ''people who stood up for you.''

89. Throughout the summer of 2010, Apple also cajoled the holdout publisher to adopt agency terms in line with those of the Publisher Defendants, including on a phone call between Apple CEO Steve Jobs and the holdout publisher's CEO. Apple flatly refused to sell the holdout publisher's e-books unless and until it agreed to an agency relationship substantially similar to the arrangement between Apple and the Publisher Defendants defined by the Apple Agency Agreements.

E. Conspiracy Succeeds at Raising and Stabilizing Consumer E-book Prices

90. The ostensible maximum prices included in the Apple Agency Agreements' price schedule represent, in practice, actual e-book prices. Indeed, at the time the Publisher Defendants snatched retail pricing authority away from Amazon and other e-book retailers, not one of them had built an internal retail pricing apparatus sufficient to do anything other than set retail prices at the Apple Agency Agreements' ostensible caps. Once their agency agreements took effect, the Publisher Defendants raised e-book prices at all retail outlets to the maximum price level within each tier. Even today, two years after the Publisher Defendants began setting e-book retail prices according to the Apple price tiers, they still set the retail prices for the electronic versions of all or nearly all of their bestselling hardcover titles at the ostensible maximum price allowed by those price tiers.

91. The Publisher Defendants' collective adoption of the Apple Agency Agreements allowed them (facilitated by Apple) to raise, fix, and stabilize retail e-book prices in three steps: (a) they took away retail pricing authority from retailers; (b) they then set retail e-book prices according to the Apple price tiers; and (c) they then exported the agency model and higher retail prices to the rest of the industry, in part to comply with the retail price MFN included in each Apple Agency Agreement.

92. Defendants' conspiracy and agreement to raise and stabilize retail e-book prices by collectively adopting the agency model and Apple price tiers led to an increase in the retail prices of newly released and bestselling e-books. Prior to the Defendants' conspiracy, consumers benefited from price competition that led to $9.99 prices for newly released and bestselling e-books. Almost immediately after Apple launched its iBookstore in April 2010 and the Publisher Defendants imposed agency model pricing on all retailers, the Publisher Defendants' e-book prices for most newly released and bestselling e-books rose to either $12.99 or $14.99.

93. Defendants' conspiracy and agreement to raise and stabilize retail e-book prices by collectively adopting the agency model and Apple price tiers for their newly released and bestselling e-books also led to an increase in average retail prices of the balance of Publisher Defendants' e-book catalogs, their so-called ''backlists.'' Now that the Publisher Defendants control the retail prices of e-books—but Amazon maintains control of its print book retail prices—Publisher Defendants' e-book prices sometimes are higher than Amazon's prices for print versions of the same titles.

VII. Violation Alleged

94. Beginning no later than 2009, and continuing to date, Defendants and their co-conspirators have engaged in a conspiracy and agreement in unreasonable restraint of interstate trade and commerce, constituting a violation of Section 1 of the Sherman Act, 15 U.S.C. 1. This offense is likely to continue and recur unless the relief requested is granted.

95. The conspiracy and agreement consists of an understanding and concert of action among Defendants and their co-conspirators to raise, fix, and stabilize retail e-book prices, to end price competition among e-book retailers, and to limit retail price competition among the Publisher Defendants, ultimately effectuated by collectively adopting and adhering to functionally identical methods of selling e-books and price schedules.

96. For the purpose of forming and effectuating this agreement and conspiracy, some or all Defendants did the following things, among others:

a. Shared their business information, plans, and strategies in order to formulate ways to raise retail e-book prices;

b. Assured each other of support in attempting to raise retail e-book prices;

c. Employed ostensible joint venture meetings to disguise their attempts to raise retail e-book prices;

d. Fixed the method of and formulas for setting retail e-book prices;

e. Fixed tiers for retail e-book prices;

f. Eliminated the ability of e-book retailers to fund retail e-book price decreases out of their own margins; and

g. Raised the retail prices of their newly released and bestselling e-books to the agreed prices—the ostensible price caps—contained in the pricing schedule of their Apple Agency Agreements.

97. Defendants' conspiracy and agreement, in which the Publisher Defendants and Apple agreed to raise, fix, and stabilize retail e-book prices, to end price competition among e-book retailers, and to limit retail price competition among the Publisher Defendants by fixing retail e-book prices, constitutes a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

98. Moreover, Defendants' conspiracy and agreement has resulted in obvious and demonstrable anticompetitive effects on consumers in the trade e-books market by depriving consumers of the benefits of competition among e-book retailers as to both retail prices and retail innovations (such as e-book clubs and subscription plans), such that it constitutes an unreasonable restraint on trade in violation of Section 1 of the Sherman Act, 15 U.S.C. 1.

99. Where, as here, defendants have engaged in a *per se* violation of Section 1 of the Sherman Act, no allegations with respect to the relevant product market, geographic market, or market power are required. To the extent such allegations may otherwise be necessary, the relevant product market for the purposes of this action is trade e-books. The anticompetitive acts at issue in this case directly affect the sale of trade e-books to consumers. No reasonable substitute exists for e-books. There are no technological alternatives to e-books, thousands of which can be stored on a single small device. E-books can be stored and read on electronic devices, while print books cannot. E-books can be located, purchased, and downloaded anywhere a customer has an internet connection, while print books cannot. Industry firms also view e-books as a separate market segment from print books, and the Publisher Defendants were able to impose and sustain a significant retail price increase for their trade e-books.

100. The relevant geographic market is the United States. The rights to license e-books are granted on territorial bases, with the United States typically forming its own territory. E-book retailers typically present a unique storefront to U.S. consumers, often with e-books bearing different retail prices than the same titles would command on the same retailer's foreign Web sites.

101. The Publisher Defendants possess market power in the market for trade e-books. The Publisher Defendants successfully imposed and sustained a significant retail price increase for their trade e-books. Collectively, they create and distribute a wide variety of popular e-books, regularly comprising over half of the *New York Times* fiction and non-fiction bestseller lists. Collectively, they provide a critical input to any firm selling trade e-books to consumers. Any retailer selling trade e-books to consumers would not be able to forgo profitably the sale of the Publisher Defendants' e-books.

102. Defendants' agreement and conspiracy has had and will continue to have anticompetitive effects, including:

a. Increasing the retail prices of trade e-books;

b. Eliminating competition on price among e-book retailers;

c. Restraining competition on retail price among the Publisher Defendants;

d. Restraining competition among the Publisher Defendants for favorable relationships with e-book retailers;

e. Constraining innovation among e-book retailers;

f. Entrenching incumbent publishers' favorable position in the sale and distribution of print books by slowing the migration from print books to e-books;

g. Making more likely express or tacit collusion among publishers; and

h. Reducing competitive pressure on print book prices.

103. Defendants' agreement and conspiracy is not reasonably necessary to accomplish any procompetitive objective, or, alternatively, its scope is broader than necessary to accomplish any such objective.

VIII. Request for Relief

104. To remedy these illegal acts, the United States requests that the Court:

a. Adjudge and decree that Defendants entered into an unlawful contract, combination, or conspiracy in unreasonable restraint of interstate trade and commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. 1;

b. Enjoin the Defendants, their officers, agents, servants, employees and attorneys and their successors and all other persons acting or claiming to act in active concert or participation with one or more of them, from continuing, maintaining, or renewing in any manner, directly or indirectly, the conduct alleged herein or from engaging in any other conduct, combination, conspiracy, agreement, understanding, plan, program, or other arrangement having the same effect as the alleged violation or that otherwise violates Section 1 of the Sherman Act, 15 U.S.C. 1, through fixing the method and manner in which they sell e-books, or otherwise agreeing to set the price or release date for e-books, or collective negotiation of e-book agreements, or otherwise collectively restraining retail price competition for e-books;

c. Prohibit the collusive setting of price tiers that can de facto fix prices;

d. Declare null and void the Apple Agency Agreements and any agreement between a Publisher Defendant and an e-book retailer that restricts, limits, or impedes the e-book retailer's ability to set, alter, or reduce the retail price of any e-book or to offer price or other promotions to encourage consumers to purchase any e-book, or contains a retail price MFN;

e. Reform the agreements between Apple and Publisher Defendants to strike the retail price MFN clauses as void and unenforceable; and

f. Award to Plaintiff its costs of this action and such other and further relief as may be appropriate and as the Court may deem just and proper.

Dated: April 11, 2012

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United States District Court for the Southern District of New York

United States Of America,

Plaintiff,

v.

Apple, Inc., *et al.,*

Defendants.

Civil Action No. 12–CV–2826 (DLC).
ECF Case.

Competitive Impact Statement

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act (''APPA'' or ''Tunney Act''), 15 U.S.C. 16(b)-(h), Plaintiff United States of America (''United States'') files this Competitive Impact Statement relating to the proposed Final Judgment against Defendants Verlagsgruppe George Von Holtzbrinck GmbH and Holtzbrinck Publishers, LLC d/b/a Macmillan (these two entities are referred to collectively herein as ''Macmillan''), submitted on February 8, 2013, for entry in this antitrust proceeding.

I. Nature and Purpose of the Proceeding

On April 11, 2012, the United States filed a civil antitrust Complaint alleging that Apple, Inc. (''Apple'') and five of the six largest publishers in the United States (''Publisher Defendants'') restrained competition in the sale of electronic books (''e-books''), in violation of Section 1 of the Sherman Act, 15 U.S.C. 1. Shortly after filing the Complaint, the United States filed a proposed final judgment (''Original Judgment'') with respect to Defendants Hachette Book Group, Inc. (''Hachette''), HarperCollins Publishers L.L.C. (''HarperCollins''), and Simon & Schuster, Inc. (''Simon & Schuster''). That Original Judgment (Docket No. 119) settled this suit as to those three defendants. Following a thorough Tunney Act review process, the Court granted the United States' Motion for Entry of the Original Judgment (Docket No. 113).

On December 18, 2012, Defendants The Penguin Group, a Division of Pearson plc, and Penguin Group (USA), Inc. (collectively ''Penguin'') agreed to settle on substantially the same terms as those contained in the Original Judgment. That proposed Final Judgment against Penguin (Docket No. 162–1) is now subject to a public comment period, which closes on March 5, 2013. Pursuant to the Court's January 7, 2013 Order (Docket No. 169), the United States will file the public comments along with its response to the comments by April 5, 2013. If the United States continues to believe that entry of the proposed Final Judgment

against Penguin is appropriate, it will move the Court for entry by April 19, 2013, and the Court will have the opportunity to determine if the proposed Final Judgment against Penguin is in the public interest.

Macmillan has now agreed to settle on substantially the same terms as those contained in the Original Judgment. A proposed Final Judgment with respect to Macmillan (''proposed Macmillan Final Judgment'' or ''PMFJ'') that embodies that settlement was filed today. The last remaining active Defendant is now Apple, Inc.

The proposed Macmillan Final Judgment is described in more detail in Section III below. Because the language of the proposed Macmillan Final Judgment closely follows the language of the Original Judgment, this Competitive Impact Statement incorporates but does not repeat the extensive record relating to the Original Judgment. (For the Court's convenience, redlines of the proposed Macmillan Final Judgment against both the Original Judgment and the proposed Penguin Final Judgment are attached as Exhibits A and B, respectively.)

The United States and Macmillan have stipulated that the proposed Macmillan Final Judgment may be entered after compliance with the APPA, unless the United States withdraws its consent. Entry of the proposed Macmillan Final Judgment would terminate this action as to Macmillan, except to the extent that Macmillan has stipulated that it will cooperate in the United States' ongoing litigation against Apple, and that this Court would retain jurisdiction to construe, modify, and enforce the proposed Macmillan Final Judgment and to punish violations thereof.

II. Brief Summary of the Events Giving Rise to the Alleged Violation of the Antitrust Laws

As described in detail in the United States' Complaint (Docket No. 1), and the two previous Competitive Impact Statements (''Original CIS,'' Docket No. 5 and ''Penguin CIS,'' Docket No. 163), Publisher Defendants desired to raise retail prices for e-books. Compl. ¶ 3. They were primarily upset by Amazon.com, Inc.'s (''Amazon's'') pricing of newly released and bestselling e-books at $9.99 or less. Compl. ¶¶ 32–34. Publisher Defendants feared that Amazon would resist any unilateral attempt to force an increase in e-book prices and that, even if an individual Publisher Defendant succeeded in such an attempt, that Publisher Defendant would lose sales to any competitors that had not forced the price of their books to supracompetitive levels. Compl. ¶¶ 35–36, 46. They met privately to discuss ways to collectively solve ''the $9.99 problem.'' Compl. ¶¶ 39–45. Ultimately, Publisher Defendants agreed to act collectively to raise retail e-book prices. Compl. ¶¶ 47–50.

Apple's entry into the e-book business provided a perfect opportunity to coordinate the Publisher Defendants' collective action to raise e-book prices. Compl. ¶ 51. At the suggestion of two Publisher Defendants, Apple began to consider selling e-books under an ''agency model,'' whereby the publishers would set the prices consumers ultimately paid for e-books and Apple would take a commission as the selling agent. Compl. ¶¶ 52–54, 63. Apple recognized that its unique ability to organize the Publisher Defendants' efforts to upset Amazon's $9.99 pricing put it in a position to realize margins (30 percent on each sale) far in excess of what other retailers then averaged on their sales of newly released and bestselling e-books, at the cost of ''the customer pay[ing] a little more.'' Compl. ¶ 56.

