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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 319

[Docket No. APHIS–2010–0005]

RIN 0579–AD36

Importation of Bromeliad Plants in Growing Media From Belgium, Denmark, and the Netherlands

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations governing the importation of plants and plant products to add Bromeliad plants of the genera *Aechmea, Cryptanthus, Guzmania, Hohenbergia, Neoregelia, Tillandsia,* and *Vriesea* from Belgium, Denmark, and the Netherlands to the list of plants that may be imported into the United States in an approved growing medium, subject to specified growing, inspection, and certification requirements. We are taking this action in response to requests from those three countries and after determining that the plants can be imported, under certain conditions, without resulting in the introduction into, or the dissemination within, the United States of a plant pest or noxious weed.

DATES: *Effective Date:* December 2, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. William Aley, Senior Import Specialist, Commodity Import Analysis and Operations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–5057.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 319 prohibit or restrict the importation into the United States of certain plants and plant products to prevent the introduction of plant pests and noxious weeds. The regulations in ''Subpart—Plants for Planting,'' §§ 319.37 through 319.37–14 (referred to below as the regulations) contain, among other things, prohibitions and restrictions on the importation of plants, plant parts, and seeds for propagation.

Paragraph (a) of § 319.37–8 requires, with certain exceptions, that plants offered for importation into the United States be free of sand, soil, earth, and other growing media. This requirement is intended to help prevent the introduction of plant pests that might be present in the growing media; the exceptions to the requirement take into account factors that mitigate that plant pest risk. Those exceptions, which are found in paragraphs (b) through (e) of § 319.37–8, consider either the origin of the plants and growing media (paragraph (b)), the nature of the growing media (paragraphs (c) and (d)), or the use of a combination of growing conditions, approved media, inspections, and other requirements (paragraph (e)).

Paragraph (e) of § 319.37–8 provides conditions under which certain plants established in growing media may be imported into the United States. In addition to specifying the types of plants that may be imported, § 319.37–8(e) also, among other things, specifies the types of growing media that may be used.

On March 15, 2011, we published in the **Federal Register** (76 FR 13890–13892, Docket No. APHIS–2010–0005) a proposal [1] to amend the regulations governing the importation of plants and plant products to add Bromeliad plants of the genera *Aechmea, Cryptanthus, Guzmania, Hohenbergia, Neoregelia, Tillandsia,* and *Vriesea* from Belgium, Denmark, and the Netherlands to the list of plants that may be imported into the United States in an approved growing medium, subject to specified growing, inspection, and certification requirements. The Animal and Plant Health Inspection Service (APHIS) took this action in response to requests from those three countries and after determining that the plants could be imported, under certain conditions, without resulting in the introduction into, or the dissemination within, the United States of a plant pest or noxious weed.

We solicited comments concerning our proposal for 60 days ending May 16, 2011. We received eight comments by that date. They were from a domestic grower, a domestic growers' association, a State Government, and two foreign exporters. They are discussed below by topic.

The comment from the domestic growers' association focused on the possible economic impacts of the proposed rule on domestic importers and growers of Bromeliads. The commenter stated that in the initial regulatory flexibility analysis (IRFA) that we made available to the public along with the proposed rule, we underestimated both the number of domestic nurseries that import Bromeliad plants from Belgium, Denmark, and the Netherlands and the potential economic impact on those nurseries. Noting that in the IRFA, we acknowledged the possibility that a few nurseries could be affected by the proposed rule to the extent that they would be eliminated from the marketing chain, the commenter stated that we neglected to consider the direct and indirect economic impacts that the closure of such nurseries could have on local economies due to the loss of jobs.

We appreciate the additional information submitted by the commenter on the potential economic effects of the rule for Florida nurseries. We acknowledged in the IRFA that we did not know exactly how many U.S. nurseries import Bromeliad plants from Belgium, Denmark, and the Netherlands, but estimated their number to be no more than three. Based upon a survey it conducted in April 2011, the association represented by the commenter found that there are seven such nurseries in the State of Florida. We agree that these are businesses that will be directly affected by the rule.

We also agree with the commenter that not only the nurseries that have been importing Bromeliad plants from Belgium, Denmark, and the Netherlands, but any nurseries that sell these plants may be affected by the rule. Importation of Bromeliad plants in growing media can be expected to alter some marketing channels, with retailers able to buy mature plants directly from European suppliers rather than rely on

[1] To view the proposed rule and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0005.*

the maturation of the plants at Florida nurseries.

The commenter stated that the Florida nurseries surveyed by the growers' association represented by the commenter (respondents included both domestic importers of Bromeliads and domestic Bromeliad producers) expected to lose as much as $6.8 million in Bromeliad plant sales (28.5 percent of their market) as a result of this rulemaking. The respondents further indicated that they would be forced to eliminate as many as 70 jobs (20 percent of their workforce).

While there may be economic shifts as businesses throughout the United States react to the rule, we are unable to project authoritatively the likely size of the impact. APHIS does not have independent information regarding the possible magnitude of business losses and is not able to evaluate nurseries' future workforce needs. Additionally, while we acknowledge the commenter's concerns with regard to potential business losses by Florida nurseries, we believe that the importation of Bromeliad plants in growing media can also result in economic gains in Florida and elsewhere. Just as there may be Florida wholesale nurseries negatively affected, there may also be other businesses, such as retailers, that gain from the rule. There may be negative employment consequences of the rule for certain wholesale nurseries, but there may also be jobs created as other businesses expand due to new marketing opportunities resulting from the rule.

Moreover, APHIS' authority to prohibit the importation of Bromeliad plants in growing media from Belgium, Denmark, and the Netherlands is based on the pest risks associated with such imports. The Agency does not have statutory authority to prohibit or restrict the importation of plants or plant products on the basis of economic or competitive considerations.

Another commenter stated that the mitigation measures in § 319.37–8(e) to which Bromeliads imported from Belgium, Denmark, and the Netherlands would be subject under this rulemaking are not adequate to prevent the spread of plant diseases such as *Fusarium oxysporum* f. sp. Additional measures, including a serological test, should be employed, according to the commenter.

Plants imported in growing media in accordance with the regulations in § 319.37–8(e) are subject to a systems approach, which includes stringent requirements that will not be affected by this rulemaking. Approved growing media for such imported plants are listed in § 319.78(e)(1). The regulations also require that mother stock and production plants be inspected by an inspector from APHIS or the national plant protection organization (NPPO) of the exporting country and found free from evidence of pests and diseases. Plants to be exported to the United States under § 319.87–8(e) must be grown in a greenhouse in which sanitary procedures adequate to exclude plant pests and diseases are always employed. There are also various requirements for written agreements between growers and the NPPO of the exporting country and oversight by the latter. It is our view that the systems approach required under § 319.37–8(e) is more than adequate to prevent the dissemination and spread of plant pests and diseases, including *Fusarium oxysporum* f. sp., via the importation of Bromeliad plants in growing media into the United States.

One commenter stated that, as a condition for allowing Bromeliads to be exported from the European Union (EU) to the United States, APHIS should require the EU to remove the whitefly restrictions it has placed on U.S. growers exporting Bromeliads to EU countries. The commenter viewed those requirements as an unfair trade barrier for U.S. growers.

APHIS makes decisions as to whether to allow the importation of agricultural products and commodities based on an evaluation of facts, data, and available scientific evidence. While the order of processing particular requests may be influenced by trade considerations, and the components of a risk management program may be a product of negotiations between APHIS and its foreign counterparts, the ultimate determination as to whether a commodity can be safely imported is based on a determination that the product can be imported without introducing a plant pest or noxious weed into the United States. In this instance, our decision to allow the importation of Bromeliad plants of the genera *Aechmea, Cryptanthus, Guzmania, Hohenbergia, Neoregelia, Tillandsia,* and *Vriesea* from Belgium, Denmark, and the Netherlands in an approved growing medium, subject to specified growing, inspection, and certification requirements, is based on the results of our pest risk analysis, which was made available for public review along with the March 2011 proposed rule.

Part of APHIS's mission is to facilitate exports, and we make every effort to assist domestic industry in securing access to export markets. Success in this area is somewhat tied to factors out of our control, however. In general, phytosanitary measures applied by importing countries or regions to mitigate the risk posed by a particular plant or plant part exported from another country or region are determined by the particular risks posed in each case. The risk posed by imported plants is dependent on the pests associated with the commodity in the country of origin and the pests' potential impact on the importing country. As such, reciprocal trade could occur under the same phytosanitary conditions if the pest dynamics in both the exporting and importing countries are the same, but those conditions may vary if the pest dynamics in the two countries differ. Because of climatic conditions and other factors, the risks posed to the EU by Bromeliad imports from the United States are not likely the same risks posed by imports of Bromeliads from the EU into the United States.

Two commenters, both Bromeliad growers from the Netherlands, wrote to inquire whether the plugs that their companies use to grow young Bromeliad plants would be regarded as acceptable growing media under the proposed rule. Along with their comments, they sent data sheets and pictures of the plugs they use.

The plugs used by these growers will be regarded as acceptable if they consist of one or a combination of the approved growing media listed in § 319.37–8(e)(1) and also meet the requirement contained in that paragraph that the growing media must not have been previously used. This final rule does not amend the list of approved growing media in § 319.37–8(e)(1).

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

This final rule allows the importation into the United States of Bromeliad plants in approved growing media from

Belgium, Denmark, and the Netherlands. Bromeliad plants are most commonly used as houseplants or landscape ornamentals in warmer climates.

Most wholesale nurseries that sell Bromeliads within the United States are located in Florida. Based upon a survey conducted in April 2011, the Florida Nursery, Growers and Landscape Association found that there are seven nurseries in that State that import immature Bromeliad plants from Belgium, Denmark, and the Netherlands for finishing before sale to retailers. These businesses will be directly affected by the rule. Under the rule, producers in Belgium, Denmark, and the Netherlands will be able to ship mature Bromeliad plants in growing media directly to U.S. retailers. Although the rule will allow the European suppliers to bypass domestic nurseries and provide finished plants directly to U.S. retailers, such a scenario is not considered to be a certainty, given difficulties associated with shipping finished plants in pots. It is possible that the European suppliers will continue to export immature plants to domestic nurseries—but in growing media instead of in bare-root form—that will then grow them out for sale as finished plants.

U.S. nurseries that produce Bromeliad plants from seed may also be affected by the rule, to the extent that their sales are displaced by Bromeliad plants in growing media imported from Belgium, Denmark, and the Netherlands. The number of these nurseries is unknown but is estimated to be fewer than 100, most or all of which are located in California, Florida, and Texas.

Most if not all U.S. wholesale nurseries that sell Bromeliad plants are small entities under the Small Business Administration's standard of not more than $750,000 in annual receipts. The impact of the rule on these nurseries will depend on the volume and life-stage of the imported Bromeliads, and on the portions of the nurseries' incomes that derive from Bromeliad plant sales. Other small entities, including retail nurseries, are expected to benefit from new business opportunities created by the importation of Bromeliad plants in growing media from Belgium, Denmark, and the Netherlands.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this final rule. The environmental assessment provides a basis for the conclusion that the importation of Bromeliad plants from Belgium, Denmark, and the Netherlands under the conditions specified in this rule will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment and finding of no significant impact may be viewed on the Regulations.gov Web site.[2] Copies of the environmental assessment and finding of no significant impact are also available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we are amending 7 CFR part 319 as follows:

PART 319—FOREIGN QUARANTINE NOTICES

■ 1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

§ 319.37–6 [Amended]

■ 2. In § 319.37–6, footnote 8 is redesignated as footnote 7.

§ 319.37–7 [Amended]

■ 3. In § 319.37–7, footnote 9 is redesignated as footnote 8.

§ 319.37–13 [Amended]

■ 4. In § 319.37–13, footnote 11 is redesignated as footnote 12.

■ 5. In § 319.37–8, paragraph (e) introductory text, the list is amended as follows:

■ a. By redesignating footnote 10 as footnote 9.

■ b. By adding a new entry, in alphabetical order, and new footnote 10 to read as set forth below.

■ c. By revising footnote 11 to read as set forth below.

§ 319.37–8 Growing media.

* * * * *

(e) * * *

Bromeliad plants of the genera *Aechmea, Cryptanthus, Guzmania, Hohenbergia, Neoregelia, Tillandsia,* and *Vriesea* from Belgium, Denmark, and the Netherlands.[10]

* * * * *

Nidularium[11]

Done in Washington, DC, this 28th day of October 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–28404 Filed 11–1–11; 8:45 am]

BILLING CODE 3410–34–P

[2] Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2010-0005.* The environmental assessment and finding of no significant impact will appear in the resulting list of documents.

[10] See footnote 9.

[11] See footnote 9.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Parts 701, 705, and 741

RIN 3133–AD91

Community Development Revolving Loan Fund Access for Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule.

SUMMARY: NCUA is issuing a final rule to change its regulation governing the process by which the agency solicits, receives, evaluates, and acts on credit union applications for loans and technical assistance grants from the Community Development Revolving Loan Fund (CDRLF or Fund). The changes update the rule to increase transparency and are intended to improve its organization, structure, and ease of use by credit unions. The revisions do not reflect a change to the fundamental mission of the CDRLF, but instead remove unnecessary detail and outdated processes in the regulation while adding clarification and flexibility. The final rule also clarifies the application process and adds requirements addressing reporting and monitoring.

DATES: This rule is effective December 2, 2011.

FOR FURTHER INFORMATION CONTACT: Pamela Williams, Credit Union Program Analyst, Office of Small Credit Union Initiatives, or Pamela Yu, Staff Attorney, Office of General Counsel, at the above address or telephone (703) 518–6643 (Ms. Williams) or (703) 518–6540 (Ms. Yu).