To achieve this goal, Apple first expressly proposed to each Publisher Defendant that it adopt an agency pricing model with every outlet that would compete with Apple for retail e-book sales, Compl. ¶ 58, and later replaced that express requirement with a unique most favored nation (''MFN'') pricing provision that effectively enforced the Publisher Defendants' commitment to impose the agency pricing model on all other retailers. Compl. ¶¶ 65–66. This MFN protected Apple from price competition from other retailers, guaranteeing that its 30 percent margin would not be disturbed. Compl. ¶ 65. Apple kept each Publisher Defendant informed about the status of its negotiations with other Publisher Defendants. Compl. ¶ 61. In January 2010, Apple sent to each Publisher Defendant substantively identical term sheets that Apple told them were devised after ''talking to all the other publishers.'' Compl. ¶¶ 62–64. Those term sheets formed the basis of the nearly identical agency agreements signed by each Publisher Defendant (''Apple Agency Agreements'').

The purpose of these agreements was to raise and stabilize e-book prices while insulating Apple from competition. Compl. ¶ 66. Apple CEO Steve Jobs explained to one Publisher Defendant that the Apple Agency Agreements provided a path for the Publisher Defendants away from $9.99 and to higher retail e-book prices. Compl. ¶ 71. He urged the Publisher Defendants to ''[t]hrow in with Apple and see if we can all make a go of this to create a real mainstream e-books market at $12.99 and $14.99.'' *Id.* Apple and the Publisher Defendants adopted these price points in all of the Apple Agency Agreements, which all were signed within a three-day span in January 2010. Compl. ¶¶ 74–75. As a result of Defendants' illegal agreement, consumers have paid higher prices for e-books than they would have paid in a market free of collusion. Compl. ¶¶ 90–93.

III. Explanation of the Proposed Macmillan Final Judgment

The language and relief contained in the proposed Macmillan Final Judgment is largely identical to the terms included in the Original Judgment and the proposed Penguin Final Judgment. Macmillan's decision to join with all the other Publisher Defendants in agreeing to the settlement terms will provide prompt, certain, and effective remedies that will continue the effort to restore competition to the marketplace. Settlement likely will lead to lower e-book prices for many Macmillan titles; prices for titles offered by HarperCollins, Hachette, and Simon & Schuster fell soon after those publishers entered into new contracts as a result of the Original Judgment.[2] The requirements and prohibitions included in the proposed Macmillan Final Judgment will eliminate Macmillan's illegal conduct, prevent recurrence of the same or similar conduct by Macmillan, and establish a robust antitrust compliance program.

A. Differences Between the Proposed Macmillan Final Judgment and the Original Judgment and the Proposed Penguin Final Judgment

Unlike the Original Judgment and the proposed Penguin Final Judgment, the

[2] *See, e.g.,* Scott Nichols, *HarperCollins Offering Discounted eBooks After Price Fixing Settlement,* TechRadar (Sept. 12, 2012), http://www.techradar.com/news/portable-devices/portable-media/harpercollins-offering-discounted-ebooks-after-price-fixing-settlement-1096467 (''Bestselling ebooks from the publisher such as 'The Fallen Angel' and 'Solo' can now be found for $9.99 on Amazon, Barnes and Noble, and other online retailers.''); Nate Hoffelder, *Hachette Has Dropped Agency Pricing on eBooks,* The Digital Reader (Dec. 4, 2012), http://www.the-digital-reader.com/2012/12/04/hachette-has-dropped-agency-pricing-on-ebooks/ (''Amazon is discounting the ebooks by $1 to $4 from the list price, and both Barnes & Noble and Apple are making similar discounts''); Jeremy Greenfield, *Simon & Schuster Has a New Deal With Amazon, Other Retailers,* Digital Book World (Dec. 9, 2012), http://www.digitalbookworld.com/2012/looks-like-simon-schuster-has-a-new-deal-with-amazon-other-retailers/ (''Ebook prices were lowered for Simon & Schuster titles over the weekend on sites like Amazon and Nook.com to levels several dollars below what they had been earlier in the week.'').

proposed Macmillan Final Judgment requires Macmillan immediately to stop enforcing restrictions on discounting or promotions contained in its contracts with retailers. The Original Judgment and the proposed Penguin Final Judgment allowed each settling publisher to choose whether to immediately allow discounting or, alternatively, to permit discounting only after the Court's approval of the settlement and the orderly termination of the publisher's existing contracts with retailers. Each Publisher Defendant under the Original Judgment and proposed Penguin Final Judgment chose the latter option and several months passed before consumers saw the benefits of the settlements through lower retail prices on many of the settling publishers' e-books. The two-year cooling-off period for those Publisher Defendants commenced when each terminated its previous contracts with retailers.

To provide for more prompt relief to consumers, the proposed Macmillan Final Judgment does not give Macmillan a choice. Macmillan must allow its e-book retailers to discount within three business days of agreeing to the settlement, even if it has not formalized new contracts with retailers. *See* PMFJ § IV.A. To induce Macmillan to accept this more stringent term, the United States agreed that the two-year cooling-off period for Macmillan would run from December 18, 2012, the date on which Penguin signed its settlement. *See* PMFJ §§ V.A–B. Consumers are better served by bringing more immediate retail price competition to the market, and, given the settlements of all the other Publisher Defendants, a 23-month cooling-off period is sufficient to ensure that future contracts entered into by these publishers will not be set under the collusive conditions that produced the Apple Agency Agreements.

The proposed Macmillan Final Judgment contains three other significant changes. First, at the time they agreed to settle with the United States, the other settling publishers each continued to operate under the Apple Agency Agreements that were the products of the Publisher Defendants' conspiracy with Apple. Because Macmillan has already terminated its Apple Agency Agreement and has entered a new Apple contract without an MFN, requiring Macmillan to terminate its existing contract with Apple would be superfluous. Second, the proposed Macmillan Final Judgment expressly carves out the sale of electronic versions of academic textbooks from its requirements and prohibitions. *See* PMFJ § II.D (defining the term ''e-book'' as used in the PMFJ to exclude ''the electronically formatted version of a book marketed solely for use in connection with academic coursework''). The conspiracy among the Publisher Defendants and Apple challenged in the Complaint concerned the sale of trade e-books, not e-book versions of academic textbooks. Compl. ¶¶ 27 n.1, 99. Unlike the other Publisher Defendants, which publish only trade e-books, Macmillan also publishes e-textbooks. Macmillan's settlement necessitates formalizing in the proposed Macmillan Final Judgment what the United States previously stated in its Response to Comments concerning the Original Judgment: '' 'e-books,' in the context of this case does not encompass '[n]on-trade e-books includ[ing] * * * academic textbooks * * *.' '' Response to Comments (Docket No. 81) at 46–47 (quoting Compl. ¶ 27 n.1). Third, to make it clear that Defendant Verlagsgruppe Georg von Holtzbrinck, Macmillan's German parent, would be subject to all provisions of the proposed Macmillan Final Judgment if it worked in concert with Macmillan to evade Macmillan's obligations under the settlement (*e.g.,* by having Macmillan transfer assets to its German parent), the Applicability section (PMFJ § III) now expressly binds Defendant Verlagsgruppe Georg von Holtzbrinck if it works with Macmillan in any such evasion.

For completeness, we describe below, in abbreviated form, the purposes of the other main provisions of the proposed Macmillan Final Judgment. These provisions mirror those of the Original Judgment and proposed Penguin Final Judgment.

B. Required Conduct (Section IV)

In order to reduce the risk that Macmillan may use future joint ventures to eliminate competition among Publisher Defendants, Section IV.C requires that Macmillan provide advance notice to the Department of Justice before forming or modifying a joint venture between it and another publisher related to e-books. *See also* Original CIS § III.A.2.

Additionally, to ensure Macmillan's compliance with the proposed Macmillan Final Judgment, Section IV.D requires that Macmillan provide, on a quarterly basis, each e-book agreement it has reached with any e-book retailer on or after January 1, 2012.

C. Prohibited Conduct (Section V)

In order to ensure that e-book retailers can compete on the price of e-books sold to consumers in the future, the proposed Macmillan Final Judgment also prohibits terms that prevent retail price competition. Sections V.A, V.B, and V.C limit Macmillan's ability to enter new agreements (and enforce old agreements) that contain either of two components of the Apple Agency Agreements: a ban on retailer discounting, or retail price-matching MFNs. Sections V.A. and V.B. prevent Macmillan, until December 18, 2014, from forbidding retailers to offer price promotions or discounts on its e-books. Prohibiting Macmillan, for a set period, from stopping e-book retailers from discounting will help ensure that Macmillan's future contracts will not be set under the collusive conditions that produced the Apple Agency Agreements. *See* PMFJ §§ V.A–B. For a five-year period, Section V.C also stops Macmillan from entering into an agreement with an e-book retailer that contains a Price MFN (defined as an MFN relating to price, revenue share, or commission available to any retailer). This will eliminate Macmillan's ability to use such MFNs to achieve, for a second time, the results of the collusive agreements. *See also* Original CIS § III.B.1.

Further, Macmillan may not retaliate against or punish an e-book retailer based on the retailer's e-book prices or its discounting or promotional choices. PMFJ § V.D. Nor may Macmillan attempt to retaliate by proxy, as this provision bars Macmillan from encouraging another company to retaliate against an e-book retailer on its behalf. However, the anti-retaliation provision does not prohibit Macmillan from unilaterally entering into and enforcing agency agreements with e-book retailers after the 23-month proscription, required in Sections V.A and V.B, has expired. *See also* Original CIS § III.B.2.

In addition to addressing terms used in the Apple Agency Agreements to implement the conspiracy, the proposed Macmillan Final Judgment also forbids a recurrence of the alleged conspiracy, and prohibits industry practices that facilitated it. Section V.E prohibits Macmillan from agreeing with e-book publishers to raise or set e-book retail prices or coordinate terms relating to the licensing, distribution, or sale of e-books. Section V.F likewise prohibits Macmillan from directly or indirectly conveying confidential or competitively sensitive information to any other e-book publisher. Banning such communications is critical here, where communications among publishing competitors were a common practice and facilitated the collusive agreement alleged in the Complaint. *See also* Original CIS § III.B.3.

D. Permitted Conduct (Section VI)

The proposed Macmillan Final Judgment also specifically carves out some conduct, which normally is permitted under the antitrust laws, that Macmillan may pursue unilaterally. Section VI.A of the proposed Macmillan Final Judgment allows Macmillan to compensate e-book retailers for services that they provide to publishers or consumers to help promote or sell more e-books. Section VI.B permits Macmillan to negotiate a commitment from an e-book retailer that a retailer's aggregate expenditure on discounts and promotions of Macmillan's e-books will not exceed the retailer's aggregate commission under an agency agreement in which Macmillan sets the e-book price and the retailer is compensated through a commission. These provisions allow Macmillan to prevent a retailer selling its entire catalogue at a sustained loss, while still permitting retailers to offer discounts under Sections V.A and V.B. Absent the collusion here, the antitrust laws normally would permit a publisher unilaterally to negotiate for such protections. *See also* Original CIS § III.C.

E. Antitrust Compliance (Section VII)

As outlined in Section VII, Macmillan also must designate an Antitrust Compliance Officer, who is required to distribute copies of the proposed Macmillan Final Judgment; ensure training related to the proposed Macmillan Final Judgment and the antitrust laws; certify compliance with the proposed Macmillan Final Judgment; and conduct an annual antitrust compliance audit. This compliance program is necessary considering the extensive communication among competitors' CEOs that facilitated Defendants' agreement. *See also* Original CIS § III.D.

IV. Alternatives to the Proposed Macmillan Final Judgment

The United States considered, as an alternative to the proposed Macmillan Final Judgment, a full trial on the merits against Macmillan. The United States believes that the relief contained in the proposed Macmillan Final Judgment will more quickly restore retail price competition to consumers.

V. Remedies Available to Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Macmillan Final Judgment will neither impair nor assist the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Macmillan Final Judgment has no *prima facie* effect in any subsequent private lawsuit that may be brought against the Defendants.

VI. Procedures Available for Modification of the Proposed Macmillan Final Judgment

The United States and Macmillan have stipulated that the proposed Macmillan Final Judgment may be entered by this Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry of the decree upon this Court's determination that the proposed Macmillan Final Judgment is in the public interest.

The APPA provides a period of at least sixty (60) days preceding the effective date of the proposed Macmillan Final Judgment within which any person may submit to the United States written comments regarding the proposed Macmillan Final Judgment. Any person who wishes to comment should do so within sixty (60) days of publication of this Competitive Impact Statement in the **Federal Register**, or the last date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later.

All comments received during this period will be considered by the United States Department of Justice, which remains free to withdraw its consent to the proposed Macmillan Final Judgment at any time prior to the Court's entry of judgment. The comments and the responses of the United States will be filed with the Court and published either in the **Federal Register** or, with the Court's permission, on the Department of Justice Web site.[3] Written comments should be submitted to: John Read, Chief, Litigation III Section, Antitrust Division, U.S. Department of Justice, 450 5th Street NW., Suite 4000, Washington, DC 20530.

The proposed Macmillan Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for modification, interpretation, or enforcement of the Final Judgment.

[3] The United States posts or links to all public materials submitted in relation to *United States* v. *Apple, Inc.* at: *http://www.justice.gov/atr/cases/applebooks.html.*

VII. Standard of Review Under the APPA for the Proposed Macmillan Final Judgment

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by the United States be subject to a sixty-day comment period, after which the court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the court is directed to consider:

> (A) The competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) The impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B); *see generally United States* v. *KeySpan Corp.,* 763 F. Supp. 2d 633, 637–38 (S.D.N.Y. 2011) (discussing Tunney Act standards); *United States* v. *SBC Commc'ns, Inc.,* 489 F. Supp. 2d 1 (D.DC 2007) (assessing standards for public interest determination).

In other words, under the Tunney Act, a court considers, among other things, the relationship between the remedy secured and the specific allegations set forth in the government's complaint, whether the decree is sufficiently clear, whether enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *See United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1458–62 (DC Cir. 1995). The court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *Id.* at 1461; *accord United States* v. *Alex. Brown & Sons, Inc.,* 963 F. Supp. 235, 238 (S.D.N.Y. 1997) (quoting *Microsoft,* 56 F.3d at 1460), *aff'd sub nom. United States* v. *Bleznak,* 153 F.3d 16 (2d Cir. 1998); *United States* v. *KeySpan,* 763 F. Supp. 2d at 637 (same). With respect to the adequacy of the relief secured by the decree, a court may not ''engage in an unrestricted evaluation of what relief would best serve the public.'' *United States* v. *BNS, Inc.,* 858 F.2d 456, 462

(9th Cir. 1988) (quoting *United States* v. *Bechtel Corp.,* 648 F.2d 660, 666 (9th Cir. 1981)); *see also Alex. Brown & Sons,* 963 F. Supp. at 238. Instead, the court should grant due respect to the United States' ''prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.'' *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.DC 2003). After all, the court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is ''*within the reaches of the public interest.*'' *Bechtel,* 648 F.2d at 666 (emphasis added) (citations omitted); *accord Alex. Brown,* 963 F. Supp. at 238.[4]

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Macmillan Final Judgment.

Dated: February 8, 2013

Respectfully submitted,

s/Mark W. Ryan
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Lawrence E. Buterman
Daniel McCuaig
Stephanie A. Fleming
Attorneys for the United States
United States Department of Justice
Antitrust Division
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Certificate of Service

I, Stephen T. Fairchild, hereby certify that on February 8, 2013, I caused a copy of the United States' Competitive Impact Statement to be served by the Electronic Case Filing System, which included the individuals listed below.

For Apple:	*For Penguin U.S.A. and the Penguin Group:*
Daniel S. Floyd Gibson, Dunn & Crutcher LLP 333 S. Grand Avenue, Suite 4600 Los Angeles, CA 90070 (213) 229–7148 *dfloyd@gibsondunn.com*	Daniel F. McInnis Akin Gump Strauss Hauer & Feld, LLP 1333 New Hampshire Avenue NW., Washington, DC 20036 (202) 887–4000 *dmcinnis@akingump.com* *For Simon & Schuster:* Yehudah Lev Buchweitz Weil, Gotshal & Manges LLP (NYC) 767 Fifth Avenue, 25th Fl. New York, NY 10153 (212) 310–8000 x8256 *yehudah.buchweitz@weil.com*
For Macmillan and Verlagsgruppe Georg Von Holtzbrinck GMBH: Joel M. Mitnick Sidley Austin LLP 787 Seventh Avenue New York, NY 10019 (212) 839–5300 *jmitnick@sidley.com* *For Hachette:* Walter B. Stuart, IV Freshfields Bruckhaus Deringer LLP 601 Lexington Avenue New York, NY 10022 (212) 277–4000 *walter.stuart@freshfields.com* *For HarperCollins:* Paul Madison Eckles Skadden, Arps, Slate, Meagher & Flom Four Times Square, 42nd Floor New York, NY 10036 (212) 735–2578 *pmeckles@skadden.com*	

Additionally, courtesy copies of this Competitive Impact Statement have been provided to the following:

For the State of Connecticut:	*For the State of Texas:*
W. Joseph Nielsen, Assistant Attorney General, Antitrust Division, Office of the Attorney General, 55 Elm Street, Hartford, CT 06106, (860) 808–5040, *Joseph.Nielsen@ct.gov* *For the Private Plaintiffs:*	Gabriel R. Gervey, Assistant Attorney General, Antitrust Division, Office of the Attorney General of Texas, 300 W. 15th Street, Austin, Texas 78701, (512) 463–1262, *gabriel.gervey@oag.state.tx.us*.

[4] *Cf. BNS,* 858 F.2d at 464 (holding that the court's ''ultimate authority under the [Tunney Act] is limited to approving or disapproving the consent decree''); *United States* v. *Gillette Co.,* 406 F. Supp. 713, 716 (D. Mass. 1975) (the court is constrained to ''look at the overall picture not hypercritically, nor with a microscope, but with an artist's reducing glass''). *See generally Microsoft,* 56 F.3d at 1461 (discussing whether ''the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest' '').

For the State of Connecticut:	*For the State of Texas:*
Jeff D. Friedman, Hagens Berman, 715 Hearst Ave., Suite 202, Berkeley, CA 94710, (510) 725–3000, *jefff@hbsslaw.com*	*s/Stephen T. Fairchild*, Stephen T. Fairchild, Attorney for the United States, United States Department of Justice, Antitrust Division, 450 Fifth Street NW., Suite 4000, Washington, DC 20530, (202) 532–4925, *stephen.fairchild@usdoj.gov*.

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EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

APPLE, INC., *et al.*,

~~HACHETTE BOOK GROUP, INC., HARPERCOLLINS PUBLISHERS L.L.C., VERLAGSGRUPPE GEORG VON HOLTZBRINCK GMBH, HOLTZBRINCK PUBLISHERS, LLC d/b/a MACMILLAN, THE PENGUIN GROUP, A DIVISION OF PEARSON PLC, PENGUIN GROUP (USA), INC., and SIMON & SCHUSTER, INC.,~~

Defendants.

Civil Action No. 1:12-CV-2826 (DLC)

ECF Case

~~Civil Action No.~~

[PROPOSED] FINAL JUDGMENT AS TO DEFENDANTS ~~HACHETTE, HARPERCOLLINS, AND SIMON & SCHUSTER~~

VERLAGSGRUPPE GEORG VON HOLTZBRINCK GMBH & HOLTZBRINCK PUBLISHERS, LLC D/B/A MACMILLAN

WHEREAS, Plaintiff, the United States of America filed its Complaint on April 11, 2012, alleging that Defendants conspired to raise retail prices of E-books in violation of Section 1 of the Sherman Act, as amended, 15 U.S.C. § 1, and Plaintiff and ~~Settling Defendants~~Macmillan, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

AND WHEREAS, this Final Judgment does not constitute any admission by ~~Settling Defendants~~Macmillan that the law has been violated or of any issue of fact or law, other than that the jurisdictional facts as alleged in the Complaint are true;

AND WHEREAS, ~~Settling Defendants agree~~Macmillan agrees to be bound by the provisions of this Final Judgment pending its approval by the Court;

AND WHEREAS, Plaintiff requires ~~Settling Defendants~~Macmillan to agree to undertake certain actions and refrain from certain conduct for the purpose of remedying the loss of competition alleged in the Complaint;

AND WHEREAS, ~~Settling Defendants have~~Macmillan has represented to the United States that the actions and conduct restrictions can and will be undertaken and that ~~they~~it will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the provisions contained below;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of ~~Settling Defendants~~Macmillan, it is ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

This Court has jurisdiction over the subject matter of this action and over ~~the Settling Defendants.~~Macmillan. The Complaint states a claim upon which relief may be granted against ~~Settling Defendants~~Macmillan under Section 1 of the Sherman Act, as amended, 15 U.S.C. § 1.

II. DEFINITIONS

As used in this Final Judgment:

A. "Agency Agreement" means an agreement between an E-book Publisher and an E-book Retailer under which the E-book Publisher Sells E-books to consumers through the E-book Retailer, which under the agreement acts as an agent of the E-book Publisher and is paid a commission in connection with the Sale of one or more of the E-book Publisher's E-books.

B. "Apple" means Apple, Inc., a California corporation with its principal place of business in Cupertino, California, its successors and assigns, and its parents, subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. "Department of Justice" means the Antitrust Division of the United States Department of Justice.

D. "E-book" means an electronically formatted book designed to be read on a computer, a handheld device, or other electronic devices capable of visually displaying E-books. For purposes of this Final Judgment, the term E-book does not include (1) an audio book, even if delivered and stored digitally; (2) a standalone specialized software application or "app" sold through an "app store" rather than through an e-book store (*e.g.*, through Apple's "App Store" rather than through its "iBookstore" or "iTunes") and not designed to be executed or read by or through a dedicated E-book reading device; ~~or~~ (3) a media file containing an electronically formatted book for which most of the value to consumers is derived from audio or video content contained in the file that is not included in the print version of the book; or (4) the electronically formatted version of a book marketed solely for use in connection with academic coursework.

E. "E-book Publisher" means any Person that, by virtue of a contract or other relationship with an E-book's author or other rights holder, owns or controls the necessary

copyright or other authority (or asserts such ownership or control) over any E-book sufficient to distribute the E-book within the United States to E-book Retailers and to permit such E-book Retailers to Sell the E-book to consumers in the United States. Publisher Defendants are E-book Publishers. For purposes of this Final Judgment, E-book Retailers are not E-book Publishers.

F. "E-book Retailer" means any Person that lawfully Sells (or seeks to lawfully Sell) E-books to consumers in the United States, or through which a Publisher Defendant, under an Agency Agreement, Sells E-books to consumers. For purposes of this Final Judgment, Publisher Defendants and all other Persons whose primary business is book publishing are not E-book Retailers.

G. "Hachette" means Hachette Book Group, Inc., a Delaware corporation with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

H. "HarperCollins" means HarperCollins Publishers L.L.C., a Delaware limited liability company with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

I. "Including" means including, but not limited to.

J. "Macmillan" means (1) Holtzbrinck Publishers, LLC d/b/a Macmillan, a New York limited liability company with its principal place of business in New York, New York, ("Holtzbrinck"), its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees; and (2)

Verlagsgruppe Georg von Holtzbrinck GmbH, a German corporation with its principal place of business in Stuttgart, Germany~~, their~~ ("VGvH"), its successors and assigns, and ~~their parents, subsidiaries,~~its divisions, groups, ~~affiliates,~~ and partnerships, and their directors, officers, managers, agents, and employees. Where the Final Judgment imposes an obligation on Macmillan to engage in or refrain from engaging in certain conduct, that obligation shall apply to Macmillan and to any joint venture or other business arrangement established by Macmillan and one or more Publisher Defendants.

K. "Penguin" means (1) Penguin Group (USA), Inc., a Delaware corporation with its principal place of business in New York, New York~~, and~~, (2) The Penguin Group, a division of ~~a~~ U.K. corporation Pearson ~~PLC~~plc with its principal place of business in London, England~~.~~; (3) The Penguin Publishing Company Ltd, a company registered in England and Wales with its principal place of business in London, England; and (4) Dorling Kindersley Holdings Limited, a company registered in England and Wales with its principal place of business in London, England; and each of their respective successors and assigns~~, and~~ (expressly including Penguin Random House, a joint venture by and between Pearson plc and Bertelsmann SE & Co. KGaA, and any similar joint venture between Penguin and Random House Inc.); each of their ~~parents,~~respective subsidiaries, divisions, groups, ~~affiliates,~~ and partnerships~~;~~ and each of their respective directors, officers, managers, agents, and employees.

L. "Person" means any natural person, corporation, company, partnership, joint venture, firm, association, proprietorship, agency, board, authority, commission, office, or other business or legal entity, whether private or governmental.

M. "Price MFN" means a term in an agreement between an E-book Publisher and an E-book Retailer under which

1. the Retail Price at which an E-book Retailer or, under an Agency Agreement, an E-book Publisher Sells one or more E-books to consumers depends in any way on the Retail Price, or discounts from the Retail Price, at which any other E-book Retailer or the E-book Publisher, under an Agency Agreement, through any other E-book Retailer Sells the same E-book(s) to consumers;

2. the Wholesale Price at which the E-book Publisher Sells one or more E-books to that E-book Retailer for Sale to consumers depends in any way on the Wholesale Price at which the E-book Publisher Sells the same E-book(s) to any other E-book Retailer for Sale to consumers; or

3. the revenue share or commission that E-book Retailer receives from the E-book Publisher in connection with the Sale of one or more E-books to consumers depends in any way on the revenue share or commission that (a) any other E-book Retailer receives from the E-book Publisher in connection with the Sale of the same E-book(s) to consumers, or (b) that E-book Retailer receives from any other E-book Publisher in connection with the Sale of one or more of the other E-book Publisher's E-books.