SUPPLEMENTARY INFORMATION:

A. Background

On May 19, 2011, the NCUA Board (Board) issued a Notice of Proposed Rulemaking (proposal or proposed rule) to make comprehensive revisions to part 705, which governs the process by which the agency solicits, receives, evaluates, and acts on credit union applications for loans and technical assistance grants from the CDRLF. 76 FR 30286 (May 25, 2011). The CDRLF was created by Congress in 1979 and has been administered exclusively by NCUA since 1986. The Fund, with over $17.6 million in assets as of June 30, 2011, serves as a source of financial support, in the form of both loans and technical assistance grants, for credit unions serving predominantly low-income members. It also serves as a source of funding to help low-income credit unions respond to emergencies arising in their communities. The Board has delegated to the Office of Small Credit Union Initiatives (OSCUI) authority to make the determination of how to allocate the finite resources of the Fund among qualifying credit unions.

The proposed rule was intended to streamline the regulation, reduce burdens, and better reflect the technological changes that have taken place since the regulation's last substantive amendment in 1993. The proposal removed some of the detail in the regulation dealing with administrative aspects of the program to provide the agency with greater flexibility to make changes to suit specific circumstances. Other proposed revisions added detail to the rule. For example, to provide greater transparency and better guidance and information to prospective applicants, the proposed rule included information about how NCUA evaluates applications. Additionally, the proposal added a new section addressing reports to and monitoring by NCUA. This new section was designed to help the agency assure that an award from the Fund is used in the manner and for the purposes represented by the recipient credit unions.

B. Summary of Comments

The public comment period for the proposed rule closed on July 25, 2011. Four commenters responded: two credit union trade associations and two state credit union leagues. All commenters were generally supportive of the proposal. In particular, several expressed support for specific aspects of the proposal, including the examples of permissible loan fund uses; the increase in the maximum loan limit to provide loans in excess of $300,000; the removal of the mandatory requirement for matching funds; the elimination of the requirement for a Community Needs Plan; and the new section to permit NCUA, on an emergency basis, to provide CDRLF funds to credit unions with unplanned or unexpected expenses. Three commenters, however, offered suggestions for improvement on one or more aspects of the proposal. Of these, one commenter made a general suggestion that NCUA offer as much assistance as necessary to credit unions seeking CDRLF funds. The other two commenters offered more specific suggestions to improve or clarify the rule. NCUA has reviewed and analyzed the comment letters it received in response to the proposal and has adopted most of the public comments either by incorporation into the final rule or through related Notices of Funding Opportunities.

C. Final Rule

Title. The word ''access'' has been added to the title of this part to more accurately describe it. As noted above, the new name of the part is ''Community Development Revolving Loan Fund Access for Credit Unions.''

§ 705.1. Authority, Purpose and Scope. No commenters opposed the proposed changes to this section. Therefore, the Board is adopting § 705.1 substantially as proposed. Minor grammatical modifications have been made for clarity. The final rule combines and summarizes the essential elements in the first three sections of the previous rule. It also contains revised language regarding NCUA's expectations for the financial awards provided through the Fund. With these revisions, NCUA offers a more precise description of the impact that awards from the Fund can have on credit unions, their membership, and their communities. In addition, this section contains a general statement that any loans or technical assistance grants from the Fund are subject to NCUA's discretion and funds availability. 12 CFR 705.1(b). To achieve a more concise and streamlined rule, a general statement is included in this section rather than repeating it throughout the regulation.

§ 705.2. Definitions. The final rule adopts § 705.2 substantially as proposed, with a few minor grammatical or typographical changes. In 2008, the Board amended the criteria for determining whether a credit union qualifies for low-income designation. 73 FR 71909 (Nov. 26, 2008); *see also* 75 FR 47171 (Aug. 5, 2010). The final rule's definition of ''low-income members'' reflects that change. The final rule also defines ''qualifying credit unions,'' which was a newly defined term in the proposed rule. A ''qualifying credit union'' is one that may be, or has agreed to be, examined by NCUA and holds a current low-income designation. The final rule clarifies that low-income designations are made pursuant to § 701.34 for federal credit unions and § 741.204 for federally insured, state-chartered credit unions. For non-federally insured, state-chartered credit unions, low-income designations must be made by the appropriate state regulator under applicable state standards with the concurrence of NCUA. However, the definition of ''qualifying credit union'' applies only to those credit unions that NCUA may examine or that agree to be examined by NCUA. This requirement will enable NCUA to obtain all relevant information about a credit union's financial condition, so that it can make the most prudent and responsible choices among credit union applicants seeking awards from the Fund. Thus, if a non-federally insured credit union is interested in participating in the CDRLF program, it must first agree to examination by NCUA. The revised definition of ''participating credit union'' is a qualifying credit union that has

submitted an application which has been approved by NCUA. Other newly defined terms in the final rule, including ''notice of funding opportunity,'' ''application,'' ''loan,'' and ''technical assistance grant'' are self-explanatory.

§ 705.3. Eligibility. This section is adopted as proposed, with minor typographical modifications. Under the final rule, a credit union must complete an application and meet the underwriting criteria established by NCUA in order to be eligible to receive an award.

§ 705.4. Permissible Uses of Loan Funds. Section 705.4 of the final rule includes examples of permissible uses of loan funds received from the CDRLF. This list is non-exhaustive and illustrative. Several commenters expressed support for this aspect of the proposal. Accordingly, the Board is adopting this section, substantially as proposed, in the final rule. Minor modifications have been made to clarify the examples given. The final rule also adds operational programs, such as security or disaster recovery, as another example of a permissible use. Additionally, NCUA may announce other funding priorities and provide examples of other permissible uses of loan funds in the related Notice of Funding Opportunity.

§ 705.5. Terms and Conditions. The final rule eliminates much of the information previously set out in former §§ 705.5 and 705.7. The final rule provides that NCUA will establish the specific terms and conditions governing each particular loan in the related Notice of Funding Opportunity and the applicable loan documents. The rule also includes general information about the maximum loan amount, the interest rate, repayment, acceleration, and matching requirements.

The Board notes that the maximum loan amount is generally $300,000, but loans may exceed this amount in certain circumstances. In the related Notice of Funding Opportunity, NCUA will include the factors it will consider when deciding whether to make a loan in excess of $300,000.

To allow NCUA greater flexibility in establishing appropriate interest rates, the final rule eliminates specific reference to the range of interest rates that may be charged on a loan from the Fund (1% to 3% under the previous rule). Instead, it references the CDRLF's Interest Rate Policy, which is located on NCUA's Web site. The specific interest rate for a particular funding will be included in the related Notice of Funding Opportunity.

The final rule generally retains the previous rule's provisions addressing repayment, maturity, matching, and acceleration. One significant difference, however, is that the matching requirement is no longer mandatory. NCUA may require matching funds at its discretion, on a case-by-case basis, depending on the financial condition of the particular credit union. One commenter generally supported the elimination of the mandatory matching requirement, but suggested that NCUA should not require that these funds be obtained from a non-government source. The Board emphasizes that the purpose of this requirement is to discourage credit unions from depending too heavily on government funding to support their operations. Allowing a credit union to match its CDRLF funding with other government funding would be contrary to this purpose. Accordingly, the final rule retains the non-government element of matching when required.

In addition, the final rule retains language indicating that, at NCUA's discretion, a loan from the Fund must be recorded as a note payable or nonmember deposit. One commenter asked for clarification regarding when a loan should be recorded as a note payable or nonmember deposit. The Board notes that specific information about how a credit union should record a loan from the Fund will be provided in the applicable loan agreement.

The final rule also provides that NCUA may allow flexible repayment of loan principal in some instances. Specific details about flexible repayment options will be provided in the related Notice of Funding Opportunity and other applicable program materials.

§ 705.6. Application and Award Processes. In order to increase transparency, the final rule combines key information about the CDRLF application and award processes into one streamlined section of the rule. This section also clarifies the way in which a credit union applies for funds and how NCUA renders a decision on that application. Each subsection is discussed in further detail below.

(a) Notice of Funding Opportunity. This subsection corresponds to former § 705.9, but provides more detail about how and where NCUA will publicly announce loan and technical assistance grant program initiatives. The proposed rule eliminated the requirement that NCUA publish an annual notice of program opportunities in the **Federal Register** because information regarding program opportunities would be provided by various other means. One commenter suggested NCUA should continue to publish an annual notice, although another commenter disagreed. The final rule adopts this subsection as proposed. The Board emphasizes that Notices of Funding Opportunities will be published as often as necessary in the **Federal Register**. Information and notice of program opportunities will also be provided on NCUA's Web site (*http://www.ncua.gov*), provided through Letters to Credit Unions and the agency's electronic mail service, or publicized through various other means. In some cases, notices will be published more frequently than once a year. If there are no changes to the program or its requirements, however, notice is not necessary and will no longer be required annually under the final rule.

(b) Application Requirements. This section describes the information that applicant credit unions must provide to NCUA when applying for financial awards from the CDRLF. To simplify and streamline the application requirements, the final rule incorporates provisions from §§ 705.5(a), (b)(1), and (b)(5) of the previous rule. Additionally, to minimize burdens on applicants, the final rule eliminates the requirement that a credit union develop a Community Needs Plan (see former § 705.6). Instead, an applicant credit union must provide a written narrative describing how it intends to use a financial award from the Fund. The narrative should demonstrate that the award will enhance the products and services the credit union provides to its members. It also should describe how those enhanced products and services will support the economic development of the community served by the credit union.

Under the proposal, CDRLF loan applicants would be required to provide financial projections to support their applications. One commenter, however, raised concerns about the cost burden imposed by this requirement. This commenter also suggested that if financial projections are required, NCUA should provide a template to assist credit union in making its projections. In most cases, the Board does not anticipate that financial projections will be necessary to support the credit union's application. Accordingly, the Board is removing this requirement from the final rule. If financial projections are necessary for a particular award, NCUA will request those projections through the related Notice of Funding Opportunity. The Board notes that OSCUI has provided training to credit unions on the development of financial projections, and NCUA will consider making

operating tools such as a template available to credit unions.

This subsection also describes the additional information that is required from non-federally insured credit unions. Notably, under the final rule, non-federally insured, state-chartered credit unions must provide documentation of the credit union's status as a low-income credit union. Also, non-federally insured, state-chartered credit unions must agree to be examined by NCUA.

(c) Evaluation and Selection of Participating Credit Unions. This subsection, which is substantively adopted as proposed, describes the criteria that NCUA will generally evaluate in deciding among competing applications for the limited CDRLF funds. As requests for funding routinely exceed available funds, the information provided in this subsection is intended to help credit unions develop and refine their applications. This information also will help credit unions better understand how the agency makes its determinations. For example, NCUA will consider financial and performance considerations, whether the proposed uses of funds are compatible with program goals, and whether the credit union is likely to be successful in accomplishing its stated objectives. The Board notes, however, that other relevant criteria may be evaluated in the agency's selection process, depending on the funding initiative, economic environment, or other factors. Any other criteria that the agency will evaluate will be identified in the related Notice of Funding Opportunity.

Under the proposal, this subsection stated that, with regard to qualifying credit unions, NCUA will consult with and consider information from an applicant credit union's examiners. The proposed rule also required the concurrence of the applicant credit union's supervising Regional Director before an award is made. One commenter did not agree with this requirement. This commenter suggested that if a credit union meets NCUA's underwriting criteria for a loan, the lending decision should not also be subject to the Regional Director's discretion. The Board disagrees. Assurance that a credit union is capable of effectively deploying, administering, and repaying the loan proceeds is necessary to NCUA's prudent management of this limited financial resource. The Board believes that input from the regional staff responsible for the direct supervision of the applicant credit union is an essential element of the evaluation process. It also will help ensure that awards from the Fund are appropriately distributed. The Board notes that consultation with examination staff and the Regional Director has been a matter of practice, and including the requirement in the regulation improves transparency.

(d) Requests for Additional Information. Under the final rule, NCUA may, at its discretion, require additional information from applicants before rendering its decision on an award. The failure to provide the requested information may result in rejection of the application.

(e) Timing. NCUA will include in the related Notice of Funding Opportunity a timeframe to submit all requested information. Where NCUA requests additional clarifying information for a particular credit union, the agency will also provide a deadline for the credit union to provide that information. A failure to submit all of the requested information by the stated deadline may result in rejection of the application without further consideration.

(f) Notice of Award and Appeals. This subsection describes the process by which NCUA will notify an applicant credit union whether it has qualified for a loan or request for technical assistance. If its application is denied, a credit union may appeal that decision to the Board. A commenter expressed concern that a credit union that is considered nonqualified based on its application would not have the ability to appeal to the Board on the question of qualification. The Board notes that § 705.6(f)(1) of the proposed rule, which is finalized in this rule, allows an applicant to appeal to the Board on the question of qualification. It is important to note, however, that the scope of Board's review on appeal is limited to the threshold question of qualification and not the issue of whether, among qualified applicants, a particular loan or technical assistance grant is funded. Awards from the Fund are discretionary and that determination is not subject to administrative appeal to the Board.

(g) Disbursement. This subsection provides that before NCUA will disburse a loan, the participating credit union must sign all applicable loan documents and the promissory note. This section also states that NCUA may, in its discretion, choose not to disburse the entire loan at once. One commenter suggested that if NCUA chooses not to disburse a particular loan all at once, it should provide written notice to the credit union with a schedule of release of subsequent loan funds and any performance measures that the credit union must meet in order to obtain the subsequent funds. The Board notes that the related Notice of Funding Opportunity will provide specific details about the disbursement process if a loan is not disbursed in a single payment.

§ 705.7. Urgency. The proposed rule provided that, on an emergency basis, NCUA may consider a funding request from a qualifying credit union experiencing an unplanned or unexpected expense that the credit union is unable to meet with its own resources. Several commenters expressed support for this provision and the Board adopts this section without substantive change.