For purposes of this Final Judgment, it will not constitute a Price MFN under subsection 3 of this definition if ~~a Settling Defendant~~Macmillan agrees, at the request of an E-book Retailer, to meet more favorable pricing, discounts, or allowances offered to the E-book Retailer by another E-book Publisher for the period during which the other E-book Publisher provides that additional compensation, so long as that agreement is not or does not result from a pre-existing agreement that requires ~~the Settling Defendant~~Macmillan to meet all requests by the E-book Retailer for more favorable pricing within the terms of the agreement.

N. "Publisher Defendants" means Hachette, HarperCollins, Macmillan, Penguin, and Simon & Schuster. Where this Final Judgment imposes an obligation on Publisher Defendants to engage in or refrain from engaging in certain conduct, that obligation shall apply to each Publisher Defendant individually and to any joint venture or other business arrangement established by any two or more Publisher Defendants.

O. "Purchase" means a consumer's acquisition of one or more E-books as a result of a Sale.

P. "Retail Price" means the price at which an E-book Retailer or, under an Agency Agreement, an E-book Publisher Sells an E-book to a consumer.

Q. "Sale" means delivery of access to a consumer to read one or more E-books (purchased alone, or in combination with other goods or services) in exchange for payment; "Sell" or "Sold" means to make or to have made a Sale of an E-book to a consumer.

~~R. "Settling Defendants" means Hachette, HarperCollins, and Simon & Schuster. Where the Final Judgment imposes an obligation on Settling Defendants to engage in or refrain from engaging in certain conduct, that obligation shall apply to each Settling Defendant~~

~~individually and to any joint venture other business arrangement established by a Settling Defendant and one or more Publisher Defendants.~~

~~S.~~R. "Simon & Schuster" means Simon & Schuster, Inc., a New York corporation with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

~~T.~~S. "Wholesale Price" means (1) the net amount, after any discounts or other adjustments (not including promotional allowances subject to Section 2(d) of the Robinson-Patman Act, 15 U.S.C. § 13(d)), that an E-book Retailer pays to an E-book Publisher for an E-book that the E-book Retailer Sells to consumers; or (2) the Retail Price at which an E-book Publisher, under an Agency Agreement, Sells an E-book to consumers through an E-book Retailer minus the commission or other payment that E-book Publisher pays to the E-book Retailer in connection with or that is reasonably allocated to that Sale.

III. APPLICABILITY

This Final Judgment applies to ~~Settling Defendants~~Holtzbrinck and VGvH, acting individually or in concert, and all other Persons in active concert or participation with ~~any of them~~Holtzbrinck or VGvH who receive actual notice of this Final Judgment by personal service or otherwise.

IV. REQUIRED CONDUCT

~~A.~~ Within ~~seven~~three business days after Macmillan's stipulation to the entry of this Final Judgment, ~~each Settling Defendant~~Macmillan shall ~~terminate any~~ notify each E-book Retailer with which Holtzbrinck has an agreement ~~with Apple~~ relating to the Sale of E-books that ~~was executed prior to the filing of the Complaint.~~

A. ~~For each~~Holtzbrinck will no longer enforce any term or terms in any such agreement ~~between a Settling Defendant and an E-book Retailer other than Apple~~ that ~~(1) restricts, limits~~restrict, limit, or ~~impedes~~impede the E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books~~; or (2)~~, except to the extent consistent with Section VI.B of this Final Judgment.

B. For each agreement between Holtzbrinck and an E-book Retailer that contains a Price MFN, ~~the Settling Defendant~~Holtzbrinck shall notify the E-book Retailer~~,~~ within ~~ten~~three business days ~~of~~ after Macmillan's stipulation to the ~~filing~~entry of ~~the Complaint.~~this Final Judgment that the E-book Retailer may terminate the agreement with thirty-days notice and shall, thirty days after the E-book Retailer provides such notice, release the E-book Retailer from the agreement. For each such agreement that the E-book Retailer has not terminated within ~~thirty~~ten days after entry of this Final Judgment, ~~each Settling Defendant~~Holtzbrinck shall, as soon as permitted under the agreement, take each step required under the agreement to cause the agreement to be terminated and not renewed or extended.

C. ~~Settling Defendants~~Holtzbrinck shall notify the Department of Justice in writing at least sixty days in advance of the formation or material modification of any joint venture or other

business arrangement relating to the Sale, development, or promotion of E-books in the United States in which ~~a Settling Defendant~~Holtzbrinck and at least one other E-book Publisher (including another Publisher Defendant) are participants or partial or complete owners. Such notice shall describe the joint venture or other business arrangement, identify all E-book Publishers that are parties to it, and attach the most recent version or draft of the agreement, contract, or other document(s) formalizing the joint venture or other business arrangement. Within thirty days after ~~a Settling Defendant~~Holtzbrinck provides notification of the joint venture or business arrangement, the Department of Justice may make a written request for additional information. If the Department of Justice makes such a request, ~~the Settling Defendant~~Holtzbrinck shall not proceed with the planned formation or material modification of the joint venture or business arrangement until thirty days after substantially complying with such additional request(s) for information. The failure of the Department of Justice to request additional information or to bring an action under the antitrust laws to challenge the formation or material modification of the joint venture shall neither give rise to any inference of lawfulness nor limit in any way the right of the United States to investigate the formation, material modification, or any other aspects or activities of the joint venture or business arrangement and to bring actions to prevent or restrain violations of the antitrust laws.

The notification requirements of this Section IV.C shall not apply to ordinary course business arrangements between ~~a Publisher Defendant~~Holtzbrinck and another E-book Publisher (not a Publisher Defendant) that do not relate to the Sale of E-books to consumers, or to business arrangements the primary or predominant purpose or focus of which involves: (i) E-book Publishers co-publishing one or more specifically identified E-book titles or a particular author's

E-books; (ii) ~~a Settling Defendant~~Holtzbrinck licensing to or from another E-book Publisher the publishing rights to one or more specifically identified E-book titles or a particular author's E-books; (iii) ~~a Settling Defendant~~Holtzbrinck providing technology services to or receiving technology services from another E-book Publisher (not a Publisher Defendant) or licensing rights in technology to or from another E-book Publisher; or (iv) ~~a Settling Defendant~~Holtzbrinck distributing E-books published by another E-book Publisher (not a Publisher Defendant).

D. ~~Each Settling Defendant~~Macmillan shall furnish to the Department of Justice (1) ~~within seven days after entry of this Final Judgment~~by February 15, 2013, one complete copy of each agreement, executed, renewed, or extended on or after January 1, 2012, between ~~the Settling Defendant~~Holtzbrinck and any E-book Retailer relating to the Sale of E-books, and, (2) thereafter, on a quarterly basis, each such agreement executed, renewed, or extended since ~~the Settling Defendant's~~Macmillan's previous submission of agreements to the Department of Justice.

V. PROHIBITED CONDUCT

A. ~~For two years, Settling Defendants~~Until December 18, 2014, Holtzbrinck shall not restrict, limit, or impede an E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books~~, such two-year period to run separately for each E-book Retailer, at the option of the Settling Defendant, from either:~~,

~~1. the termination of an agreement between the Settling Defendant and the E-book Retailer that restricts, limits, or impedes the E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books; or~~

~~2. the date on which the Settling Defendant notifies the E-book Retailer in writing that the Settling Defendant will not enforce any term(s) in its agreement with the E-book Retailer that restrict, limit, or impede the E-book Retailer from setting, altering, or reducing the Retail Price of one or more E-books, or from offering price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books.~~

~~Each Settling Defendant shall notify the Department of Justice of the option it selects for each E-book Retailer within seven days of making its selection.~~

B. ~~For two years after the filing of the Complaint, Settling Defendants~~Until December 18, 2014, Holtzbrinck shall not enter into any agreement with any E-book Retailer that restricts, limits, or impedes the E-book Retailer from setting, altering, or reducing the Retail Price of one or more E-books, or from offering price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books.

C. ~~Settling Defendants~~Holtzbrinck shall not enter into any agreement with an E-book Retailer relating to the Sale of E-books that contains a Price MFN.

D. ~~Settling Defendants~~Macmillan shall not retaliate against, or urge any other E-book Publisher or E-book Retailer to retaliate against, an E-book Retailer for engaging in any activity that ~~the Settling Defendants are~~Holtzbrinck is prohibited by Sections V.A, V.B, and VI.B.2 of this Final Judgment from restricting, limiting, or impeding in any agreement with an E-book Retailer. After the expiration of prohibitions in Sections V.A and V.B of this Final Judgment, this Section V.D shall not prohibit ~~any Settling Defendant~~Holtzbrinck from unilaterally entering into or enforcing any agreement with an E-book Retailer that restricts, limits, or impedes the E-book Retailer from setting, altering, or reducing the Retail Price of any of ~~the Settling~~

~~Defendant's~~Holtzbrinck's E-books or from offering price discounts or any other form of promotions to encourage consumers to Purchase any of ~~the Settling Defendant's~~Holtzbrinck's E-books.

E. ~~Settling Defendants~~Holtzbrinck shall not enter into or enforce any agreement, arrangement, understanding, plan, program, combination, or conspiracy with any E-book Publisher (including another Publisher Defendant) to raise, stabilize, fix, set, or coordinate the Retail Price or Wholesale Price of any E-book or fix, set, or coordinate any term or condition relating to the Sale of E-books.

This Section V.E shall not prohibit ~~a Settling Defendant~~Holtzbrinck from entering into and enforcing agreements relating to the distribution of another E-book Publisher's E-books (not including the E-books of another Publisher Defendant) or to the co-publication with another E-book Publisher of specifically identified E-book titles or a particular author's E-books, or from participating in output-enhancing industry standard-setting activities relating to E-book security or technology.

F. ~~A Settling Defendant (including~~Holtzbrinck (and each officer of ~~each parent of the Settling Defendant~~VGvH who exercises direct control over ~~the Settling Defendant's~~Holtzbrinck's business decisions or strategies) shall not convey or otherwise communicate, directly or indirectly (including by communicating indirectly through an E-book Retailer with the intent that the E-book Retailer convey information from the communication to another E-book Publisher or knowledge that it is likely to do so), to any other E-book Publisher (including to an officer of a parent of a Publisher Defendant) any competitively sensitive information, including:

1. its business plans or strategies;

2. its past, present, or future wholesale or retail prices or pricing strategies for books sold in any format (*e.g.*, print books, E-books, or audio books);

3. any terms in its agreement(s) with any retailer of books Sold in any format; or

4. any terms in its agreement(s) with any author.

This Section V.F shall not prohibit ~~a Settling Defendant~~Holtzbrinck from communicating (a) in a manner and through media consistent with common and reasonable industry practice, the cover prices or wholesale or retail prices of books sold in any format to potential purchasers of those books; or (b) information ~~the Settling Defendant~~Holtzbrinck needs to communicate in connection with (i) its enforcement or assignment of its intellectual property or contract rights, (ii) a contemplated merger, acquisition, or purchase or sale of assets, (iii) its distribution of another E-book Publisher's E-books, or (iv) a business arrangement under which E-book Publishers agree to co-publish, or an E-book Publisher agrees to license to another E-book Publisher the publishing rights to, one or more specifically identified E-book titles or a particular author's E-books.

VI. PERMITTED CONDUCT

A. Nothing in this Final Judgment shall prohibit ~~a Settling Defendant~~Macmillan unilaterally from compensating a retailer, including an E-book Retailer, for valuable marketing or other promotional services rendered.

B. Notwithstanding Sections V.A and V.B of this Final Judgment, ~~a Settling Defendant~~Holtzbrinck may enter into Agency Agreements with E-book Retailers under which the aggregate dollar value of the price discounts or any other form of promotions to encourage consumers to Purchase one or more of ~~the Settling Defendant's~~Holtzbrinck's E-books (as opposed

to advertising or promotions engaged in by the E-book Retailer not specifically tied or directed to ~~the Settling Defendant's~~Holtzbrinck's E-books) is restricted; *provided that* (1) such agreed restriction shall not interfere with the E-book Retailer's ability to reduce the final price paid by consumers to purchase ~~the Settling Defendant's~~Holtzbrinck's E-books by an aggregate amount equal to the total commissions ~~the Settling Defendant~~Holtzbrinck pays to the E-book Retailer, over a period of at least one year, in connection with the Sale of ~~the Settling Defendant's~~Holtzbrinck's E-books to consumers; (2) ~~the Settling Defendant~~Holtzbrinck shall not restrict, limit, or impede the E-book Retailer's use of the agreed funds to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books; and (3) the method of accounting for the E-book Retailer's promotional activity does not restrict, limit, or impede the E-book Retailer from engaging in any form of retail activity or promotion.