Under the final rule, the credit union will be required to demonstrate a compelling need for immediate assistance without which its continued operations would be threatened or severely disrupted. NCUA will evaluate these applications to determine if emergency funding is warranted. Urgent needs for funding are not part of any specific initiative, but rather an ongoing process that will not be included in specific Notices of Funding Opportunities. The Board emphasizes that technical assistance grants and loans provided under this section are on an emergency basis and should not be a regular source of funding for credit unions. Credit unions requesting urgent funding must still demonstrate a purpose consistent with the goals of the Fund.

§ 705.8. Qualifying State-Chartered Credit Unions. This section incorporates language from § 705.8 of the previous regulation, and sets out the specific requirements that are applicable to state-chartered credit unions. These requirements include obtaining written concurrence from the credit union's state regulatory authority, making state examination reports available to NCUA, and agreeing to examination by NCUA. In the proposal, an examination under this subsection would allow NCUA to examine the credit union only to verify compliance with this part. Upon consideration, however, the Board has determined that prudent management of the Fund requires NCUA to be able to examine the entire financial condition of a state-chartered credit union. Thus, the final rule removes this limitation. Additionally, the Board notes that written concurrence from a state regulatory authority does not guarantee NCUA approval of a credit union's application.

§ 705.9. Reporting and Monitoring. The final rule establishes a new framework for NCUA to monitor the use of CDRLF funding to ensure that award recipients actually use the funds for intended purposes. Under the final rule, participating credit unions are required,

at such times and in such formats as NCUA shall direct, to submit reports to describe how the funds have been used and the results that have been obtained. Additionally, NCUA may, at its discretion, review certain existing information, such as call report data and examination reports, to evaluate the effectiveness of the loan and technical assistance programs. One commenter raised concerns that the language permitting NCUA to require reporting ''at such times and in such formats as NCUA shall direct'' is overly broad. The Board notes that in the event NCUA requires reporting, it will provide specific detail about the post-award reporting requirements in the related Notice of Funding Opportunity. As such, credit unions will likely have ample advance notice of the nature and format of information that award recipients will be required to report.

§ 705.10. Technical Assistance Grants. Section 705.10 of the proposal is adopted, unchanged from the proposed rule. In general, technical assistance grants are provided on a reimbursement basis to cover expenditures approved in advance and supported by receipts. This section describes the permissible uses of technical assistance grant funds and discusses the appeal rights for technical assistance grant reimbursement denials in accordance with NCUA Interpretative Ruling and Policy Statement (IRPS) 11–1. 76 FR 3674 (Jan. 20, 2011). IRPS 11–1 provides that technical assistance grant reimbursement denials may only be appealed to NCUA's Supervisory Review Committee. Credit unions must make appeals within 30 days from the date of the denial. *Id.* The determination of NCUA's Supervisory Review Committee is final and its decisions may not be appealed to the Board.

D. Conforming Amendments

The Board is making two technical amendments to § 701.32(c) and § 741.207 to conform to the changes in this final rule. The conforming amendments modify existing cross-references to part 705.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires NCUA to prepare an analysis to describe any significant economic impact any proposed regulation may have on a substantial number of small entities. NCUA considers credit unions having less than ten million dollars in assets to be small for purposes of RFA. IRPS 87–2, as amended by IRPS 03–2. The revisions to part 705 are designed to update and streamline the rule, thereby reducing the burden for credit unions that are seeking CDRLF awards. Moreover, the rule implements a program that is entirely voluntary on the part of credit unions. It has no impact on credit unions that elect not to pursue this funding opportunity. NCUA has determined and certifies that this final rule does not have a significant economic impact on a substantial number of small credit unions. Accordingly, the NCUA has determined that an RFA analysis is not required.

Paperwork Reduction Act

There are aspects of the CDRLF program that involve information collection within the meaning of the Paperwork Reduction Act of 1995 (PRA). 44 U.S.C. 3507(d). Previously, NCUA sought and obtained Office of Management and Budget (OMB) approval for its use of certain documents, including the application and report forms used to monitor and follow up on how credit unions have used CDRLF funds. These documents were assigned OMB Control No. 3133–0138, which remained valid through December 2010. Documentation was submitted with the proposed rule, however, it was incorrect. NCUA has corrected and resubmitted an application for reinstatement of OMB Control No. 3133–0138 for the CDRLF loan program. Comment has been requested on this submission. 76 FR 62456 (Oct. 7, 2011). Organizations and individuals that wish to submit comments on this information collection requirement must do so by November 7, 2011.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the Executive Order. The financial award programs administered through the CDRLF are available to FCUs as well as to state-chartered credit unions. By law, state-chartered institutions with federal share insurance are already subject to numerous provisions of NCUA's rules, based on the agency's role as the insurer of member share accounts and the significant interest NCUA has in the safety and soundness of their operations. The final 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. NCUA has determined that this rule does not constitute a policy that has federalism implications for purposes of the Executive Order.

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

List of Subjects

12 CFR Part 701

Advertising, Aged, Civil rights, Credit, Credit unions, Fair housing, Individuals with disabilities, Insurance, Marital status discrimination, Mortgages, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination, Signs and symbols, Surety bonds.

12 CFR Part 705

Credit unions, Loans, Grants, Revolving fund, Community programs, Low income.

12 CFR Part 741

Bank deposit insurance, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on October 27, 2011.

Mary F. Rupp,

Secretary of the Board.

For the reasons discussed above, NCUA amends 12 CFR parts 701, 705, and 741 of title 12, chapter VII, of the Code of Federal Regulations as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

■ 1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1758, 1759, 1761A, 1761B, 1766, 1767, 1782, 1784, 1786, 1787, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601 *et seq.;* 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 42 U.S.C. 4311–4312.

§ 701.32 [Amended]

■ 2. Section 701.32 is amended by removing in paragraph (c) the citation ''§ 705.7(b)'' and adding in its place the citation ''§ 705.5(g)''.

■ 3. Revise part 705 to read as follows:

PART 705—COMMUNITY DEVELOPMENT REVOLVING LOAN FUND ACCESS FOR CREDIT UNIONS

Sec.
705.1 Authority, purpose, and scope
705.2 Definitions
705.3 Eligibility requirements
705.4 Permissible uses of loan funds
705.5 Terms and conditions
705.6 Application and award processes
705.7 Urgency
705.8 Qualifying state-chartered credit unions
705.9 Reporting and monitoring
705.10 Technical assistance grants

Authority: 12 U.S.C. 1756, 1757(5)(D), and (7)(I), 1766, 1782, 1784, 1785 and 1786.

§ 705.1 Authority, purpose, and scope.

(a) This part 705 is issued by the National Credit Union Administration (NCUA) under section 130 of the Federal Credit Union Act, 12 U.S.C. 1772c–1, which implements the Community Development Credit Union Revolving Loan Fund Transfer Act (Pub. L. 99–609, 100 Stat. 3475 (Nov. 6, 1986)).

(b) This Part describes how NCUA makes money available to credit unions from its Community Development Revolving Loan Fund (Fund). NCUA administers the Fund and makes both loans and technical assistance grants to credit unions in accordance with the eligibility criteria and other qualifications, subject to the terms and conditions set out in this Part. All loans and technical assistance grants made under this Part are subject to funds availability and NCUA's discretion.

(c) The Fund is intended to support the efforts of credit unions through loans and technical assistance grants needed for:

(1) Providing basic financial and related services to members in their communities;

(2) Enhancing their capacity to better serve their members and the communities in which they operate; and

(3) Responding to emergencies.

(d) The policy of NCUA is to revolve funds to credit unions as often as practical in order to achieve maximum economic impact on as many credit unions as possible. NCUA anticipates the financial awards provided to credit unions through the Fund will better enable them to support the communities in which they operate. With these awards, credit unions will be able to provide basic financial services to low-income members of these communities, resulting in more opportunities for these members to improve their financial circumstances.

(e) This Part generally establishes the following:

(1) Definitions;

(2) The application process and requirements for qualifying for a loan from the Fund;

(3) The evaluation process;

(4) How loan funds are to be made available and their repayment; and

(5) Technical assistance grants to be provided to credit unions.

§ 705.2 Definitions.

For purposes of this Part, the following terms shall have the meanings assigned to them in this section.

Application means a form supplied by the NCUA by which a Qualifying Credit Union may apply for a loan or a technical assistance grant from the Fund.

Board refers to the National Credit Union Administration Board.

Credit Union means a credit union chartered under the Federal Credit Union Act or under the laws of any state of the United States.

Fund means the Community Development Revolving Loan Fund.

Loan is an award in the form of an extension of credit from the Fund to a Participating Credit Union that must be repaid, with interest.

Low-income Members are those members defined in § 701.34 of this chapter.

Notice of Funding Opportunity, as more fully described in § 705.6 of this part, means the notice NCUA publishes describing one or more loan or technical assistance grant programs or initiatives currently being supported by the Fund and inviting interested Qualifying Credit Unions to submit applications to participate in the program(s) or initiative(s).

Participating Credit Union refers to a Qualifying Credit Union that has submitted an application for a loan or a technical assistance grant from the Fund which has been approved by NCUA. A Participating Credit Union shall not be deemed to be an agency, department, or instrumentality of the United States because of its receipt of a financial award from the Fund.

Program means the Community Development Revolving Loan Fund Program under which NCUA makes loans and technical assistance grants available to credit unions.

Qualifying Credit Union means a credit union that may be, or has agreed to be, examined by NCUA, with a current low-income designation pursuant to § 701.34(a)(1) or § 741.204 of this chapter or, in the case of a non-federally insured, state-chartered credit union, a low-income designation from a state regulator, made under appropriate state standards with the concurrence of NCUA. Services to low-income members must include, at a minimum, offering share accounts and loans.

Technical Assistance Grant means an award of money from the Fund to a Participating Credit Union that does not have to be repaid.

§ 705.3 Eligibility requirements.

To be eligible to receive a CDRLF award, in the form of either a loan or a technical assistance grant, a Qualifying Credit Union must, within the timeframes specified in any Notice of Funding Opportunity:

(a) Complete and submit an Application; and

(b) Meet the underwriting standards established by NCUA, including those pertaining to financial viability, as set forth in the Application and any related materials developed by NCUA.

§ 705.4 Permissible uses of loan funds.

NCUA may make loans from the Fund to Participating Credit Unions for various uses. The following is a non-exhaustive list of permissible uses or projects:

(a) Development of new products or services for members, including new or expanded share draft or credit card programs;

(b) Partnership arrangements with community-based service organizations or government agencies;

(c) Loan programs, including, but not limited to, microbusiness loans, payday loan alternatives, education loans, and real estate loans;

(d) Acquisition, expansion, or improvement of office space or equipment, including branch facilities, ATMs, and electronic banking facilities; and

(e) Operational programs such as security or disaster recovery.

§ 705.5 Terms and conditions.

(a) NCUA may make loans, in such amounts and subject to such terms and conditions as it may determine, from the Fund to Participating Credit Unions.

(b) *Funding Limits.* Loans may be granted in amounts up to $300,000 in the aggregate, depending on the creditworthiness of the Qualifying Credit Union, its financial need, and its demonstrated capability to provide financial and related services to its members. NCUA may, however, make loans that exceed $300,000 in certain circumstances. NCUA will include in the related Notice of Funding Opportunity the particular criteria used to evaluate an Application for a loan that exceeds $300,000.

(c) *Recording of a loan.* At the discretion of NCUA, a loan will be

recorded by a Participating Credit Union as either a note payable or a nonmember deposit.

(d) *Interest rate.* The rate of interest on loans is governed by the CDRLF Loan Interest Rate Policy, which can be found on NCUA's Web site or by contacting NCUA's Office of Small Credit Union Initiatives. The specific interest rate for a particular funding will be announced in the related Notice of Funding Opportunity. The Board will announce changes, if any, to the CDRLF Loan Interest Rate Policy and those changes will apply to loans made under future Notices of Funding Opportunities.

(e) *Repayment and maturity.* (1) Awards made available through loans, whether recorded as a note payable or nonmember deposit, must be repaid to NCUA. All loans will be scheduled for repayment consistent with sound business practices and the objectives of the Program, but in no case will the term exceed five years.

(2) Interest payments will be required semiannually beginning six months after the initial distribution of a loan.

(3) NCUA may allow flexible repayment of loan principal. Details and specific provisions will be addressed in the Notice of Funding Opportunity and other program materials.

(f) *Acceleration.* The terms of each loan agreement will provide for the immediate acceleration of the unpaid balance for breach or default in performance by the Participating Credit Union of the terms or conditions of the loan. Default and breach include misrepresentation; failure to make interest or principal payments when due; failure to file required reports; insolvency of the Participating Credit Union; and, if required by NCUA, failure to maintain adequate matching funds for the duration of the loan. Other specific causes of default and breach will be identified in the loan documents between the Participating Credit Union and NCUA. The unpaid balance will also be accelerated and immediately due if any part of the loan funds are improperly used or if uninvested loan proceeds remain unused for an unreasonable or unjustified period of time.

(g) *Matching requirements.* At its discretion, NCUA may require a Participating Credit Union to develop and implement a plan to match all or a portion of the funds represented by loan proceeds. Such requirement will be based on the financial condition of the Participating Credit Union, which will be evaluated under criteria contained in the related Notice of Funding Opportunity. Matching funds must be from non-governmental member or nonmember share deposits. Participating Credit Unions required to provide matching funds are subject to the following general provisions and any other conditions in the related Notice of Funding Opportunity and agreements between the Participating Credit Union and NCUA:

(1) Loan monies made available generally must be matched by the Participating Credit Union in an amount equal to the loan amount. Any loan monies matched by nonmember share deposits are not subject to the 20% limitation on nonmember deposits under § 701.32 of this chapter. Participating Credit Unions must maintain the increase in the total amount of share deposits for the duration of the loan. Once the loan is repaid, nonmember share deposits accepted to meet the matching requirement are subject to § 701.32 of this chapter.

(2) Upon approval of its loan application, and before it meets its matching, if required, a Participating Credit Union may receive the entire loan commitment in a single payment. If, at NCUA's discretion, any funds are withheld, the remainder of the funds committed will be available to the Participating Credit Union only after it has documented that it has met the match requirement.