VII. ANTITRUST COMPLIANCE

Within thirty days after entry of this Final Judgment, ~~each Settling Defendant~~Macmillan shall designate ~~its~~Holtzbrinck's general counsel or chief legal officer, or an employee reporting directly to its general counsel or chief legal officer, as Antitrust Compliance Officer with responsibility for ensuring ~~the Settling Defendant's~~Macmillan's compliance with this Final Judgment. The Antitrust Compliance Officer shall be responsible for the following:

A. furnishing a copy of this Final Judgment, within thirty days of its entry, to each of ~~the Settling Defendant's~~Holtzbrinck's officers and directors, ~~and~~ to each of ~~the Settling Defendant's~~Holtzbrinck's employees engaged, in whole or in part, in the distribution or Sale of E-books, and to each of VGvH's officers, directors, or employees involved in the development of Holtzbrinck's plans or strategies relating to E-books;

B. furnishing a copy of this Final Judgment in a timely manner to each officer, director, or employee who succeeds to any position identified in Section VII.A of this Final Judgment;

C. ensuring that each person identified in Sections VII.A and VII.B of this Final Judgment receives at least four hours of training annually on the meaning and requirements of this Final Judgment and the antitrust laws, such training to be delivered by an attorney with relevant experience in the field of antitrust law;

D. obtaining, within sixty days after entry of this Final Judgment and on each anniversary of the entry of this Final Judgment, from each person identified in Sections VII.A and VII.B of this Final Judgment, and thereafter maintaining, a certification that each such person (a) has read, understands, and agrees to abide by the terms of this Final Judgment; and (b) is not aware of any violation of this Final Judgment or the antitrust laws or has reported any potential violation to the Antitrust Compliance Officer;

E. conducting an annual antitrust compliance audit covering each person identified in Sections VII.A and VII.B of this Final Judgment, and maintaining all records pertaining to such audits;

F. communicating annually to ~~the Settling Defendant's employees~~Holtzbrinck's employees and to all VGvH employees identified in Sections VII.A and VII.B of this Final Judgment that they may disclose to the Antitrust Compliance Officer, without reprisal, information concerning any potential violation of this Final Judgment or the antitrust laws;

G. taking appropriate action, within three business days of discovering or receiving credible information concerning an actual or potential violation of this Final Judgment, to

terminate or modify ~~the Settling Defendant's~~Macmillan's conduct to assure compliance with this Final Judgment; and, within seven days of taking such corrective actions, providing to the Department of Justice a description of the actual or potential violation of this Final Judgment and the corrective actions taken;

H. furnishing to the Department of Justice on a quarterly basis electronic copies of any non-privileged communications with any Person containing allegations of ~~Settling Defendants'~~Macmillan's noncompliance with any provisions of this Final Judgment;

I. maintaining, and furnishing to the Department of Justice on a quarterly basis, a log of all oral and written communications, excluding privileged or public communications, between or among (1) any of ~~the Settling Defendant's~~Macmillan's officers, directors, or employees involved in the development of ~~the Settling Defendant's~~Holtzbrinck's plans or strategies relating to E-books, and (2) any person employed by or associated with another Publisher Defendant, relating, in whole or in part, to the –distribution or sale in the United States of books sold in any format, including an identification (by name, employer, and job title) of the author and recipients of and all participants in the communication, the date, time, and duration of the communication, the medium of the communication, and a description of the subject matter of the communication (for a collection of communications solely concerning a single business arrangement that is specifically exempted from the reporting requirements of Section IV.C of this Final Judgment, ~~the Settling Defendant~~Macmillan may provide a summary of the communications rather than logging each communication individually); and

J. providing to the Department of Justice annually, on or before the anniversary of the entry of this Final Judgment, a written statement as to the fact and manner of ~~the Settling Defendant's~~Macmillan's compliance with Sections IV, V, and VII of this Final Judgment.

VIII. COMPLIANCE INSPECTION

A. For purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time duly authorized representatives of the Department of Justice, including consultants and other persons retained by the Department of Justice, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to ~~Settling Defendants~~Macmillan, be permitted:

1. access during ~~the Settling Defendants'~~Macmillan's office hours to inspect and copy, or at the option of the United States, to require ~~Settling Defendants~~Macmillan to provide to the United States hard copy or electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of ~~Settling Defendants~~Macmillan, relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, ~~the Settling Defendants'~~Macmillan's officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by ~~Settling Defendants~~Macmillan.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, ~~Settling Defendants~~Macmillan shall submit written reports or respond to written interrogatories, under oath if requested, relating to any of the matters

contained in this Final Judgment as may be requested. Written reports authorized under this paragraph may, in the sole discretion of the United States, require ~~Settling Defendants~~Macmillan to conduct, at their cost, an independent audit or analysis relating to any of the matters contained in this Final Judgment.

C. No information or documents obtained by the means provided in this Section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by ~~a Settling Defendant~~Macmillan to the United States, ~~the Settling Defendant~~Macmillan represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and ~~the Settling Defendant~~Macmillan marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure," then the United States shall give ~~the Settling Defendant~~Macmillan ten calendar days notice prior to divulging such material in any civil or administrative proceeding.

IX. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any party to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

X. NO LIMITATION ON GOVERNMENT RIGHTS

Nothing in this Final Judgment shall limit the right of the United States to investigate and bring actions to prevent or restrain violations of the antitrust laws concerning any past, present, or future conduct, policy, or practice of ~~the Settling Defendants.~~Macmillan.

XI. EXPIRATION OF FINAL JUDGMENT

Unless this Court grants an extension, this Final Judgment shall expire five years from the date of its entry.

XII. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

Court approval subject to procedures set forth in the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16

_____

United States District Judge

EXHIBIT B

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. APPLE, INC., *et al.*, Defendants.	Civil Action No. 1:12-CV-2826 (DLC) ECF Case

[PROPOSED] FINAL JUDGMENT AS TO DEFENDANTS ~~THE PENGUIN GROUP, A DIVISION OF PEARSON PLC, AND PENGUIN GROUP (USA), INC.~~ VERLAGSGRUPPE GEORG VON HOLTZBRINCK GMBH & HOLTZBRINCK PUBLISHERS, LLC D/B/A MACMILLAN

WHEREAS, Plaintiff, the United States of America filed its Complaint on April 11, 2012, alleging that Defendants conspired to raise retail prices of E-books in violation of Section 1 of the Sherman Act, as amended, 15 U.S.C. § 1, and Plaintiff and ~~Penguin~~Macmillan, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

AND WHEREAS, this Final Judgment does not constitute any admission by ~~Penguin~~Macmillan that the law has been violated or of any issue of fact or law, other than that the jurisdictional facts as alleged in the Complaint are true;

AND WHEREAS, ~~Penguin~~Macmillan agrees to be bound by the provisions of this Final Judgment pending its approval by the Court;

AND WHEREAS, Plaintiff requires ~~Penguin~~Macmillan to agree to undertake certain actions and refrain from certain conduct for the purpose of remedying the loss of competition alleged in the Complaint;

AND WHEREAS, ~~Penguin~~Macmillan has represented to the United States that the actions and conduct restrictions can and will be undertaken and that it will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the provisions contained below;

NOW THEREFORE, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of ~~Penguin~~Macmillan, it is ORDERED, ADJUDGED, AND DECREED:

I. JURISDICTION

This Court has jurisdiction over the subject matter of this action and over ~~Penguin~~Macmillan. The Complaint states a claim upon which relief may be granted against ~~Penguin~~Macmillan under Section 1 of the Sherman Act, as amended, 15 U.S.C. § 1.

II. DEFINITIONS

As used in this Final Judgment:

A. "Agency Agreement" means an agreement between an E-book Publisher and an E-book Retailer under which the E-book Publisher Sells E-books to consumers through the E-book Retailer, which under the agreement acts as an agent of the E-book Publisher and is paid a commission in connection with the Sale of one or more of the E-book Publisher's E-books.

B. "Apple" means Apple, Inc., a California corporation with its principal place of business in Cupertino, California, its successors and assigns, and its parents, subsidiaries,

divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. "Department of Justice" means the Antitrust Division of the United States Department of Justice.

D. "E-book" means an electronically formatted book designed to be read on a computer, a handheld device, or other electronic devices capable of visually displaying E-books. For purposes of this Final Judgment, the term E-book does not include (1) an audio book, even if delivered and stored digitally; (2) a standalone specialized software application or "app" sold through an "app store" rather than through an e-book store (*e.g.*, through Apple's "App Store" rather than through its "iBookstore" or "iTunes") and not designed to be executed or read by or through a dedicated E-book reading device; ~~or~~ (3) a media file containing an electronically formatted book for which most of the value to consumers is derived from audio or video content contained in the file that is not included in the print version of the book; or (4) the electronically formatted version of a book marketed solely for use in connection with academic coursework.

E. "E-book Publisher" means any Person that, by virtue of a contract or other relationship with an E-book's author or other rights holder, owns or controls the necessary copyright or other authority (or asserts such ownership or control) over any E-book sufficient to distribute the E-book within the United States to E-book Retailers and to permit such E-book Retailers to Sell the E-book to consumers in the United States. Publisher Defendants are E-book Publishers. For purposes of this Final Judgment, E-book Retailers are not E-book Publishers.

F. "E-book Retailer" means any Person that lawfully Sells (or seeks to lawfully Sell) E-books to consumers in the United States, or through which a Publisher Defendant, under an

Agency Agreement, Sells E-books to consumers. For purposes of this Final Judgment, Publisher Defendants and all other Persons whose primary business is book publishing are not E-book Retailers.

G. "Hachette" means Hachette Book Group, Inc., a Delaware corporation with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

H. "HarperCollins" means HarperCollins Publishers L.L.C., a Delaware limited liability company with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

I. "Including" means including, but not limited to.

J. "Macmillan" means (1) Holtzbrinck Publishers, LLC d/b/a Macmillan, a New York limited liability company with its principal place of business in New York, New York ("Holtzbrinck"), its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees; and (2) Verlagsgruppe Georg von Holtzbrinck GmbH, a German corporation with its principal place of business in Stuttgart, Germany ~~their~~ ("VGvH"), its successors and assigns, and ~~their parents, subsidiaries,~~ its divisions, groups, ~~affiliates,~~ and partnerships, and their directors, officers, managers, agents, and employees. Where the Final Judgment imposes an obligation on Macmillan to engage in or refrain from engaging in certain conduct, that obligation shall apply to

Macmillan and to any joint venture or other business arrangement established by Macmillan and one or more Publisher Defendants.

K. "Penguin" means (1) Penguin Group (USA), Inc., a Delaware corporation with its principal place of business in New York, New York; (2) The Penguin Group, a division of U.K. corporation Pearson plc with its principal place of business in London, England; (3) The Penguin Publishing Company Ltd, a company registered in England and Wales with its principal place of business in London, England; and (4) Dorling Kindersley Holdings Limited, a company registered in England and Wales with its principal place of business in London, England; and each of their respective successors and assigns (expressly including Penguin Random House, a joint venture by and between Pearson plc and Bertelsmann SE & Co. KGaA, and any similar joint venture between Penguin and Random House Inc.); each of their respective subsidiaries, divisions, groups, partnerships, and each of their respective directors, officers, managers, agents, and employees. Where Section IV.A, IV.B, IV.D, or VII imposes an obligation on Penguin to engage in certain conduct by either a date certain or by a specified day after entry of this Final Judgment, any successor or assign whose acquisition of or combination or other relationship with Penguin is consummated after entry of this Final Judgment shall meet each such obligation within thirty days after consummation. The prohibitions of Section V.A of this Final Judgment shall expire for any successor or assign of Penguin on the dates on which such prohibitions would have expired for Penguin had the acquisition, combination, or other relationship not occurred. Where the Final Judgment imposes an obligation on Penguin to engage in or refrain from engaging in certain conduct, that obligation shall apply to Penguin and to any joint venture or other business

~~arrangement established by Penguin and one or more Publisher Defendants~~and partnerships; and each of their respective directors, officers, managers, agents, and employees.

~~L. "Penguin Random House" means the joint venture entities, which will operate under the name "Penguin Random House," that will be formed pursuant to the Contribution Agreement, dated October 29, 2012, by and between Pearson plc and Bertelsmann SE & Co. KGaA.~~

~~M.~~I. "Person" means any natural person, corporation, company, partnership, joint venture, firm, association, proprietorship, agency, board, authority, commission, office, or other business or legal entity, whether private or governmental.

~~N.~~M. "Price MFN" means a term in an agreement between an E-book Publisher and an E-book Retailer under which

1. the Retail Price at which an E-book Retailer or, under an Agency Agreement, an E-book Publisher Sells one or more E-books to consumers depends in any way on the Retail Price, or discounts from the Retail Price, at which any other E-book Retailer or the E-book Publisher, under an Agency Agreement, through any other E-book Retailer Sells the same E-book(s) to consumers;

2. the Wholesale Price at which the E-book Publisher Sells one or more E-books to that E-book Retailer for Sale to consumers depends in any way on the Wholesale Price at which the E-book Publisher Sells the same E-book(s) to any other E-book Retailer for Sale to consumers; or

3. the revenue share or commission that E-book Retailer receives from the E-book Publisher in connection with the Sale of one or more E-books to consumers depends in any

way on the revenue share or commission that (a) any other E-book Retailer receives from the E-book Publisher in connection with the Sale of the same E-book(s) to consumers, or (b) that E-book Retailer receives from any other E-book Publisher in connection with the Sale of one or more of the other E-book Publisher's E-books.