(3) Failure of a Participating Credit Union to generate the required match within the time specified in the loan documents may result in the reduction of the loan proportionate to the amount of match actually generated. Payment of any additional funds initially approved may be limited as appropriate to reflect the revised amount of the loan approved. Any funds already advanced to the Participating Credit Union in excess of the revised amount of loan approval must be repaid immediately to NCUA. Failure to repay such funds to NCUA upon demand may result in the default of the entire loan.

(h) *Other terms and conditions.* Other terms and conditions pertaining to loans, including but not necessarily limited to duration, repayment obligations, and covenants, will be specified in the related Notice of Funding Opportunity or applicable loan documents to be signed by the Participating Credit Union.

§ 705.6 Application and award processes.

(a) *Notice of Funding Opportunity.* NCUA will publish a Notice of Funding Opportunity in the **Federal Register**, on applicable government Web sites, and its own Web site. The Notice of Funding Opportunity will describe the loan and technical assistance grant programs for the period in which funds are available. It also will announce special initiatives, the amount of funds available, funding priorities, permissible uses of funds, funding limits, deadlines, and other pertinent details. The Notice of Funding Opportunity will also advise potential applicants on how to obtain an Application and related materials. NCUA may supplement the information contained in the Notice of Funding Opportunity through such other media as it determines appropriate, including Letters to Credit Unions, direct notices to Qualifying Credit Unions, and announcements on its Web site.

(b) *Application requirements.* A Qualifying Credit Union must demonstrate a sound financial position and ability to manage its day-to-day business affairs. It also must show that its planned use of proceeds is consistent with the purpose of the Program, the requirements of this Part, and the related Notice of Funding Opportunity. The related Notice of Funding Opportunity may include additional details and requirements.

(1) Applications to participate and qualify for a loan or technical assistance grant under the Program may be obtained from the National Credit Union Administration as outlined in the related Notice of Funding Opportunity.

(2) With respect to loans, NCUA will also require a Qualifying Credit Union to develop and submit a narrative describing how the Qualifying Credit Union intends to use the money obtained from the Fund to enhance the products or services it provides to its membership and how those enhanced products or services support the membership and community served by the Qualifying Credit Union.

(3) In addition to those items required in this section, a Qualifying Credit Union that is a non-federally insured state-chartered credit union must also include the following:

(i) A copy of its most recent external audit report;

(ii) Proof of deposit and surety bond insurance which states the maximum insurance levels permitted by the policies;

(iii) A balance sheet, an income and expense statement, and a schedule of delinquent loans, for each of the four most recent quarter-ends;

(iv) Documentation of the credit union's status as a low-income credit union by the appropriate state supervisory agency consistent with NCUA Rules and Regulations at §§ 701.34(a) and 741.204(b); and

(v) An agreement to be subject to examination by NCUA.

(c) *Evaluation and selection of Qualifying Credit Unions.* NCUA will generally evaluate applications submitted by Qualifying Credit Unions in accordance with the criteria described in this section. Nothing in this section, however, precludes NCUA from considering other criteria included in the related Notice of Funding Opportunity that NCUA determines to be necessary based on the type of funding initiative, economic environment, or other factors or conditions that warrant the evaluation of additional or alternative criteria. Generally, NCUA will evaluate complete applications to determine if the Qualifying Credit Union satisfies the following:

(1) *Financial and Performance.* The Qualifying Credit Union must exhibit a safe and sound financial condition, including a demonstrated ability to perform the requirements associated with the type of award being sought and compliance with NCUA's underwriting standards. In this respect, NCUA will consider the Qualifying Credit Union's long-term financial viability, including absence of indicators suggesting the Qualifying Credit Union is a candidate for merger, a purchase and assumption transaction, or conservatorship. NCUA will also consider the Qualifying Credit Union's compliance with the provisions of any previous loan or technical assistance grant received. NCUA may also consider information concerning the Qualifying Credit Union to which it already has access, including information obtained through the examination process and data contained in Call Reports.

(2) *Compatibility.* NCUA will evaluate whether the stated objectives to be accomplished through the use of the loan or technical assistance grant proceeds conform to the broad purposes and rationale underlying the Fund. Specifically, NCUA will consider whether the award will enable the Qualifying Credit Union to provide basic financial products and related services to its members or enhance its capacity to better serve its members and the community in which it operates. NCUA will also consider whether the use of the financial award will conform to any applicable funding priority, special initiative, or special instruction announced in the related Notice of Funding Opportunity.

(3) *Feasibility.* NCUA will consider the likelihood of the Qualifying Credit Union's success in accomplishing its stated objectives, based on its Application and the factors NCUA determines are relevant.

(4) *Examination Information and Concurrence from Regional Director for Qualifying Federal Credit Unions.* In evaluating the Qualifying Credit Union, NCUA will consider information and statements provided by NCUA staff or State Supervisory Authority staff that performed the Qualifying Credit Union's most recent examination. NCUA will only provide a loan or a technical assistance grant to a Qualifying Credit Union with the concurrence of that credit union's supervising Regional Director. Examination information for a Qualifying Credit Union that is a state-chartered credit union is discussed in § 705.8 of this Part.

(d) *Requests for additional information.* NCUA will make its funding determinations among the several qualified Applications based on its discretion and consideration of which best meet the priorities and initiatives established and announced by NCUA. During its evaluation process, however, NCUA may request a Qualifying Credit Union to provide additional clarifying or technical information to support its application. NCUA may determine not to provide further consideration of any Application failing to provide additional required information.

(e) *Timing.* NCUA will announce, in the related Notice of Funding Opportunity, the deadline for Qualifying Credit Unions to submit all required documentation, including the Application. Failure to submit all of the requested information or to submit the information within the timeframe specified in the Notice of Funding Opportunity, or in the case of requests for additional clarifying or technical information, within the time specified by NCUA, may result in rejection of the Application without further consideration.

(f) *Notice of Award and Appeals.* NCUA will determine whether an application meets NCUA's standards established by this Part and the related Notice of Funding Opportunity. NCUA will provide written notice to a Qualifying Credit Union as to whether or not it has qualified for a loan or technical assistance grant under this Part. A Qualifying Credit Union whose application has been denied for failure of a qualification may appeal that decision to the NCUA Board in accordance with the following:

(1) Within thirty days of its receipt of a notice of non-qualification, a credit union may appeal the decision to the NCUA Board. The scope of the NCUA Board's review is limited to the threshold question of qualification and not the issue of whether, among qualified applicants, a particular loan or technical assistance grant is funded.

(2) The foregoing procedure shall apply only with respect to Applications received by NCUA during an open period in which funds are available and NCUA has called for Applications. Any Application submitted by an applicant during a period in which NCUA has not called for Applications will be rejected, except for those Applications submitted under § 705.7 of this section. Any such rejection shall not be subject to appeal or review by the NCUA Board.

(g) *Disbursement.* Before NCUA will disburse a loan, the Participating Credit Union must sign the loan agreement, promissory note, and any other loan related documents. NCUA may, in its discretion, choose not to disburse the entire amount of the loan at once.

§ 705.7 Urgency.

On an emergency basis, subject to funds availability, NCUA may consider a funding request from a Qualifying Credit Union experiencing an unplanned or unexpected expense that the Qualifying Credit Union is unable to meet with its own resources. The Qualifying Credit Union must demonstrate a compelling need for immediate assistance without which its continued operations would be threatened or severely disrupted. NCUA, in its discretion, will determine whether the situation constitutes an emergency and if the Qualifying Credit Union is required to submit any additional information to show why the funds are needed on an emergency basis. NCUA will determine and substantiate any reason to expedite funding in such case. Requests for loans or technical assistance grants under this section will be addressed on an ongoing basis and are outside the scope of the related Notice of Funding Opportunity. Technical assistance grants and loans provided on this basis must still demonstrate a purpose consistent with the goals of the Fund. Loans and technical assistance grants made under this section are not anticipated to be a regular source of funding for any Qualifying Credit Unions.

§ 705.8 Qualifying state-chartered credit unions.

A Qualifying Credit Union that is a state-chartered credit union and has submitted an Application to NCUA for participation must obtain written concurrence from its respective state regulatory authority before NCUA will approve its Application. A Qualifying Credit Union that is a state-chartered credit union must also make copies of its state examination reports available to

NCUA and must agree to examination by NCUA.

§ 705.9 Reporting and monitoring.

(a) *General.* NCUA's policy is to monitor Participating Credit Unions to assure that loan and technical assistance grant funds awarded under this Part have been used in accordance with their intended purposes and to determine whether anticipated outcomes have been achieved. Particular emphasis will be placed on reviewing loan funds earmarked for programs or initiatives proposed by the Participating Credit Union to determine if the funds have been used as represented and whether the program or initiative has had the impact anticipated by the Participating Credit Union.

(b) *Reporting.* A Participating Credit Union must complete and submit all required reports, at such times and in such formats as NCUA will direct. Such reports must describe how the Participating Credit Union has used the loan or technical assistance grant proceeds and the results it has obtained, in relation to the programs, policies, or initiatives identified by the Participating Credit Union in its application. In addition, the Participating Credit Union's board of directors must report on the progress of providing needed community services to the Participating Credit Union's members once a year, either at the annual meeting or in a written report sent to all members. The Participating Credit Union must also submit to NCUA the written report or a summary of the report given at the annual meeting. NCUA may request additional information as it determines appropriate.

(c) *Monitoring.* At its discretion, for verification purposes and as part of its evaluation of the effectiveness of the loan and technical assistance grant programs, NCUA may elect to review information concerning Participating Credit Unions to which it already has access, including information obtained through the examination process and data contained in Call Reports.

§ 705.10 Technical assistance grants.

Technical assistance grants may be funded in such amounts, and in accordance with such terms and conditions, as NCUA may establish. In general, technical assistance grants are provided on a reimbursement basis, to cover expenditures approved in advance by NCUA and supported by receipts evidencing payment by the Participating Credit Union.

(a) *Permissible uses of technical assistance grant funds.* Section 705.4(a) and (b) of this part also apply to technical assistance grants made under this section. Those sections provide examples and other information with respect to the permissible use of CDRLF funds. In addition, technical assistance grants generally should enhance and support the Participating Credit Union's internal capacity to serve its members and better enable it to provide financial services to the community in which the Participating Credit Union is located.

(b) *Appeals of technical assistance grant reimbursement denials.* Pursuant to NCUA Interpretative Ruling and Policy Statement 11–1, any Participating Credit Union may appeal a denial of a technical assistance grant reimbursement to NCUA's Supervisory Review Committee. All appeals of technical assistance grant reimbursements must be submitted to the Supervisory Review Committee within 30 days from the date of the denial. The decisions of the Supervisory Review Committee are final and may not be appealed to the NCUA Board.

PART 741—REQUIREMENTS FOR INSURANCE

■ 4. The authority citation for part 741 continues to read as follows:

Authority: 12 U.S.C. 1757, 1766(a), 1781—1790, and 1790d; 31 U.S.C. 3717.

§ 741.207 [Amended]

■ 5. Section 741.207 is amended by removing the citation ''§ 705.3'' and adding in its place the citation ''§ 705.2''.

[FR Doc. 2011–28335 Filed 11–1–11; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0273; Directorate Identifier 2011–NE–08–AD; Amendment 39–16845; AD 2011–22–03]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Corporation Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Rolls-Royce Corporation (RRC) AE 3007A, AE 3007A1/1, AE 3007A1, AE 3007A1/3, AE 3007A1E, AE 3007A1P, and AE 3007A3 turbofan engines. This AD requires initial and repetitive eddy current inspections (ECI) of certain 6th-through-13th stage compressor wheel knife edge seals, and initial and repetitive ECIs of the compressor wheel outer circumference, for cracks. This AD was prompted by reports of low-cycle fatigue cracks found during shop visits, in the 6th-through-13th stage compressor wheels having chrome-carbide coated or uncoated knife edge seals. We are issuing this AD to prevent uncontained failure of the 6th-through-13th stage compressor wheel, leading to damage to the airplane.

DATES: This AD is effective November 17, 2011.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of November 17, 2011.

We must receive comments on this AD by December 19, 2011.

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

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

For service information identified in this AD, contact Rolls-Royce Corporation, P.O. Box 420, Indianapolis, IN 46206; *phone:* (317) 230–3774; fax: (317) 230–6084; *email: indy.pubs.services@rolls-royce.com.* You may review copies of the referenced service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (*phone:* (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kyri Zaroyiannis, Aerospace Engineer, Chicago Aircraft Certification Office, Small Airplane Directorate, FAA, 2300 E. Devon Ave., Des Plaines, IL 60018; *phone:* (847) 294–7836; fax: (847) 294–7834; *email: kyri.zaroyiannis@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We received reports of low-cycle fatigue cracks found during shop visits, in the 6th-through-13th stage compressor wheels having chrome-carbide coated or uncoated knife edge seals, on RRC AE 3007A, AE 3007A1/1, AE 3007A1, AE 3007A1/3, AE 3007A1E, AE 3007A1P, and AE 3007A3 turbofan engines. These cracks can deteriorate the integrity of the compressor wheel by lengthening into the outer circumference of the wheel. This condition, if not corrected, could result in uncontained failure of the 6th-through-13th stage compressor wheel, leading to damage to the airplane.

Relevant Service Information

We reviewed RRC Alert Service Bulletin (ASB) No. AE 3007A–A–72–386, Revision 4, dated June 27, 2011, which describes procedures for performing a one-time comprehensive ECI of the compressor wheel outer circumference, for cracks. We also reviewed RRC ASB No. AE 3007A–A–72–390, Revision 3, dated June 27, 2011, which describes procedures for initial and repetitive inspections of affected 6th-through-13th stage compressor wheel knife edge seals and the compressor wheel outer circumference, for cracks.