For purposes of this Final Judgment, it will not constitute a Price MFN under subsection 3 of this definition if ~~Penguin~~Macmillan agrees, at the request of an E-book Retailer, to meet more favorable pricing, discounts, or allowances offered to the E-book Retailer by another E-book Publisher for the period during which the other E-book Publisher provides that additional compensation, so long as that agreement is not or does not result from a pre-existing agreement that requires ~~Penguin~~Macmillan to meet all requests by the E-book Retailer for more favorable pricing within the terms of the agreement.

~~O.~~N. "Publisher Defendants" means Hachette, HarperCollins, Macmillan, Penguin, and Simon & Schuster. Where this Final Judgment imposes an obligation on Publisher Defendants to engage in or refrain from engaging in certain conduct, that obligation shall apply to each Publisher Defendant individually and to any joint venture or other business arrangement established by any two or more Publisher Defendants.

~~P.~~O. "Purchase" means a consumer's acquisition of one or more E-books as a result of a Sale.

~~Q.~~P. "Retail Price" means the price at which an E-book Retailer or, under an Agency Agreement, an E-book Publisher Sells an E-book to a consumer.

R.Q. "Sale" means delivery of access to a consumer to read one or more E-books (purchased alone, or in combination with other goods or services) in exchange for payment; "Sell" or "Sold" means to make or to have made a Sale of an E-book to a consumer.

S.R. "Simon & Schuster" means Simon & Schuster, Inc., a New York corporation with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

T.S. "Wholesale Price" means (1) the net amount, after any discounts or other adjustments (not including promotional allowances subject to Section 2(d) of the Robinson-Patman Act, 15 U.S.C. § 13(d)), that an E-book Retailer pays to an E-book Publisher for an E-book that the E-book Retailer Sells to consumers; or (2) the Retail Price at which an E-book Publisher, under an Agency Agreement, Sells an E-book to consumers through an E-book Retailer minus the commission or other payment that E-book Publisher pays to the E-book Retailer in connection with or that is reasonably allocated to that Sale.

III. APPLICABILITY

This Final Judgment applies to PenguinHoltzbrinck and VGvH, acting individually or in concert, and all other Persons in active concert or participation with PenguinHoltzbrinck or VGvH who receive actual notice of this Final Judgment by personal service or otherwise.

IV. REQUIRED CONDUCT

A. Within seventhree business days after entry of this Final Judgment, Penguin shall terminate any agreement with Apple relating to the Sale of E-books that was executed prior to Penguin'sMacmillan's stipulation to the entry of this Final Judgment.

A. ~~For,~~ Macmillan shall notify each ~~agreement between Penguin and an~~ E-book Retailer ~~other than Apple~~ with which Holtzbrinck has an agreement relating to the Sale of E-books that Holtzbrinck will no longer enforce any term or terms in any such agreement that ~~(1) restricts, limits~~restrict, limit, or ~~impedes~~impede the E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books~~, or (2)~~, except to the extent consistent with Section VI.B of this Final Judgment.

B. For each agreement between Holtzbrinck and an E-book Retailer that contains a Price MFN, ~~Penguin~~Holtzbrinck shall notify the E-book Retailer~~, by January 8, 2013,~~ within three business days after Macmillan's stipulation to the entry of this Final Judgment that the E-book Retailer may terminate the agreement with thirty-days notice and shall, thirty days after the E-book Retailer provides such notice, release the E-book Retailer from the agreement. For each such agreement that the E-book Retailer has not terminated within ten days after entry of this Final Judgment, ~~Penguin~~Holtzbrinck shall, as soon as permitted under the agreement, take each step required under the agreement to cause the agreement to be terminated and not renewed or extended.

C. ~~Penguin~~Holtzbrinck shall notify the Department of Justice in writing at least sixty days in advance of the formation or material modification of any joint venture or other business arrangement relating to the Sale, development, or promotion of E-books in the United States in which ~~Penguin~~Holtzbrinck and at least one other E-book Publisher (including another Publisher Defendant) are participants or partial or complete owners. Such notice shall describe the joint venture or other business arrangement, identify all E-book Publishers that are parties to it, and

attach the most recent version or draft of the agreement, contract, or other document(s) formalizing the joint venture or other business arrangement. Within thirty days after ~~Penguin~~Holtzbrinck provides notification of the joint venture or business arrangement, the Department of Justice may make a written request for additional information. If the Department of Justice makes such a request, ~~Penguin~~Holtzbrinck shall not proceed with the planned formation or material modification of the joint venture or business arrangement until thirty days after substantially complying with such additional request(s) for information. The failure of the Department of Justice to request additional information or to bring an action under the antitrust laws to challenge the formation or material modification of the joint venture shall neither give rise to any inference of lawfulness nor limit in any way the right of the United States to investigate the formation, material modification, or any other aspects or activities of the joint venture or business arrangement and to bring actions to prevent or restrain violations of the antitrust laws.

The notification requirements of this Section IV.C shall not apply to ordinary course business arrangements between ~~Penguin~~Holtzbrinck and another E-book Publisher (not a Publisher Defendant) that do not relate to the Sale of E-books to consumers, or to business arrangements the primary or predominant purpose or focus of which involves: (i) E-book Publishers co-publishing one or more specifically identified E-book titles or a particular author's E-books; (ii) ~~Penguin~~Holtzbrinck licensing to or from another E-book Publisher the publishing rights to one or more specifically identified E-book titles or a particular author's E-books; (iii) ~~Penguin~~Holtzbrinck providing technology services to or receiving technology services from another E-book Publisher (not a Publisher Defendant) or licensing rights in technology to or from another E-book Publisher; or (iv) ~~Penguin~~Holtzbrinck distributing E-books published by another

E-book Publisher (not a Publisher Defendant). ~~The notification requirements of this Section IV.C shall also not apply to the formation of Penguin Random House, review of which is pending before the Department of Justice.~~

D. ~~Penguin~~Macmillan shall furnish to the Department of Justice (1) by ~~January 8~~February 15, 2013, one complete copy of each agreement, executed, renewed, or extended on or after January 1, 2012, between ~~Penguin~~Holtzbrinck and any E-book Retailer relating to the Sale of E-books, and, (2) thereafter, on a quarterly basis, each such agreement executed, renewed, or extended since ~~Penguin's~~Macmillan's previous submission of agreements to the Department of Justice.

V. PROHIBITED CONDUCT

A. ~~For two years, Penguin~~Until December 18, 2014, Holtzbrinck shall not restrict, limit, or impede an E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books~~, such two-year period to run separately for each E-book Retailer, at Penguin's option, from either:~~

~~1. the termination of an agreement between Penguin and the E-book Retailer that restricts, limits, or impedes the E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books; or~~

~~2. the date on which Penguin notifies the E-book Retailer in writing that Penguin will not enforce any term(s) in its agreement with the E-book Retailer that restrict, limit, or impede the E-book Retailer from setting, altering, or reducing the Retail Price of one or more~~

~~E-books, or from offering price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books.~~

~~Penguin shall notify the Department of Justice of the option it selects for each E-book Retailer within seven days of making its selection.~~

B. ~~For two years after Penguin's stipulation to the entry of this Final Judgment,~~ ~~Penguin~~Until December 18, 2014, Holtzbrinck shall not enter into any agreement with any E-book Retailer that restricts, limits, or impedes the E-book Retailer from setting, altering, or reducing the Retail Price of one or more E-books, or from offering price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books.

C. ~~Penguin~~Holtzbrinck shall not enter into any agreement with an E-book Retailer relating to the Sale of E-books that contains a Price MFN.

D. ~~Penguin~~Macmillan shall not retaliate against, or urge any other E-book Publisher or E-book Retailer to retaliate against, an E-book Retailer for engaging in any activity that ~~Penguin~~Holtzbrinck is prohibited by Sections V.A, V.B, and VI.B.2 of this Final Judgment from restricting, limiting, or impeding in any agreement with an E-book Retailer. After the expiration of prohibitions in Sections V.A and V.B of this Final Judgment, this Section V.D shall not prohibit ~~Penguin~~Holtzbrinck from unilaterally entering into or enforcing any agreement with an E-book Retailer that restricts, limits, or impedes the E-book Retailer from setting, altering, or reducing the Retail Price of any of ~~Penguin's~~Holtzbrinck's E-books or from offering price discounts or any other form of promotions to encourage consumers to Purchase any of ~~Penguin's~~Holtzbrinck's E-books.

E. ~~Penguin~~Holtzbrinck shall not enter into or enforce any agreement, arrangement, understanding, plan, program, combination, or conspiracy with any E-book Publisher (including another Publisher Defendant) to raise, stabilize, fix, set, or coordinate the Retail Price or Wholesale Price of any E-book or fix, set, or coordinate any term or condition relating to the Sale of E-books.

This Section V.E shall not prohibit ~~Penguin~~Holtzbrinck from entering into and enforcing agreements relating to the distribution of another E-book Publisher's E-books (not including the E-books of another Publisher Defendant) or to the co-publication with another E-book Publisher of specifically identified E-book titles or a particular author's E-books, or from participating in output-enhancing industry standard-setting activities relating to E-book security or technology.

F. ~~Penguin (including~~Holtzbrinck (and each officer of ~~each parent of Penguin~~VGvH who exercises direct control over ~~Penguin's~~Holtzbrinck's business decisions or strategies) shall not convey or otherwise communicate, directly or indirectly (including by communicating indirectly through an E-book Retailer with the intent that the E-book Retailer convey information from the communication to another E-book Publisher or knowledge that it is likely to do so), to any other E-book Publisher (including to an officer of a parent of a Publisher Defendant) any competitively sensitive information, including:

1. its business plans or strategies;

2. its past, present, or future wholesale or retail prices or pricing strategies for books sold in any format (*e.g.*, print books, E-books, or audio books);

3. any terms in its agreement(s) with any retailer of books Sold in any format; or

4. any terms in its agreement(s) with any author.

This Section V.F shall not prohibit ~~Penguin~~Holtzbrinck from communicating (a) in a manner and through media consistent with common and reasonable industry practice, the cover prices or wholesale or retail prices of books sold in any format to potential purchasers of those books; or (b) information ~~Penguin~~Holtzbrinck needs to communicate in connection with (i) its enforcement or assignment of its intellectual property or contract rights, (ii) a contemplated merger, acquisition, or purchase or sale of assets, (iii) its distribution of another E-book Publisher's E-books, or (iv) a business arrangement under which E-book Publishers agree to co-publish, or an E-book Publisher agrees to license to another E-book Publisher the publishing rights to, one or more specifically identified E-book titles or a particular author's E-books.

VI. PERMITTED CONDUCT

A. Nothing in this Final Judgment shall prohibit ~~Penguin~~Macmillan unilaterally from compensating a retailer, including an E-book Retailer, for valuable marketing or other promotional services rendered.

B. Notwithstanding Sections V.A and V.B of this Final Judgment, ~~Penguin~~Holtzbrinck may enter into Agency Agreements with E-book Retailers under which the aggregate dollar value of the price discounts or any other form of promotions to encourage consumers to Purchase one or more of ~~Penguin's~~Holtzbrinck's E-books (as opposed to advertising or promotions engaged in by the E-book Retailer not specifically tied or directed to ~~Penguin's~~Holtzbrinck's E-books) is restricted; *provided that* (1) such agreed restriction shall not interfere with the E-book Retailer's ability to reduce the final price paid by consumers to purchase ~~Penguin's~~Holtzbrinck's E-books by an aggregate amount equal to the total commissions

~~Penguin~~Holtzbrinck pays to the E-book Retailer, over a period of at least one year, in connection with the Sale of ~~Penguin's~~Holtzbrinck's E-books to consumers; (2) ~~Penguin~~Holtzbrinck shall not restrict, limit, or impede the E-book Retailer's use of the agreed funds to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books; and (3) the method of accounting for the E-book Retailer's promotional activity does not restrict, limit, or impede the E-book Retailer from engaging in any form of retail activity or promotion.