FAA's Determination

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

AD Requirements

This AD requires accomplishing the actions specified in the service information described previously. The AD also requires sending the inspection results to AE Service Data, Rolls-Royce Corporation, *Attn:* AE Service Data Manager, P.O. Box 420, Speed Code U17, Indianapolis, IN 46206–0420, *email: cra.rel.data@rolls-royce.com.*

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because our risk assessment indicates these parts, uninspected, pose an unacceptable level of risk to the traveling public. Therefore, we find that notice and opportunity for prior public comment are impracticable and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2011–0273 and Directorate Identifier 2011–NE–08–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

Costs of Compliance

We estimate that this AD will affect 1,402 RRC AE 3007A, AE 3007A1/1, AE 3007A1, AE 3007A1/3, AE 3007A1E, AE 3007A1P, and AE 3007A3 turbofan engines installed on 616 airplanes of U.S. registry. We also estimate that it will take about 6 hours to perform one inspection of the affected 6th-through-13th stage compressor wheel knife edge seals and the compressor wheel outer circumference, for each engine. The average labor rate is $85 per work-hour. We anticipate required parts costs to be $35,546,000. Based on these figures, we estimate the total cost of the AD to U.S. operators to be $36,259,926.

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

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

For the reasons discussed above, I certify that this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2011–22–03 Rolls-Royce Corporation (Formerly Allison Engine Company): Amendment 39–16845; Docket No. FAA–2011–0273; Directorate Identifier 2011–NE–08–AD.

(a) Effective Date

This AD is effective November 17, 2011.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Corporation (RRC) AE 3007A, AE 3007A1/1, AE 3007A1, AE 3007A1/3, AE 3007A1E, AE 3007A1P, and AE 3007A3 turbofan engines, with any of the 6th-through-13th stage compressor wheel part numbers (P/Ns) in Table 1 of this AD installed.

TABLE 1—6TH-THROUGH-13TH STAGE COMPRESSOR WHEEL P/NS AFFECTED BY THIS AD

Compressor wheel stage	Wheel P/Ns with chrome-carbide coated knife seals	Wheel P/Ns with uncoated knife seals
6th	23074717	23062666, 23071261, 23071396
7th	23074719, 23074217	23062667, 23071262, 23071397
8th	23074721	23061628, 23071263
9th	23074722	23061629, 23071264
10th	23074723	23061630, 23071265
11th	23074724	23061631, 23066231
12th	23074725	23061632, 23071267
13th	23074213, 23074726	23061633, 23071268

(d) Unsafe Condition

This AD was prompted by reports of low-cycle fatigue cracks found during shop visits, in the 6th-through-13th stage compressor wheels having chrome-carbide coated or uncoated knife edge seals. We are issuing this AD to prevent uncontained failure of the 6th-through-13th stage compressor wheel, leading to damage to the airplane.

(e) Compliance

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

(f) Initial Inspection

The initial inspection compliance times for the 6th-through-13th stage compressor wheels are based on cycles-since-new (CSN) and cycles-in-service (CIS) of their 12th and 13th stage compressor wheels. For engines that one or both 12th and 13th stage compressor wheels have chrome-carbide coated knife edge seals, use the compliance times listed in Table 2 of this AD. For engines that both 12th and 13th stage compressor wheels do not have chrome-carbide coated knife edge seals, use the compliance times listed in Table 3 of this AD.

(1) Perform a one-time comprehensive eddy current inspection (ECI) of the 6th-through-13th stage compressor wheel knife edge seals for cracks, using paragraph 2, Accomplishment Instructions, of RRC Alert Service Bulletin (ASB) No. AE 3007A–A–72–386, Revision 4, dated June 27, 2011 (Completion of this one-time comprehensive ECI relieves you thereafter of the repetitive inspection requirements of this AD); or

(2) Perform an initial ECI of the 6th-through-13th stage compressor wheel outer circumferences for cracks, using paragraph 2, Accomplishment Instructions, of RRC ASB No. AE 3007A–A–72–390, Revision 3, dated June 27, 2011.

TABLE 2—INITIAL INSPECTION COMPLIANCE TIMES FOR ENGINES, THAT ONE OR BOTH 12TH AND 13TH STAGE COMPRESSOR WHEELS HAVE CHROME-CARBIDE COATED KNIFE EDGE SEALS

For 12th and or 13th stage compressor wheels with the following CSN on the effective date of this AD	Initially inspect after the effective date of this AD
(i) 18,185 or more CSN	Within 15 CIS.
(ii) 16,700 to 18,184 CSN	Before accumulating 18,200 CSN.
(iii) 16,000 to 16,699 CSN	Within 1,500 CIS.
(iv) 15,100 to 15,999 CSN	Within 2,000 CIS.
(v) 14,300 to 15,099 CSN	Within 2,800 CIS.
(vi) 13,000 to 14,299 CSN	Within 3,400 CIS.
(vii) 12,300 to 12,999 CSN	Within 4,000 CIS.
(viii) 11,200 to 12,299 CSN	Within 4,600 CIS.
(ix) 9,700 to 11,199 CSN	Within 5,300 CIS.
(x) Fewer than 9,700 CSN	Before accumulating 15,000 CSN or at the next shop visit when the engine has more than 7,000 cycles, whichever occurs first.

TABLE 3—INITIAL INSPECTION COMPLIANCE TIMES FOR ENGINES, THAT BOTH 12TH AND 13TH STAGE COMPRESSOR WHEELS DO NOT HAVE CHROME-CARBIDE COATED KNIFE EDGE SEALS

For 12th and or 13th stage compressor wheels with the following CSN on the effective date of this AD:	Initially inspect after the effective date of this AD:
(i) 18,300 or more CSN	Within 200 CIS.
(ii) 16,000 to 18,299 CSN	Within 1,500 CIS.
(iii) 15,100 to 15,999 CSN	Within 2,000 CIS.
(iv) 14,300 to 15,099 CSN	Within 2,800 CIS.
(v) 13,000 to 14,299 CSN	Within 3,400 CIS.
(vi) 12,300 to 12,999 CSN	Within 4,000 CIS.
(vii) 11,200 to 12,299 CSN	Within 4,600 CIS.
(viii) 9,700 to 11,199 CSN	Within 5,300 CIS.

TABLE 3—INITIAL INSPECTION COMPLIANCE TIMES FOR ENGINES, THAT BOTH 12TH AND 13TH STAGE COMPRESSOR WHEELS DO NOT HAVE CHROME-CARBIDE COATED KNIFE EDGE SEALS—Continued

For 12th and or 13th stage compressor wheels with the following CSN on the effective date of this AD:	Initially inspect after the effective date of this AD:
(ix) Fewer than 9,700 CSN	Before accumulating 15,000 CSN or at the next shop visit when the engine has more than 7,000 cycles, whichever occurs first.

(g) Repetitive Inspections

(1) After passing the initial inspection, perform repetitive ECIs of the compressor wheel outer circumference, for cracks, within every 5,000 cycles-since-last-inspection (CSLI), using paragraph 2, Accomplishment Instructions, of RRC ASB No. AE 3007A–A–72–390, Revision 3, dated June 27, 2011; or

(2) Perform a one-time comprehensive ECI of the 6th-through-13th stage compressor wheel knife edge seals for cracks, within 5,000 CSLI using paragraph 2, Accomplishment Instructions, of RRC ASB No. AE 3007A–A–72–386, Revision 4, dated June 27, 2011. Completion of this one-time ECI comprehensive inspection relieves you thereafter of the repetitive inspection requirements of this AD.

(h) 6th-Through-13th Stage Compressor Wheels Found Cracked

Remove from service before further flight 6th-through-13th stage compressor wheels that are found cracked.

(i) Special Flight Permits

Special Flight Permits are limited to essential flight crew only.

(j) Reporting Requirements

Report all inspection results within 10 days, to AE Service Data, Rolls-Royce Corporation, Attn: AE Service Data Manager, P.O. Box 420, Speed Code U17, Indianapolis, IN 46206–0420, *email: cra.rel.data@rolls-royce.com.* Use the reporting instructions in:

(1) Paragraph 2.D. of ASB No. AE 3007A–A–72–386, Revision 4, dated June 27, 2011.

(2) Service Bulletin Compliance Form of RRC ASB No. AE 3007A–A–72–390, Revision 3, dated June 27, 2011.

(k) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, *Attn:* Information Collection Clearance Officer, AES–200.

(l) Previous Inspection Credit

(1) If you previously performed an ECI of the 6th-through-13th stage compressor wheels using RRC ASB No. AE 3007A–A–390, Revision 1, dated February 14, 2011 or Revision 2, dated June 10, 2011, or Revision 3, dated June 27, 2011, you met the initial inspection requirements of this AD.

(2) If you previously performed a one-time comprehensive ECI of the 6th-through-13th stage compressor wheel knife edge seals, using RRC ASB No. AE 3007A–A–72–386, dated October 20, 2010, or Revision 1, dated December 17, 2010, or Revision 2 dated January 10, 2011, or Revision 3, dated June 10, 2011, you met the initial inspection requirements of paragraph (f) of this AD. Completion of this one-time comprehensive inspection relieves you of the repetitive inspection requirements of this AD.

(3) If you previously performed an ultrasonic inspection of the compressor wheel knife edge seals, using RRC Service Bulletin No. AE 3007A–72–382, dated April 6, 2010, prior to publication of RRC ASB No. AE 3007A–A–72–386, dated October 20, 2010, you met the initial inspection requirements of this AD. Completion of this one-time ultrasonic inspection relieves you of the repetitive inspection requirements of this AD.

(m) Alternative Methods of Compliance (AMOCs)

The Manager, Chicago Aircraft Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(n) Related Information

For more information about this AD, contact Kyri Zaroyiannis, Aerospace Engineer, Chicago Aircraft Certification Office, Small Airplane Directorate, FAA, 2300 E. Devon Ave., Des Plaines, IL 60018; *phone:* (847) 294–7836; *fax:* (847) 294–7834; *email: kyri.zaroyiannis@faa.gov.*

(o) Material Incorporated by Reference

You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51 of the following service information on the date specified:

(1) Rolls-Royce Corporation Alert Service Bulletin No. AE 3007A–A–72–386, Revision 4, dated June 27, 2011, approved for IBR November 17, 2011.

(2) Rolls-Royce Corporation Alert Service Bulletin No. AE 3007A–A–72–390, Revision 3, dated June 27, 2011, approved for IBR November 17, 2011.

(3) For service information identified in this AD, contact Rolls-Royce Corporation, P.O. Box 420, Indianapolis, IN 46206; *phone:* (317) 230–3774; *fax:* (317) 230–6084; *email: indy.pubs.services@rolls-royce.com.*

(4) You may review copies of the service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

(5) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Burlington, Massachusetts, on October 25, 2011.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011–28352 Filed 11–1–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0942; Directorate Identifier 2011–NE–29–AD; Amendment 39–16840; AD 2011–21–17]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all General Electric Company (GE) CT7–8A, CT7–8A1, CT7–8E, and CT7–8F5 turboshaft engines with a fuel filter differential pressure switch, part number (P/N) TD028VF0H7Y5 (part of the fuel filter assembly, P/N

4110T53P06) installed. This AD requires daily visual inspections of the fuel filter differential pressure switch for fuel leaks and for excessive cracking of the switch mounting flanges due to stress-corrosion. This AD also requires the installation of a collar kit over the fuel filter differential pressure switch as terminating action to the daily inspections. This AD was prompted by reports of 47 fuel filter differential pressure switches found with stress-corrosion cracking of the mounting flanges. We are issuing this AD to prevent unrecoverable in-flight engine shutdown, engine bay fire due to fuel leakage, and forced landing or accident.

DATES: This AD is effective November 17, 2011.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of November 17, 2011.

We must receive comments on this AD by December 19, 2011.

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

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

For service information identified in this AD, contact GE-Aviation, M/D Rm. 285, One Neumann Way, Cincinnati, OH 45215, *phone:* (513) 552–3272; *email: geae.aoc@ge.com.* You may review copies of the service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Walter Meibaum, Aerospace Engineer, Engine & Propeller Directorate, FAA, 12 New England Executive Park, Burlington, MA 01803; *phone:* (781) 238–7119; *fax:* (781) 238–7199; *email: walter.meibaum@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

Since March of 2011, we have received reports of 47 fuel filter differential pressure switches found with cracked mounting flanges. The pressure switch, P/N TD028VF0H7Y5, is part of the fuel filter assembly, P/N 4110T53P06. Investigation has revealed that the two cap screws securing the switch to the fuel filter assembly, apply a bending stress to the aluminum mounting flanges of the switch. This bending stress, coupled with contaminants in the operating environment, can lead to stress-corrosion cracking of the mounting flanges on the switch. This condition, if not corrected, could result in unrecoverable in-flight engine shutdown, engine bay fire due to fuel leakage, and forced landing or accident.

Relevant Service Information

We reviewed GE Alert Service Bulletin (ASB) No. CT7–8–S/B 73–A0007, dated July 8, 2011, and ASB No. CT7–8–S/B 73–A0008, dated August 17, 2011. The service information describes procedures for performing daily visual inspections of the fuel filter differential pressure switch for fuel leaks and for excessive cracking of the switch mounting flanges, and for installing a collar kit over the fuel filter differential pressure switch as terminating action to the daily inspections. The collar kit will retain the pressure switch from separating from the filter head of the fuel filter assembly due to cracks in the pressure switch flanges, and will prevent the pressure switch from leaking.

FAA's Determination

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

AD Requirements

This AD requires accomplishing the actions specified in the service information described previously.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because about 20% of the affected fuel filter differential pressure switches in service have been found cracked. Many of the affected engines are used on Sikorsky S–92 helicopters in offshore applications. Therefore, we find that notice and opportunity for prior public comment are impracticable and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety and was not preceded by notice and an opportunity for public comment. However, we invite you to send any written data, views, or arguments about this AD. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA–2011–0942 and Directorate Identifier 2011–NE–29–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

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

Costs of Compliance

We estimate that this AD will affect 80 engines installed on helicopters of U.S. registry. We also estimate that it would take about 0.1 work-hour per engine to perform a daily visual inspection and about 0.1 hour to install a collar over the fuel filter differential pressure switch. The average labor rate is $85 per work-hour. Required parts would cost about $200 per engine. Based on these figures, we estimate the total cost of the AD for one visual inspection and installation of the collar to U.S. operators to be $17,360.