VII. ANTITRUST COMPLIANCE

Within thirty days after entry of this Final Judgment, ~~Penguin~~Macmillan shall designate ~~its~~Holtzbrinck's general counsel or chief legal officer, or an employee reporting directly to its general counsel or chief legal officer, as Antitrust Compliance Officer with responsibility for ensuring ~~Penguin's~~Macmillan's compliance with this Final Judgment. The Antitrust Compliance Officer shall be responsible for the following:

A. furnishing a copy of this Final Judgment, within thirty days of its entry, to each of ~~Penguin's~~Holtzbrinck's officers and directors, ~~and~~ to each of ~~Penguin's~~Holtzbrinck's employees engaged, in whole or in part, in the distribution or Sale of E-books, and to each of VGvH's officers, directors, or employees involved in the development of Holtzbrinck's plans or strategies relating to E-books;

B. furnishing a copy of this Final Judgment in a timely manner to each officer, director, or employee who succeeds to any position identified in Section VII.A of this Final Judgment;

C. ensuring that each person identified in Sections VII.A and VII.B of this Final Judgment receives at least four hours of training annually on the meaning and requirements of this

Final Judgment and the antitrust laws, such training to be delivered by an attorney with relevant experience in the field of antitrust law;

D. obtaining, within sixty days after entry of this Final Judgment and on each anniversary of the entry of this Final Judgment, from each person identified in Sections VII.A and VII.B of this Final Judgment, and thereafter maintaining, a certification that each such person (a) has read, understands, and agrees to abide by the terms of this Final Judgment; and (b) is not aware of any violation of this Final Judgment or the antitrust laws or has reported any potential violation to the Antitrust Compliance Officer;

E. conducting an annual antitrust compliance audit covering each person identified in Sections VII.A and VII.B of this Final Judgment, and maintaining all records pertaining to such audits;

F. communicating annually to ~~Penguin's employees~~Holtzbrinck's employees and to all VGvH employees identified in Sections VII.A and VII.B of this Final Judgment that they may disclose to the Antitrust Compliance Officer, without reprisal, information concerning any potential violation of this Final Judgment or the antitrust laws;

G. taking appropriate action, within three business days of discovering or receiving credible information concerning an actual or potential violation of this Final Judgment, to terminate or modify ~~Penguin's~~Macmillan's conduct to assure compliance with this Final Judgment; and, within seven days of taking such corrective actions, providing to the Department of Justice a description of the actual or potential violation of this Final Judgment and the corrective actions taken;

H. furnishing to the Department of Justice on a quarterly basis electronic copies of any non-privileged communications with any Person containing allegations of ~~Penguin's~~Macmillan's noncompliance with any provisions of this Final Judgment;

I. maintaining, and furnishing to the Department of Justice on a quarterly basis, a log of all oral and written communications, excluding privileged or public communications, between or among (1) any of ~~Penguin's~~Macmillan's officers, directors, or employees involved in the development of ~~Penguin's~~Holtzbrinck's plans or strategies relating to E-books, and (2) any person employed by or associated with another Publisher Defendant, relating, in whole or in part, to the distribution or sale in the United States of books sold in any format, including an identification (by name, employer, and job title) of the author and recipients of and all participants in the communication, the date, time, and duration of the communication, the medium of the communication, and a description of the subject matter of the communication (for a collection of communications solely concerning a single business arrangement that is specifically exempted from the reporting requirements of Section IV.C of this Final Judgment, ~~Penguin~~Macmillan may provide a summary of the communications rather than logging each communication individually); and

J. providing to the Department of Justice annually, on or before the anniversary of the entry of this Final Judgment, a written statement as to the fact and manner of ~~Penguin's~~Macmillan's compliance with Sections IV, V, and VII of this Final Judgment.

VIII. COMPLIANCE INSPECTION

A. For purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally

recognized privilege, from time to time duly authorized representatives of the Department of Justice, including consultants and other persons retained by the Department of Justice, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to ~~Penguin~~Macmillan, be permitted:

1. access during ~~Penguin's~~Macmillan's office hours to inspect and copy, or at the option of the United States, to require ~~Penguin~~Macmillan to provide to the United States hard copy or electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of ~~Penguin~~Macmillan, relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, ~~Penguin's~~Macmillan's officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by ~~Penguin~~Macmillan.

B. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, ~~Penguin~~Macmillan shall submit written reports or respond to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested. Written reports authorized under this paragraph may, in the sole discretion of the United States, require ~~Penguin~~Macmillan to conduct, at their cost, an independent audit or analysis relating to any of the matters contained in this Final Judgment.

C. No information or documents obtained by the means provided in this Section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the

United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

D. If at the time information or documents are furnished by ~~Penguin~~Macmillan to the United States, ~~Penguin~~Macmillan represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and ~~Penguin~~Macmillan marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure," then the United States shall give ~~Penguin~~Macmillan ten calendar days notice prior to divulging such material in any civil or administrative proceeding.

IX. RETENTION OF JURISDICTION

This Court retains jurisdiction to enable any party to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

X. NO LIMITATION ON GOVERNMENT RIGHTS

Nothing in this Final Judgment shall limit the right of the United States to investigate and bring actions to prevent or restrain violations of the antitrust laws concerning any past, present, or future conduct, policy, or practice of ~~Penguin~~Macmillan.

XI. EXPIRATION OF FINAL JUDGMENT

Unless this Court grants an extension, this Final Judgment shall expire five years from the date of its entry.

XII. PUBLIC INTEREST DETERMINATION

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

Court approval subject to procedures set forth in the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16

_____

United States District Judge

BILLING CODE C

United States District Court for the Southern District of New York

United States of America,

Plaintiff,

v.

Apple, Inc., *et al.,*

Defendants.

Civil Action No. 1:12–CV–2826 (DLC).
ECF Case.

[Proposed] Final Judgment as to Defendants Verlagsgruppe Georg Von Holtzbrinck GMBH & Holtzbrinck Publishers, LLC D/B/A Macmillan

Whereas, Plaintiff, the United States of America filed its Complaint on April 11, 2012, alleging that Defendants conspired to raise retail prices of E-books in violation of Section 1 of the Sherman Act, as amended, 15 U.S.C. 1, and Plaintiff and Macmillan, by their respective attorneys, have consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law;

And whereas, this Final Judgment does not constitute any admission by Macmillan that the law has been violated or of any issue of fact or law, other than that the jurisdictional facts as alleged in the Complaint are true;

And whereas, Macmillan agrees to be bound by the provisions of this Final Judgment pending its approval by the Court;

And whereas, Plaintiff requires Macmillan to agree to undertake certain actions and refrain from certain conduct for the purpose of remedying the loss of competition alleged in the Complaint;

And whereas, Macmillan has represented to the United States that the actions and conduct restrictions can and will be undertaken and that it will later raise no claim of hardship or difficulty as grounds for asking the Court to modify any of the provisions contained below;

Now therefore, before any testimony is taken, without trial or adjudication of any issue of fact or law, and upon consent of Macmillan, it is *ordered, adjudged, and decreed:*

I. Jurisdiction

This Court has jurisdiction over the subject matter of this action and over Macmillan. The Complaint states a claim upon which relief may be granted against Macmillan under Section 1 of the Sherman Act, as amended, 15 U.S.C. 1.

II. Definitions

As used in this Final Judgment:

A. ''Agency Agreement'' means an agreement between an E-book Publisher and an E-book Retailer under which the E-book Publisher Sells E-books to consumers through the E-book Retailer, which under the agreement acts as an agent of the E-book Publisher and is paid a commission in connection with the Sale of one or more of the E-book Publisher's E-books.

B. ''Apple'' means Apple, Inc., a California corporation with its principal place of business in Cupertino, California, its successors and assigns, and its parents, subsidiaries, divisions, groups, affiliates, partnerships, and joint ventures, and their directors, officers, managers, agents, and employees.

C. ''Department of Justice'' means the Antitrust Division of the United States Department of Justice.

D. ''E-book'' means an electronically formatted book designed to be read on a computer, a handheld device, or other electronic devices capable of visually displaying E-books. For purposes of this Final Judgment, the term E-book does not include (1) an audio book, even if delivered and stored digitally; (2) a standalone specialized software application or ''app'' sold through an ''app store'' rather than through an e-book store (*e.g.,* through Apple's ''App Store'' rather than through its ''iBookstore'' or ''iTunes'') and not designed to be executed or read by or through a dedicated E-book reading device; (3) a media file containing an electronically formatted book for which most of the value to consumers is derived from audio or video content contained in the file that is not included in the print version of the book; or (4) the electronically formatted version of a book marketed solely for use in connection with academic coursework.

E. ''E-book Publisher'' means any Person that, by virtue of a contract or other relationship with an E-book's author or other rights holder, owns or controls the necessary copyright or other authority (or asserts such ownership or control) over any E-book sufficient to distribute the E-book within the United States to E-book Retailers and to permit such E-book Retailers to Sell the E-book to consumers in the United States. Publisher Defendants are E-book Publishers. For purposes of this Final Judgment, E-book Retailers are not E-book Publishers.

F. ''E-book Retailer'' means any Person that lawfully Sells (or seeks to lawfully Sell) E-books to consumers in the United States, or through which a Publisher Defendant, under an Agency Agreement, Sells E-books to consumers. For purposes of this Final Judgment, Publisher Defendants and all other Persons whose primary business is book publishing are not E-book Retailers.

G. ''Hachette'' means Hachette Book Group, Inc., a Delaware corporation with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

H. ''HarperCollins'' means HarperCollins Publishers L.L.C., a Delaware limited liability company with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

I. ''Including'' means including, but not limited to.

J. ''Macmillan'' means (1) Holtzbrinck Publishers, LLC d/b/a Macmillan, a New York limited liability company with its principal place of business in New York, New York (''Holtzbrinck''), its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees; and (2) Verlagsgruppe Georg von Holtzbrinck GmbH, a German corporation with its principal place of business in Stuttgart, Germany (''VGvH''), its successors and assigns, and its divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees. Where the Final Judgment imposes an obligation on Macmillan to engage in or refrain from engaging in certain conduct, that obligation shall apply to Macmillan and to any joint venture or other business arrangement established by Macmillan and one or more Publisher Defendants.

K. ''Penguin'' means (1) Penguin Group (USA), Inc., a Delaware corporation with its principal place of business in New York, New York; (2) The Penguin Group, a division of U.K. corporation Pearson plc with its principal place of business in London, England; (3) The Penguin Publishing Company Ltd, a company registered in England and Wales with its principal place of business in London, England; and (4) Dorling Kindersley Holdings Limited, a company registered in England and Wales with its principal place of business in London, England; and each of their respective successors and assigns (expressly including Penguin Random House, a joint venture by and between Pearson plc and Bertelsmann SE & Co. KGaA, and any similar joint venture between Penguin and Random House Inc.); each of their respective subsidiaries, divisions, groups, and partnerships; and each of their respective directors, officers, managers, agents, and employees.

L. ''Person'' means any natural person, corporation, company, partnership, joint venture, firm, association, proprietorship, agency, board, authority, commission, office, or other business or legal entity, whether private or governmental.

M. ''Price MFN'' means a term in an agreement between an E-book Publisher and an E-book Retailer under which

1. the Retail Price at which an E-book Retailer or, under an Agency Agreement, an E-book Publisher Sells one or more E-books to consumers depends in any way on the Retail Price, or discounts from the Retail Price, at which any other E-book Retailer or the E-book Publisher, under an Agency Agreement, through any other E-book Retailer Sells the same E-book(s) to consumers;

2. the Wholesale Price at which the E-book Publisher Sells one or more E-books to that E-book Retailer for Sale to consumers depends in any way on the Wholesale Price at which the E-book Publisher Sells the same E-book(s) to any other E-book Retailer for Sale to consumers; or

3. the revenue share or commission that E-book Retailer receives from the E-book Publisher in connection with the Sale of one or more E-books to consumers depends in any way on the revenue share or commission that (a)

any other E-book Retailer receives from the E-book Publisher in connection with the Sale of the same E-book(s) to consumers, or (b) that E-book Retailer receives from any other E-book Publisher in connection with the Sale of one or more of the other E-book Publisher's E-books.

For purposes of this Final Judgment, it will not constitute a Price MFN under subsection 3 of this definition if Macmillan agrees, at the request of an E-book Retailer, to meet more favorable pricing, discounts, or allowances offered to the E-book Retailer by another E-book Publisher for the period during which the other E-book Publisher provides that additional compensation, so long as that agreement is not or does not result from a pre-existing agreement that requires Macmillan to meet all requests by the E-book Retailer for more favorable pricing within the terms of the agreement.

N. ''Publisher Defendants'' means Hachette, HarperCollins, Macmillan, Penguin, and Simon & Schuster. Where this Final Judgment imposes an obligation on Publisher Defendants to engage in or refrain from engaging in certain conduct, that obligation shall apply to each Publisher Defendant individually and to any joint venture or other business arrangement established by any two or more Publisher Defendants.

O. ''Purchase'' means a consumer's acquisition of one or more E-books as a result of a Sale.

P. ''Retail Price'' means the price at which an E-book Retailer or, under an Agency Agreement, an E-book Publisher Sells an E-book to a consumer.

Q. ''Sale'' means delivery of access to a consumer to read one or more E-books (purchased alone, or in combination with other goods or services) in exchange for payment; ''Sell'' or ''Sold'' means to make or to have made a Sale of an E-book to a consumer.

R. ''Simon & Schuster'' means Simon & Schuster, Inc., a New York corporation with its principal place of business in New York, New York, its successors and assigns, and its subsidiaries, divisions, groups, and partnerships, and their directors, officers, managers, agents, and employees.

S. ''Wholesale Price'' means (1) the net amount, after any discounts or other adjustments (not including promotional allowances subject to Section 2(d) of the Robinson-Patman Act, 15 U.S.C. 13(d)), that an E-book Retailer pays to an E-book Publisher for an E-book that the E-book Retailer Sells to consumers; or (2) the Retail Price at which an E-book Publisher, under an Agency Agreement, Sells an E-book to consumers through an E-book Retailer minus the commission or other payment that E-book Publisher pays to the E-book Retailer in connection with or that is reasonably allocated to that Sale.

III. Applicability

This Final Judgment applies to Holtzbrinck and VGvH, acting individually or in concert, and all other Persons in active concert or participation with Holtzbrinck or VGvH who receive actual notice of this Final Judgment by personal service or otherwise.

IV. Required Conduct

A. Within three business days after Macmillan's stipulation to the entry of this Final Judgment, Macmillan shall notify each E-book Retailer with which Holtzbrinck has an agreement relating to the Sale of E-books that Holtzbrinck will no longer enforce any term or terms in any such agreement that restrict, limit, or impede the E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books, except to the extent consistent with Section VI.B of this Final Judgment.

B. For each agreement between Holtzbrinck and an E-book Retailer that contains a Price MFN, Holtzbrinck shall notify the E-book Retailer within three business days after Macmillan's stipulation to the entry of this Final Judgment that the E-book Retailer may terminate the agreement with thirty-days notice and shall, thirty days after the E-book Retailer provides such notice, release the E-book Retailer from the agreement. For each such agreement that the E-book Retailer has not terminated within ten days after entry of this Final Judgment, Holtzbrinck shall, as soon as permitted under the agreement, take each step required under the agreement to cause the agreement to be terminated and not renewed or extended.

C. Holtzbrinck shall notify the Department of Justice in writing at least sixty days in advance of the formation or material modification of any joint venture or other business arrangement relating to the Sale, development, or promotion of E-books in the United States in which Holtzbrinck and at least one other E-book Publisher (including another Publisher Defendant) are participants or partial or complete owners. Such notice shall describe the joint venture or other business arrangement, identify all E-book Publishers that are parties to it, and attach the most recent version or draft of the agreement, contract, or other document(s) formalizing the joint venture or other business arrangement. Within thirty days after Holtzbrinck provides notification of the joint venture or business arrangement, the Department of Justice may make a written request for additional information. If the Department of Justice makes such a request, Holtzbrinck shall not proceed with the planned formation or material modification of the joint venture or business arrangement until thirty days after substantially complying with such additional request(s) for information. The failure of the Department of Justice to request additional information or to bring an action under the antitrust laws to challenge the formation or material modification of the joint venture shall neither give rise to any inference of lawfulness nor limit in any way the right of the United States to investigate the formation, material modification, or any other aspects or activities of the joint venture or business arrangement and to bring actions to prevent or restrain violations of the antitrust laws.

The notification requirements of this Section IV.C shall not apply to ordinary course business arrangements between Holtzbrinck and another E-book Publisher (not a Publisher Defendant) that do not relate to the Sale of E-books to consumers, or to business arrangements the primary or predominant purpose or focus of which involves: (i) E-book Publishers co-publishing one or more specifically identified E-book titles or a particular author's E-books; (ii) Holtzbrinck licensing to or from another E-book Publisher the publishing rights to one or more specifically identified E-book titles or a particular author's E-books; (iii) Holtzbrinck providing technology services to or receiving technology services from another E-book Publisher (not a Publisher Defendant) or licensing rights in technology to or from another E-book Publisher; or (iv) Holtzbrinck distributing E-books published by another E-book Publisher (not a Publisher Defendant).

D. Macmillan shall furnish to the Department of Justice (1) by February 15, 2013, one complete copy of each agreement, executed, renewed, or extended on or after January 1, 2012, between Holtzbrinck and any E-book Retailer relating to the Sale of E-books, and, (2) thereafter, on a quarterly basis, each such agreement executed, renewed, or extended since Macmillan's previous submission of agreements to the Department of Justice.

V. Prohibited Conduct

A. Until December 18, 2014, Holtzbrinck shall not restrict, limit, or impede an E-book Retailer's ability to set, alter, or reduce the Retail Price of any E-book or to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books.

B. Until December 18, 2014, Holtzbrinck shall not enter into any agreement with any E-book Retailer that restricts, limits, or impedes the E-book Retailer from setting, altering, or reducing the Retail Price of one or more E-books, or from offering price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books.

C. Holtzbrinck shall not enter into any agreement with an E-book Retailer relating to the Sale of E-books that contains a Price MFN.

D. Macmillan shall not retaliate against, or urge any other E-book Publisher or E-book Retailer to retaliate against, an E-book Retailer for engaging in any activity that Holtzbrinck is prohibited by Sections V.A, V.B, and VI.B.2 of this Final Judgment from restricting, limiting, or impeding in any agreement with an E-book Retailer. After the expiration of prohibitions in Sections V.A and V.B of this Final Judgment, this Section V.D shall not prohibit Holtzbrinck from unilaterally entering into or enforcing any agreement with an E-book Retailer that restricts, limits, or impedes the E-book Retailer from setting, altering, or reducing the Retail Price of any of Holtzbrinck's E-books or from offering price discounts or any other form of promotions to encourage consumers to Purchase any of Holtzbrinck's E-books.

E. Holtzbrinck shall not enter into or enforce any agreement, arrangement, understanding, plan, program, combination, or conspiracy with any E-book Publisher (including another Publisher Defendant) to raise, stabilize, fix, set, or coordinate the Retail Price or Wholesale Price of any E-book or fix, set, or coordinate any term or condition relating to the Sale of E-books.

This Section V.E shall not prohibit Holtzbrinck from entering into and enforcing agreements relating to the distribution of another E-book Publisher's E-books (not including the E-books of another Publisher Defendant) or to the co-publication with another E-book Publisher of specifically identified E-book titles or a particular author's E-books, or from participating in output-enhancing industry standard-setting activities relating to E-book security or technology.

F. Holtzbrinck (and each officer of VGvH who exercises direct control over Holtzbrinck's business decisions or strategies) shall not convey or otherwise communicate, directly or indirectly (including by communicating indirectly through an E-book Retailer with the intent that the E-book Retailer convey information from the communication to another E-book Publisher or knowledge that it is likely to do so), to any other E-book Publisher (including to an officer of a parent of a Publisher Defendant) any competitively sensitive information, including:

1. its business plans or strategies;

2. its past, present, or future wholesale or retail prices or pricing strategies for books sold in any format (*e.g.,* print books, E-books, or audio books);

3. any terms in its agreement(s) with any retailer of books Sold in any format; or

4. any terms in its agreement(s) with any author.

This Section V.F shall not prohibit Holtzbrinck from communicating (a) in a manner and through media consistent with common and reasonable industry practice, the cover prices or wholesale or retail prices of books sold in any format to potential purchasers of those books; or (b) information Holtzbrinck needs to communicate in connection with (i) its enforcement or assignment of its intellectual property or contract rights, (ii) a contemplated merger, acquisition, or purchase or sale of assets, (iii) its distribution of another E-book Publisher's E-books, or (iv) a business arrangement under which E-book Publishers agree to co-publish, or an E-book Publisher agrees to license to another E-book Publisher the publishing rights to, one or more specifically identified E-book titles or a particular author's E-books.

VI. Permitted Conduct

A. Nothing in this Final Judgment shall prohibit Macmillan unilaterally from compensating a retailer, including an E-book Retailer, for valuable marketing or other promotional services rendered.

B. Notwithstanding Sections V.A and V.B of this Final Judgment, Holtzbrinck may enter into Agency Agreements with E-book Retailers under which the aggregate dollar value of the price discounts or any other form of promotions to encourage consumers to Purchase one or more of Holtzbrinck's E-books (as opposed to advertising or promotions engaged in by the E-book Retailer not specifically tied or directed to Holtzbrinck's E-books) is restricted; *provided that* (1) such agreed restriction shall not interfere with the E-book Retailer's ability to reduce the final price paid by consumers to purchase Holtzbrinck's E-books by an aggregate amount equal to the total commissions Holtzbrinck pays to the E-book Retailer, over a period of at least one year, in connection with the Sale of Holtzbrinck's E-books to consumers; (2) Holtzbrinck shall not restrict, limit, or impede the E-book Retailer's use of the agreed funds to offer price discounts or any other form of promotions to encourage consumers to Purchase one or more E-books; and (3) the method of accounting for the E-book Retailer's promotional activity does not restrict, limit, or impede the E-book Retailer from engaging in any form of retail activity or promotion.

VII. Antitrust Compliance

Within thirty days after entry of this Final Judgment, Macmillan shall designate Holtzbrinck's general counsel or chief legal officer, or an employee reporting directly to its general counsel or chief legal officer, as Antitrust Compliance Officer with responsibility for ensuring Macmillan's compliance with this Final Judgment. The Antitrust Compliance Officer shall be responsible for the following:

A. furnishing a copy of this Final Judgment, within thirty days of its entry, to each of Holtzbrinck's officers and directors, to each of Holtzbrinck's employees engaged, in whole or in part, in the distribution or Sale of E-books, and to each of VGvH's officers, directors, or employees involved in the development of Holtzbrinck's plans or strategies relating to E-books;

B. furnishing a copy of this Final Judgment in a timely manner to each officer, director, or employee who succeeds to any position identified in Section VII.A of this Final Judgment;

C. ensuring that each person identified in Sections VII.A and VII.B of this Final Judgment receives at least four hours of training annually on the meaning and requirements of this Final Judgment and the antitrust laws, such training to be delivered by an attorney with relevant experience in the field of antitrust law;

D. obtaining, within sixty days after entry of this Final Judgment and on each anniversary of the entry of this Final Judgment, from each person identified in Sections VII.A and VII.B of this Final Judgment, and thereafter maintaining, a certification that each such person (a) has read, understands, and agrees to abide by the terms of this Final Judgment; and (b) is not aware of any violation of this Final Judgment or the antitrust laws or has reported any

potential violation to the Antitrust Compliance Officer;

E. conducting an annual antitrust compliance audit covering each person identified in Sections VII.A and VII.B of this Final Judgment, and maintaining all records pertaining to such audits;

F. communicating annually to Holtzbrinck's employees and to all VGvH employees identified in Sections VII.A and VII.B of this Final Judgment that they may disclose to the Antitrust Compliance Officer, without reprisal, information concerning any potential violation of this Final Judgment or the antitrust laws;

G. taking appropriate action, within three business days of discovering or receiving credible information concerning an actual or potential violation of this Final Judgment, to terminate or modify Macmillan's conduct to assure compliance with this Final Judgment; and, within seven days of taking such corrective actions, providing to the Department of Justice a description of the actual or potential violation of this Final Judgment and the corrective actions taken;

H. furnishing to the Department of Justice on a quarterly basis electronic copies of any non-privileged communications with any Person containing allegations of Macmillan's noncompliance with any provisions of this Final Judgment;

I. maintaining, and furnishing to the Department of Justice on a quarterly basis, a log of all oral and written communications, excluding privileged or public communications, between or among (1) any of Macmillan's officers, directors, or employees involved in the development of Holtzbrinck's plans or strategies relating to E-books, and (2) any person employed by or associated with another Publisher Defendant, relating, in whole or in part, to the distribution or sale in the United States of books sold in any format, including an identification (by name, employer, and job title) of the author and recipients of and all participants in the communication, the date, time, and duration of the communication, the medium of the communication, and a description of the subject matter of the communication (for a collection of communications solely concerning a single business arrangement that is specifically exempted from the reporting requirements of Section IV.C of this Final Judgment, Macmillan may provide a summary of the communications rather than logging each communication individually); and

J. providing to the Department of Justice annually, on or before the anniversary of the entry of this Final Judgment, a written statement as to the fact and manner of Macmillan's compliance with Sections IV, V, and VII of this Final Judgment.

VIII. Compliance Inspection

T. For purposes of determining or securing compliance with this Final Judgment, or of determining whether the Final Judgment should be modified or vacated, and subject to any legally recognized privilege, from time to time duly authorized representatives of the Department of Justice, including consultants and other persons retained by the Department of Justice, shall, upon written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to Macmillan, be permitted:

1. access during Macmillan's office hours to inspect and copy, or at the option of the United States, to require Macmillan to provide to the United States hard copy or electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Macmillan, relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Macmillan's officers, employees, or agents, who may have their individual counsel present, regarding such matters. The interviews shall be subject to the reasonable convenience of the interviewee and without restraint or interference by Macmillan.

U. Upon the written request of an authorized representative of the Assistant Attorney General in charge of the Antitrust Division, Macmillan shall submit written reports or respond to written interrogatories, under oath if requested, relating to any of the matters contained in this Final Judgment as may be requested. Written reports authorized under this paragraph may, in the sole discretion of the United States, require Macmillan to conduct, at their cost, an independent audit or analysis relating to any of the matters contained in this Final Judgment.

V. No information or documents obtained by the means provided in this Section shall be divulged by the United States to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party (including grand jury proceedings), or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

W. If at the time information or documents are furnished by Macmillan to the United States, Macmillan represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and Macmillan marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' then the United States shall give Macmillan ten calendar days notice prior to divulging such material in any civil or administrative proceeding.

IX. Retention of Jurisdiction

This Court retains jurisdiction to enable any party to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

X. No Limitation On Government Rights

Nothing in this Final Judgment shall limit the right of the United States to investigate and bring actions to prevent or restrain violations of the antitrust laws concerning any past, present, or future conduct, policy, or practice of Macmillan.

XI. Expiration Of Final Judgment

Unless this Court grants an extension, this Final Judgment shall expire five years from the date of its entry.

XII. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including making copies available to the public of this Final Judgment, the Competitive Impact Statement, and any comments thereon and the United States' responses to comments. Based upon the record before the Court, which includes the Competitive Impact Statement and any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Court approval subject to procedures set forth in the Antitrust Procedures and Penalties Act, 15 U.S.C. 16

United States District Judge

[FR Doc. 2013–04234 Filed 2–22–13; 8:45 am]

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