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

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

For the reasons discussed above, I certify that this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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):

2011–21–17 General Electric Company: Amendment 39–16840; Docket No. FAA–2011–0942; Directorate Identifier 2011–NE–29–AD.

(a) Effective Date

This AD is effective November 17, 2011.

(b) Affected ADs

None.

(c) Applicability

This AD applies to General Electric Company (GE) CT7–8A, CT7–8A1, CT7–8E, and CT7–8F5 turboshaft engines, with fuel filter differential pressure switch, part number (P/N) TD028VF0H7Y5 (part of fuel filter assembly, P/N 4110T53P06), installed.

(d) Unsafe Condition

This AD was prompted by reports of 47 fuel filter differential pressure switches found with stress-corrosion cracking of the mounting flanges. We are issuing this AD to prevent unrecoverable in-flight engine shutdown, engine bay fire due to fuel leakage, and forced landing or accident.

(e) Compliance

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

(1) Starting on the effective date of this AD, perform daily visual inspections of the fuel filter differential pressure switch for leaks and excessive cracking of the mounting flanges.

(2) Visually inspect in accordance with paragraph 3, Accomplishment Instructions, of GE Alert Service Bulletin (ASB) No. CT7–8–S/B 73–A0007, dated July 8, 2011.

(f) Mandatory Terminating Action

(1) As mandatory terminating action to the daily visual inspections, within 4 months after the effective date of this AD, install collar kit, P/N 59TC02800K1T, over the fuel filter differential pressure switch.

(2) Install the collar kit in accordance with paragraph 3, Accomplishment Instructions of GE ASB No. CT7–8–S/B 73–A0008, dated August 17, 2011.

(g) Special Flight Permits

Special flight permits are prohibited.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(i) Related Information

For more information about this AD, contact Walter Meibaum, Aerospace Engineer, Engine & Propeller Directorate, FAA, 12 New England Executive Park, Burlington, MA 01803; *phone:* (781) 238–7119; *fax:* (781) 238–7199; *email:* walter.meibaum@faa.gov.

(j) Material Incorporated by Reference

You must use the following service information to do the actions required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference (IBR) under 5 U.S.C. 552(a) and 1 CFR part 51 of the following service information on the date specified:

(1) General Electric Company Alert Service Bulletin No. CT7–8–S/B 73–A0007, dated July 8, 2011, approved for IBR as of November 17, 2011.

(2) General Electric Company Alert Service Bulletin No. CT7–8–S/B 73–A0008, dated August 17, 2011, approved for IBR as of November 17, 2011.

(3) For service information identified in this AD, contact GE-Aviation, M/D Rm. 285, One Neumann Way, Cincinnati, OH 45215, *phone:* (513) 552–3272; *email: geae.aoc@ge.com.*

(4) You may review copies of the service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

(5) You may also review copies of the service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at an NARA facility, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Burlington, Massachusetts, on October 4, 2011.

Peter A. White,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2011–28353 Filed 11–1–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2011–0431; Airspace Docket No. 11–AGL–11]

Amendment of Class E Airspace; Spearfish, SD

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Spearfish, SD, to accommodate new Area Navigation (RNAV) Standard Instrument Approach Procedures at Black Hills Airport—Clyde Ice Field, and updates the geographic coordinates of the airport. There also is a minor correction to the coordinates of controlled airspace 1,200 feet above the surface, and a minor change in the airport name. The FAA is taking this action to enhance the safety and management of Instrument Flight Rule (IFR) operations at the airport.

DATES: *Effective date:* 0901 UTC, February 9, 2012. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual

revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, Operations Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76137; telephone (817) 321–7716.

SUPPLEMENTARY INFORMATION:

History

On July 21, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend Class E airspace for Spearfish, SD, creating additional controlled airspace at Black Hills Airport—Clyde Ice Field (76 FR 43610) Docket No. FAA–2011–0431. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received. Subsequent to publication, errors was found in the boundaries of the controlled airspace extending upward from 1,200 feet above the surface. This rule makes the corrections to be in concert with the FAAs aeronautical database. Also, there is a minor correction to the airport name.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700 feet above the surface to accommodate new standard instrument approach procedures at Black Hills Airport—Clyde Ice Field, Spearfish, SD. This action is necessary for the safety and management of IFR operations at the airport. This action also corrects the geographic coordinates of the airport, as well as the first boundary coordinates listed in the regulatory text of the airspace extending upward from 1,200 feet above the surface. Also, the airport name is changed from Black Hills—Clyde Ice Field, to Black Hills Airport—Clyde Ice Field. With the exception of editorial changes and the changes described above, this action is the same as that proposed in the NPRM.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends controlled airspace at Black Hills Airport—Clyde Ice Field, Spearfish, SD.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9V, Airspace Designations and Reporting Points, dated August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface.

* * * * *

AGL SD E5 Spearfish, SD [Amended]

Black Hills Airport-Clyde Ice Field, SD
(Lat. 44°28′52″ N., long. 103°47′09″ W.)

That airspace extending upward from 700 feet above the surface within a 7-mile radius of Black Hills Airport-Clyde Ice Field, and within 2.1 miles each side of the 305° bearing from the airport extending from the 7-mile radius to 8.3 miles northwest of the airport, and within 2 miles each side of the 135° bearing from the airport extending from the 7-mile radius to 18.3 miles southeast of the airport; and that airspace extending upward from 1,200 feet above the surface within an area bounded by a line beginning at lat. 44°29′16″ N., long. 103°56′55″ W.; to lat. 44°13′37″ N., long. 104°14′00″ W.; to lat. 44°18′41″ N., long. 104°23′24″ W.; to lat. 44°44′11″ N., long. 103°57′49″ W.; to lat. 44°50′13″ N., long. 103°28′11″ W.; to lat. 44°47′27″ N., long. 102°57′40″ W.; to lat. 44°39′31″ N., long. 102°56′34″ W.; to lat. 44°38′27″ N., long. 103°12′26″ W.; to lat. 44°25′51″ N., long. 103°37′45″ W.; to lat. 44°25′58″ N., long. 103°38′15″ W.; thence clockwise via the 7-mile radius of the airport to the point of beginning.

Issued in Fort Worth, Texas, on October 11, 2011.

David P. Medina,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2011–28289 Filed 11–1–11; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 34–65628]

Technical Amendment to Delegation of Authority to the Director of the Division of Trading and Markets

AGENCY: Securities and Exchange Commission.

ACTION: Final rule; technical amendment.

SUMMARY: The Securities and Exchange Commission (''Commission'') is making a technical amendment to the rule that delegates authority to the Director of the Division of Trading and Markets to grant exemptions upon specified terms, conditions, and periods to persons subject to Rule 17f–2 under the Securities Exchange Act of 1934 (''Exchange Act'').

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Jerry W. Carpenter, Assistant Director, or

David Karasik, Special Counsel, at (202) 551–5710, Securities and Exchange Commission, Division of Trading and Markets, Room 7321 SP1, 100 F Street NE., Washington, DC 20549–7010.

SUPPLEMENTARY INFORMATION:

I. Background

Section 17(f)(2) of the Exchange Act requires every member of a national securities exchange, broker, dealer, registered transfer agent, and registered clearing agency to require that each of its partners, directors, officers, and employees be fingerprinted and to submit such fingerprints to the U.S. Attorney General for identification and processing.[1] In order to permit some flexibility in the administration of the fingerprinting requirement, Section 17(f)(2) also provides ''The Commission, by rule, may exempt from the provisions of this paragraph [Section 17(f)(2)] upon specified terms, conditions, and periods, any class of partners, directors, officers, or employees of any such member, broker, dealer, transfer agent, or clearing agency, if the Commission finds that such action is not inconsistent with the public interest or the protection of investors.'' [2]

Pursuant to this statutory authority, the Commission adopted Rule 17f–2 in 1976 to provide for certain exemptions from the fingerprinting requirement of Section 17(f)(2) of the Exchange Act.[3] As adopted by the Commission in 1976, exemptions from the fingerprinting requirements of Section 17(f)(2) could also be requested by persons that did not meet certain conditions specified in Rule 17f–2 by applying to the Commission for exemptive relief pursuant to a prior paragraph (g) of Rule 17f–2.[4]

After adopting Rule 17f–2, the Commission delegated its authority, pursuant to Rule 30–3(a)(17) of the Commission's Rules of Organization and Program Management, to grant exemptions under Rule 17f–2(g) to the Director of the Division of Market Regulation (now known as the Division of Trading and Markets) (''Division Director'').[5] In 1982, the Commission amended Rule 17f–2 in order to simplify the process of claiming exemptions from the fingerprinting requirements.[6] Part of this simplification effort involved a change consisting of moving the entire text of paragraph (g) of Rule 17f–2, without any modifications, to a new subparagraph (a)(2). However, the Commission did not update references to Rule 17f–2(g) contained in Rule 30–3(a)(17) to reflect this change. In order to correct this oversight, the Commission is making a technical amendment to Rule 30–3(a)(17) to reflect the authority of the Division Director to grant exemptions upon specified terms, conditions, and periods to persons subject to Rule 17f–2 pursuant to Rule 17f–2(a)(2).

II. Administrative Law Matters

The Administrative Procedure Act (''APA'') [7] generally requires an agency to publish, before adopting a rule, notice of a proposed rulemaking in the **Federal Register**.[8] This requirement does not apply, however, to, ''interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.'' [9]

This amendment consisting of replacing an outdated reference to ''Rule 17f–2(g)'' with a reference to ''Rule 17f–2(a)(2)'' within Rule 30–3 of the Commission's Rules of Organization and Program Management is a technical change, being adopted solely to interpret references to a statutory provision that has been moved but otherwise remains unchanged and which relates solely to the delegation of authority or duties within the Commission. Accordingly, the Commission finds that because the amendments relate solely to interpretive rules and rules of agency organization, procedure, or practice, that publishing the changes for comment is unnecessary.[10] In addition, the APA generally requires that an agency publish a rule in the **Federal Register** 30 days before the rule becomes effective.[11] This requirement, however, does not apply to ''interpretative rules and statements of policy.'' [12] Because this amendment functions as an interpretative rule that would merely interpret references to an outdated ''Rule 17f–2(g)'' (that presently does not exist) as applying to ''Rule 17f–2(a)(2)'' this amendment may take effect immediately. Similarly, the amendment does not require analysis under the Regulatory Flexibility Act or analysis of major rule status under the Small Business Regulatory Fairness Act.[13]

III. Consideration of the Competitive Effects of Amendment

Section 3(f) of the Exchange Act,[14] provides that whenever the Commission is engaged in rulemaking and is required to consider or determine whether an action is necessary or appropriate in the public interest, the Commission shall consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation. In addition, Section 23(a)(2) of the Exchange Act requires the Commission in adopting rules under the Exchange Act to consider the competitive effects of such rules.[15] Because this amendment merely makes a technical change to update a statutory reference, the Commission does not anticipate that the amendment would have an effect on efficiency, competition, or capital formation, and the Commission does not anticipate any competitive advantages or disadvantages would be created.

IV. Statutory Authority and Text of Amendments

We are adopting this technical amendment under the authority set forth in Section 23(a) of the Exchange Act.[16]

List of Subjects 17 CFR Part 200

Administrative practice and procedure, Conflict of interests, and Freedom of information.

Text of Amendment

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows:

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[1] 15 U.S.C. 78q(f)(2).

[2] *Id.*

[3] 17 CFR 240.17f–2. Securities Exchange Act Release No. 12214 (Mar. 16, 1976), 41 FR 13594 (Mar. 31, 1976).

[4] Prior Rule 17f–2(g) (as reflected in 1976 at the time of adoption of the rule) provided:

The Commission, upon specified terms, conditions and periods, may grant exemptions to any class of partners, directors, officers, or employees of any member of a national securities exchange, broker, dealer, registered transfer agent, or registered clearing agency, if the Commission finds that such action is not inconsistent with the public interest or the protection of investors.

[5] Rule 30–3 of the Commission's Rules of Organization and Program Management has been updated to reflect the name of the division is now the Division of Trading and Markets. See 17 CFR 200.30–3.

[6] Securities Exchange Act Release No. 19268 (Nov. 18, 1982), 47 FR 54060 (Dec. 1, 1982).

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

[8] *See* 5 U.S.C. 553(b).

[9] *Id.*

[10] *Id.*

[11] *See* 5 U.S.C. 553(d).

[12] *Id.*

[13] *See* 5 U.S.C. 601(2) (for purposes of Regulatory Flexibility Act analysis, the term ''rule'' means any rule for which the agency publishes a general notice of proposed rulemaking); and 5 U.S.C. 804(3)(C) (for purposes of Congressional review of agency rulemaking, the term ''rule'' does not include any rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties).

[14] 15 U.S.C. 78c(f).

[15] 15 U.S.C. 78w(a)(2).

[16] 15 U.S.C. 782w(a).

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

■ 1. The authority citation for part 200, subpart A, continues to read in part as follows:

Authority: 15 U.S.C. 77o, 77s, 77sss, 78d, 78d–1, 78d–2, 78w, 78ll(d), 78mm, 80a–37, 80b–11, and 7202 unless otherwise noted.

* * * * *

■ 2. Section 200.30–3 is amended by revising paragraph (a)(17)(ii) to read as follows:

§ 200.30–3 Delegation of authority to Director of Division of Trading and Markets.

* * * * *

(a) * * *

(17) * * *

(ii) To grant exemptions upon specified terms, conditions, and periods, for classes of persons subject to Rule 17f–2 pursuant to Rule 17f–2(a)(2) (§ 240.17f–2(a)(2) of this chapter).

* * * * *

Dated: October 26, 2011.

Elizabeth M. Murphy,

Secretary.

[FR Doc. 2011–28313 Filed 11–1–11; 8:45 am]

BILLING CODE 8011–01–P

OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

32 CFR Part 1701

Privacy Act of 1974: Implementation

AGENCY: Office of the Director of National Intelligence.

ACTION: Final rule.

SUMMARY: The Office of the Director of National Intelligence (ODNI) is issuing a final rule exempting six new systems of records from certain provisions of the Privacy Act. In addition, the ODNI invokes a subsection of the Privacy Act as an additional basis for exempting records in ODNI/OIG–003 (Office of Inspector General Investigation and Interview Records, published in the **Federal Register** on Dec. 28, 2007) from these provisions of the Act.

DATES: This final rule is effective November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. John F. Hackett, Chief, Information Management Group, (703) 874–8085.

SUPPLEMENTARY INFORMATION:

Background

On July 19, 2011, the Office of the Director of National Intelligence (ODNI) published notice of the following new systems of records: Human Resources Records (ODNI–16); Personnel Security Records (ODNI–17); Freedom of Information Act, Privacy Act and Mandatory Declassification Review Request Records (ODNI–18); IT Systems Activity and Access Records (ODNI–19); Security Clearance Reciprocity Hotline Records (ODNI–20); and IT Network Support, Administration and Analysis Records (21). These systems of records contain records that range from Unclassified to Top Secret. In conjunction with publication of these systems notices, the ODNI initiated a rulemaking to exempt the systems of records, in relevant part, from subsections (c)(3); (d)(1), (2), (3), (4); (e)(1) and (e)(4)(G), (H),(I); and (f) of the Privacy Act pursuant to exemption authority afforded agency heads by subsection (k) of the Privacy Act. The systems notices and proposed exemption rule are published at 76 FR 42737 and 43629. The enumerated exemptions will be invoked on a case-by-case basis, as necessary to preclude interference with investigatory, intelligence and counterterrorism functions and responsibilities of the ODNI.

Public Comments

ODNI received a single comment on its proposed rule and six new systems of records notices. ODNI has determined that the comment received does not warrant modifying the proposed exemptions or the systems notices prior to implementation.

Regulatory Flexibility Act

This rule affects only the manner in which ODNI collects and maintains information about individuals. ODNI certifies that this rulemaking does not impact small entities and that analysis under the Regulatory Flexibility Act, 5 U.S.C. 601–612, is not required.

Small Entity Inquiries

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires the ODNI to comply with small entity requests for information and advice about compliance with statutes and regulations within the ODNI jurisdiction. Any small entity that has a question regarding this document may address it to the information contact listed above. Further information regarding SBREFA is available on the Small Business Administration's Web page at *http://www.sba.gov/advo/laws/law-lib.html.*

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 944 U.S.C. 3507(d)) requires that the ODNI consider the impact of paperwork and other burdens imposed on the public associated with the collection of information. There are no information collection requirements associated with this rule and therefore no analysis of burden is required.

Executive Order 12866, Regulatory Planning and Review

This rule is not a ''significant regulatory action,'' within the meaning of Executive Order 12866. This rule will not adversely affect the economy or a sector of the economy in a material way; will not create inconsistency with or interfere with other agency action; will not materially alter the budgetary impact of entitlements, grants, fees or loans or the right and obligations of recipients thereof; or raise legal or policy issues arising out of legal mandates, the President's priorities or the principles set forth in the Executive Order. Accordingly, further regulatory evaluation is not required.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, 109 Stat. 48 (Mar. 22, 1995), requires Federal agencies to assess the effects of certain regulatory actions on State, local and tribal governments, and the private sector. This rule imposes no Federal mandate on any State, local or tribal government or on the private sector. Accordingly, no UMRA analysis of economic and regulatory alternatives is required.

Executive Order 13132, Federalism

Executive Order 13132 requires agencies to examine the implications for the distribution of power and responsibilities among the various levels of government resulting from their rules. ODNI concludes that this rule does not affect the rights, roles and responsibilities of the States, involves no preemption of State law and does not limit state policymaking discretion. This rule has no federalism implications as defined by the Executive Order.

Environmental Impact

This rulemaking will not have a significant effect on the human environment under the provisions of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4347.

Energy Impact

This rulemaking is not a major regulatory action under the provisions of the Energy Policy and Conservation Act (EPCA), Public Law 94–163) as amended, 42 U.S.C. 6362.

List of Subjects in 32 CFR Part 1701

Privacy, Reporting and recordkeeping requirements.

For the reasons set forth above, ODNI amends 32 CFR Part 1701 as follows:

PART 1701—ADMINISTRATION OF RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for part 1701 continues to read as follows:

Authority: 50 U.S.C. 401–442; 5 U.S.C. 552a.

Subpart B—[Amended]

■ 2. Amend § 1701.24 by revising paragraph (a) introductory text, and adding paragraphs (a)(15) through (a)(20), and (b)(7) through (b)(12), to read as follows:

§ 1701.24 Exemption of Office of the Director of National Intelligence (ODNI) systems of records.

(a) The ODNI exempts the following systems of records from the requirements of subsections (c)(3); (d)(1),(2),(3) and (4); (e)(1); (e)(4)(G),(H),(I); and (f) of the Privacy Act to the extent that information in the system is subject to exemption pursuant subsections (k)(1), (k)(2) or (k)(5) of the Act as noted in the individual new systems notices and in the existing system notice entitled Office of Inspector General Investigation and Interview Records (ODNI/OIG–003), published at 72 FR 37902 (December 28, 2007):

* * * * *

(15) Human Resources Records (ODNI–16).

(16) Personnel Security Records (ODNI–17).

(17) Freedom of Information Act, Privacy Act and Mandatory Declassification Review Requests Records (ODNI–18).

(18) IT Systems Activity and Access Records (ODNI–19).

(19) Security Clearance Reciprocity Hotline Records (ODNI–20).

(20) IT Network Support, Administration and Analysis Records (ODNI–21).

(b) * * *

(7) From subsection (c)(3) (accounting of disclosures) because an accounting of disclosures from records concerning the record subject would specifically reveal an intelligence or investigative interest on the part of the ODNI or recipient agency and could result in release of properly classified national security or foreign policy information.

(8) From subsections (d)(1), (2), (3) and (4) (record subject's right to access and amend records) because affording access and amendment rights could alert the record subject to the investigative interest of intelligence or law enforcement agencies or compromise sensitive information classified in the interest of national security. In the absence of a national security basis for exemption, records in this system may be exempted from access and amendment to the extent necessary to honor promises of confidentiality to persons providing information concerning a candidate for position. Inability to maintain such confidentiality would restrict the free flow of information vital to a determination of a candidate's qualifications and suitability.

(9) From subsection (e) (1) (maintain only relevant and necessary records) because it is not always possible to establish relevance and necessity before all information is considered and evaluated in relation to an intelligence concern. In the absence of a national security basis for exemption under subsection (k)(1), records in this system may be exempted from the relevance requirement pursuant to subsection (k)(5) because it is not possible to determine in advance what exact information may assist in determining the qualifications and suitability of a candidate for position. Seemingly irrelevant details, when combined with other data, can provide a useful composite for determining whether a candidate should be appointed.

(10) From subsections (e)(4)(G) and (H) (publication of procedures for notifying subjects of the existence of records about them and how they may access records and contest contents) because the system is exempted from subsection (d) provisions regarding access and amendment, and from the subsection (f) requirement to promulgate agency rules. Nevertheless, the ODNI has published notice concerning notification, access, and contest procedures because it may in certain circumstances determine it appropriate to provide subjects access to all or a portion of the records about them in a system of records.

(11) From subsection (e)(4)(I) (identifying sources of records in the system of records) because identifying sources could result in disclosure of properly classified national defense or foreign policy information, intelligence sources and methods, and investigatory techniques and procedures. Notwithstanding its proposed exemption from this requirement, ODNI identifies record sources in broad categories sufficient to provide general notice of the origins of the information it maintains in its systems of records.

(12) From subsection (f) (agency rules for notifying subjects to the existence of records about them, for accessing and amending records, and for assessing fees) because the system is exempt from subsection (d) provisions regarding access and amendment of records by record subjects. Nevertheless, the ODNI has published agency rules concerning notification of a subject in response to his request if any system of records named by the subject contains a record pertaining to him and procedures by which the subject may access or amend the records. Notwithstanding exemption, the ODNI may determine it appropriate to satisfy a record subject's access request.

Dated: October 19, 2011.

Mark W. Ewing,

Chief Management Officer.

[FR Doc. 2011–28442 Filed 11–1–11; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52

[EPA–R06–OAR–2011–0426; FRL–9485–3]

Approval and Promulgation of Implementation Plans; Texas; Regulations for Control of Air Pollution by Permits for New Construction or Modification

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving portions of three revisions to the Texas State Implementation Plan (SIP) submitted by the State of Texas on August 31, 1993; July 22, 1998; and October 5, 2010. These revisions amend existing sections and create new sections in Title 30 of the Texas Administrative Code (TAC), Chapter 116—Control of Air Pollution by Permits for New Construction or Modification. The August 31, 1993, revision creates two new sections for the use of emission reductions as offsets in new source review permitting. The July 22, 1998, revision allows for the use of Discrete Emission Reduction Credits (DERC) to exceed emission limits in permits (permit allowables) and updates internal citations to other Texas regulations. The October 5, 2010, revision updates internal citations to other Texas regulations. EPA has determined that these SIP revisions comply with the Clean Air Act and EPA regulations and are consistent with EPA

policies. This action is being taken under authority of the Federal Clean Air Act (the Act or CAA).

DATES: This final rule is effective on December 2, 2011.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R06–OAR–2011–0426. All documents in the docket are listed in the *http://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, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at (214) 665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

The State submittal related to this SIP revision, and which is part of the EPA docket, is also available for public inspection at the State Air Agency listed below during official business hours by appointment:

Texas Commission on Environmental Quality, Office of Air Quality, 12124 Park 35 Circle, Austin, Texas 78753.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning today's final action, please contact Ms. Erica Le Doux (6PD–R), Air Permits Section, Environmental Protection Agency, Region 6, 1445 Ross Avenue (6PD–R), Suite 1200, Dallas, Texas 75202–2733, *telephone* (214) 665–7265; *fax number* (214) 665–6762; *email address ledoux.erica@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document wherever, any reference to ''we,'' ''us,'' or ''our'' is used, we mean EPA.

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I. What final action is EPA taking?
II. What is the background for this action?
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I. What final action is EPA taking?

We are fully approving severable portions of three revisions to the Texas SIP submitted on August 31, 1993; July 22, 1998; and October 5, 2010. The August 31, 1993, SIP submittal creates two new sections, 116.174 and 116.175, establishing the requirements for use and recordkeeping of emission reductions in New Source Review (NSR) permitting. The July 22, 1998 SIP submittal creates a new section at 116.116(f) that allows Discrete Emission Reduction Credits (DERCs) to be used to exceed permit allowables; and amends existing section 116.174 to correctly cross-reference other Texas permitting regulations. The October 5, 2010, SIP submittal amends section 116.116(f) to correctly cross-reference the SIP-approved DERC rules at Title 30 of the Texas Administrative Code (30 TAC) Chapter 101, Subchapter H, Division 4. We are fully approving new sections 116.174 and 116.175 submitted on August 31, 1993. We are approving new section 116.116(f) and amendments to section 116.174 submitted on July 22, 1998. Finally, we are fully approving the amendment to section 116.116(f) submitted on October 5, 2010.

EPA acted on the above SIP revisions through a direct final rulemaking and accompanying proposed rule action on July 25, 2011 at 76 FR 44271 and 76 FR 44293, respectively. In our direct final action we stated that we would withdraw our direct final approval if we received relevant adverse comments before August 24, 2011. Because EPA received one adverse comment, we withdrew our direct final action on September 15, 2011 at 76 FR 56982. As we discussed in our direct final and proposed rulemaking actions, in this notice we are proceeding with a final action and responding to the comment. The revisions submitted by Texas amend existing sections and create new sections in 30 TAC Chapter 116—Control of Air Pollution by Permits for New Construction or Modification and they comply with the CAA and EPA regulations, are consistent with EPA policies, and will improve air quality. This final approval is being taken under section 110 and parts C and D of the CAA.

Finally, EPA is revising the title used in the direct final action to remove a reference to Permits by Rule. Because this action does not change any provision of Texas' Permits by Rule program, we are removing the reference to Permits by Rule to clarify that such rules are not part of this action.

II. What is the background for this action?

We are approving severable provisions of three SIP revisions that the Texas Commission on Environmental Quality (TCEQ) adopted on August 16, 1993; June 17, 1998; and September 15, 2010; and submitted to EPA on August 31, 1993; July 22, 1998; and October 5, 2010; respectively. Copies of the revised rules as well as the Technical Support Document (TSD) can be obtained from the Docket, as discussed in the ''Docket'' section above. A discussion of the specific Texas rule changes that we are approving is included in the TSD and summarized below. The TSD also contains a discussion as to why EPA is not taking action on certain provisions of each Texas SIP submittal and documents why these provisions are severable from the provisions that we are approving.

A. August 31, 1993, Submittal

1. Section 116.174—Determination by Executive Director To Authorize Reductions

The TCEQ adopted section 116.174 on August 16, 1993, to provide the criteria by which the TCEQ Executive Director (ED) will determine whether emission reductions can be used for purposes of NSR permitting. Section 116.174 requires that the ED approve reductions for use pursuant with requirements set forth in SIP-approved section 116.170. Additionally, any emission reductions approved for use as offsets by the ED must be made as enforceable permit conditions.

2. Section 116.175—Recordkeeping

The TCEQ adopted new section 116.175 on August 16, 1993, to establish that the recordkeeping burden for the generation and use of emission reductions in NSR permitting is on the applicant. The TCEQ will only maintain records associated with the permit application and files. The permit applicant is responsible for making all records related to the emission reductions available upon request by the ED.

B. July 22, 1998, Submittal

1. Section 116.116(f)—Use of Credits

The TCEQ adopted new section 116.116(f) on June 17, 1998, to provide that DERCs generated under the TCEQ's banking and trading provisions at 30 TAC 101.29 can be used to exceed permit allowables, if all applicable requirements of section 101.29 are

satisfied. Since the adoption of section 116.116(f), the TCEQ has recodified the SIP-approved DERC provisions from 30 TAC 101.29 to 30 TAC 101.376. The use of DERCs cannot be used to authorize any physical changes to a facility.

EPA reviewed and conditionally approved the DERC program on September 6, 2006 at 71 FR 52703. This conditional approval was converted to a full approval on May 18, 2010 at 75 FR 27644. The full approval action resulted after we found that TCEQ satisfied all elements that were outlined in a commitment letter submitted by TCEQ, dated September 8, 2005. This commitment letter can be found in the docket for our approval of the DERC program at EPA–R06–OAR–2005–TX–0029. The DERC rules establish a type of Economic Incentive Program (EIP), in particular an open market emission trading (OMT) program as described in EPA's EIP Guidance document, ''Improving Air Quality with Economic Incentive Programs'' (EPA–452/R–01–001, January 2001). In an OMT program, a source generates short-term emission credits (called discrete emission reduction credits, or DERCs, in the Texas program) by reducing its emissions. The source can then use these DERCs at a later time, or trade them to another source to use at a later time. The trading program assumes that many sources will participate and continuously generate new DERCs to balance with other sources using previously generated discrete credits. DERCs are quantified, banked and traded in terms of mass (tons) and may be generated and used statewide. Reductions of all criteria pollutants, with the exception of lead, may be certified as DERCs.

2. Section 116.174—Determination by Executive Director To Authorize Reductions

The TCEQ adopted amendments to section 116.174 on June 17, 1998, to remove outdated references to the Texas Air Control Board, and to update references to other sections of the Texas NSR permitting regulations where emission reductions can be used in permits.

C. October 5, 2010, Submittal

Section 116.116(f)—Use of Credits

The TCEQ adopted amendments to section 116.116(f) on September 15, 2010, to change references to outdated section 101.29 to the current SIP-approved section 101.376.

In our July 25, 2011, direct final action, we presented our evaluation of these revisions to amend existing sections and create new sections in 30 TAC Chapter 116—Control of Air Pollution by Permits for New Construction or Modification. Generally, SIP rules must be enforceable and must not relax existing requirements. See CAA sections 110(a), 110(l), and 193. EPA's review of the August 31, 1993; July 22, 1998; and October 5, 2010; SIP revisions finds that all three submittals are consistent with the requirements at 40 CFR part 51 and are considered complete SIP submittals in accordance with 40 CFR part 51, appendix V. This detailed analysis is available in the TSD for this rulemaking.

III. What are EPA's responses to comments received on the proposed action?

EPA received one adverse comment on our proposed action, available in the docket. As discussed previously, because we received an adverse comment within the comment period, EPA withdrew our direct final rulemaking on September 15, 2011, 76 FR 56982. We are proceeding with a final action in this notice.

A summary of the comment EPA received is as follows: The implementation of this rule would shutdown the Luminant Big Brown Mine and Power Plant in Freestone County, Texas. The effects would be disastrous to the community of Fairfield, Texas, where the commenter lives and works. The closure of this facility would cause an economic decline because the plant is the main economic driving force for this community; as a result, people will leave the area to find work. People vacating the area would cause a decline in the housing and retail market, both of which, the commenter and his wife are active participants. The commenter wants the government to reconsider the rule.

The commenter did not provide any basis for why this action will cause the shutdown of the mentioned power plants and consequently cause the economic decline of the surrounding communities, nor did he call attention to any specific parts of the rule that would cause this to happen. While EPA is just now approving these rules as revisions to the Texas SIP, Texas has been implementing these rules since they became effective in 1993 and 1998. If these rules had the potential to result in the plant closures and the local community's economic decline outlined in the comments, this potential would have existed since the 1993 and 1998 revisions associated with these rules. However, the commenter did not identify any past plant closures and economic decline as a result of these rules. Accordingly, these SIP revisions and amendments should be approved.

The Clean Air Act was enacted by Congress. 42 U.S.C.A. 7401. Under the Act, EPA is authorized to set clean air standards. 42 U.S.C.A. 7409. States are authorized to choose control strategies to meet these standards. 42 U.S.C.A. 7410(a). EPA can approve the strategies into state implementation plans, as long as the strategies are consistent with the Act. 42 U.S.C.A. 7410(l). As we stated in our proposal, and in section II of this notice, EPA finds the submitted SIP revisions to 30 TAC Chapter 116 as identified earlier herein are consistent with the Act. EPA is making no changes to our proposed action as a result of this comment.

IV. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 3, 2012. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: October 21, 2011.

Al Armendariz,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

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

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

Subpart SS—Texas

■ 2. The table in § 52.2270(c) entitled ''EPA Approved Regulations in the Texas SIP'' is amended as follows:

■ a. By revising the entry for § 116.116;

■ b. By adding new entries for §§ 116.174 and 116.175.

The additions and revisions read as follows:

§ 52.2270 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE TEXAS SIP

State citation	Title/subject	State approval/ submittal date	EPA approval date	Explanation
*	*	*	*	*
Chapter 116 (Reg 6)—Control of Air Pollution by Permits for New Construction or Modification			
*	*	*	*	*
Subchapter B—New Source Review Permits				
Division 1—Permit Application				
Section 116.116	Changes to Facilities.	9/15/2010	11/2/2011 [Insert *FR* page number where document begins].	The SIP does not include paragraph (b)(3) and (b)(4), and subsection (e).
*	*	*	*	*
Division 7—Emission Reductions: Offsets *				
Section 116.174	Determination by Executive Director to Authorize Reductions.	6/17/1998	11/2/2011 [Insert *FR* page number where document begins].	
Section 116.175	Recordkeeping	8/16/1993	11/2/2011 [Insert *FR* page number where document begins].	
*	*	*	*	*

* * * * *

[FR Doc. 2011–28256 Filed 11–1–11; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 80

[WT Docket No. 00–48; FCC 10–110]

Maritime Communications

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) addresses a number of issues pertaining to the Maritime Radio Services that were raised in the *Third Further Notice of Proposed Rulemaking* (*Third FNPRM*), and amends its rules accordingly. The decisions adopted by the Commission herein advance the key objectives underlying this proceeding, which are to promote maritime safety, maximize effective and efficient use of the spectrum available for maritime communications, accommodate technological innovation, avoid unnecessary regulatory burdens, maintain consistency with international maritime standards to the extent consistent with the United States public interest, and regulate the Maritime Radio Services in a manner that advances our nation's homeland security.

DATES: Effective January 3, 2012. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of January 3, 2012.

FOR FURTHER INFORMATION CONTACT: Jeffrey Tobias, *Jeff.Tobias@FCC.gov,* Wireless Telecommunications Bureau, (202) 418–1617, or TTY (202) 418–7233.

SUPPLEMENTARY INFORMATION: This is a summary of the Federal Communications Commission's *Fourth Report and Order and Second Memorandum Opinion and Order* (*Fourth R&O*) in WT Docket No. 00–48, FCC 10–110, adopted on June 7, 2010, and released on June 10, 2010. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW., Washington, DC 20554. The complete text may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.* Alternative formats are available to persons with disabilities by sending an email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty).

1. The WT Docket No. 00–48 rulemaking proceeding was established to develop rules for domestic implementation of the Global Maritime Distress and Safety System (GMDSS), a ship-to-shore and ship-to-ship distress communications system using satellite and digital selective calling (DSC) technology. The Commission takes the following significant actions in the *Fourth R&O* in WT Docket No. 00–48: (1) Prohibits the certification, manufacture, importation, sale, installation, or continued use of INMARSAT–E emergency position indicating radiobeacons (EPIRBs); (2) concludes that VHF–DSC handheld radiotelephones should include integrated Global Positioning System (GPS) capability, but defers adopting such a requirement until the Radio Technical Commission for Maritime Services (RTCM) completes work on GPS performance standards; (3) requires that any small passenger vessel that does not have a reserve power supply carry at least one VHF handheld marine radio transceiver; (4) declines at this time to provide additional spectrum for ship station facsimile communications or to permit the transmission of data on maritime voice channels; (5) eliminates the limits on the number of frequencies that can be assigned to a private coast station or marine utility station; (6) revises the part 80 rules to incorporate by reference the latest international standards for radar and other equipment; and (7) clarifies that vessels subject to GMDSS requirements are required to test their radiotelephone equipment on a daily basis.

I. Procedural Matters

A. Paperwork Reduction Act Analysis

2. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

B. Report to Congress

3. The Commission will send a copy of this *Fourth R&O* in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

C. Final Regulatory Flexibility Analysis

4. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Third FNPRM,* at 71 FR 65448, November 8, 2006. The Commission sought written public comment on the proposals in the *Third FNPRM,* including comment on the IRFA. This present Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

Need for, and Objectives of, the Report and Order

5. The rules adopted in the *Fourth R&O* are intended to promote maritime safety, maximize effective and efficient use of the spectrum available for maritime communications, accommodate technological innovation, avoid unnecessary regulatory burdens, maintain consistency with international maritime standards to the extent consistent with the United States public interest, and regulate the Maritime Radio Services in a manner that advances our nation's homeland security. Specifically, in the *Fourth R&O,* the Commission (1) prohibits the certification, manufacture, importation, installation, or continued use of INMARSAT–E emergency position indicating radiobeacons (EPIRBs); (2) concludes that VHF–DSC handheld radiotelephones should include integrated Global Positioning System (GPS) capability, but defers adopting such a requirement until the Radio Technical Commission for Maritime Services (RTCM) completes work on GPS performance standards; (3) requires carriage of at least one VHF handheld radio transceiver on all small passenger vessels that do not carry a reserve power supply; (4) declines to take any immediate action to provide additional spectrum for ship station facsimile communications or to permit the transmission of data on maritime voice channels; (5) removes limits on the number of frequencies that can be assigned to a private coast station or marine utility station; (6) revises the part 80 rules to incorporate by reference the latest international standards for radar and other equipment; and (7) clarifies that vessels subject to the GMDSS requirements are required to test their radiotelephone equipment on a daily basis.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

6. No comments were submitted specifically in response to the IRFA. The Commission nonetheless considered the potential economic impact on small entities of the rules discussed in the IRFA, and has considered alternatives that would reduce the potential economic impact on small entities of the rules adopted herein, regardless of whether the potential economic impact was discussed in any comments.

Description and Estimate of the Number of Small Entities to Which Rules Will Apply

7. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A small business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

8. Small businesses in the aviation and marine radio services use a marine very high frequency (VHF), medium frequency (MF), or high frequency (HF) radio, any type of emergency position indicating radio beacon (EPIRB) and/or radar, an aircraft radio, and/or any type of emergency locator transmitter (ELT). The Commission has not developed a definition of small entities specifically applicable to these small businesses. For purposes of this FRFA, therefore, the applicable definition of small entity is the definition under the SBA rules applicable to wireless telecommunications. Pursuant to this definition, a ''small entity'' for purposes of the ship station licensees, public coast station licensees, or other marine radio users that may be affected by these rules, is any entity employing 1,500 of fewer persons. 13 CFR 121.201 (NAICS Code 517212).

9. Nationwide, there are a total of approximately 29.6 million small businesses, according to the SBA. A ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' Nationwide, as of 2002, there were approximately 1.6 million small organizations. The term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' Census Bureau data for 2002 indicate that there were 87,525 local governmental jurisdictions in the United States. We estimate that, of this total, 84,377 entities were ''small governmental jurisdictions.'' Thus, we estimate that most governmental jurisdictions are small.

10. *Wireless Service Providers.* Since 2007, the Census Bureau has placed wireless firms within the broad, economic census category of Wireless Telecommunications Categories (Except Satellite). Prior to that time, such firms were within the now-superseded categories of ''Paging'' and ''Cellular and Other Wireless Telecommunications.'' Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. Because Census Bureau data are not yet available for the new category, we will estimate small business prevalence using the prior categories and associated data. For the category of Paging, data for 2002 show that there were 807 firms that operated for the entire year. Of this total, 804 firms had employment of 999 or fewer employees, and three firms had employment of 1,000 employees or more. For the category of Cellular and Other Wireless Telecommunications, data for 2002 show that there were 1,397 firms that operated for the entire year. Of this total, 1,378 firms had employment of 999 or fewer employees, and 19 firms had employment of 1,000 employees or more. Thus, we estimate that the majority of wireless firms are small.

11. *Aviation and Marine Services.* Small businesses in the aviation and marine radio services use a very high frequency (VHF) marine or aircraft radio and, as appropriate, an emergency position-indicating radio beacon (and/or radar) or an emergency locator transmitter. The Commission has not developed a small business size standard specifically applicable to these small businesses. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees. Most applicants for recreational licenses are individuals. Approximately 581,000 ship station licensees and 131,000 aircraft station licensees operate domestically and are not subject to the radio carriage requirements of any statute or treaty. For purposes of our evaluations in this analysis, we estimate that there are up to approximately 712,000 licensees that are small businesses (or individuals) under the SBA standard. In addition, between December 3, 1998 and December 14, 1998, the Commission held an auction of 42 VHF Public Coast licenses in the 157.1875–157.4500 MHz (ship transmit) and 161.775–162.0125 MHz (coast transmit) bands. For purposes of the auction, the Commission defined a ''small'' business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed $15 million dollars. In addition, a ''very small'' business is one that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed $3 million dollars. There are approximately 10,672 licensees in the Marine Coast Service, and the Commission estimates that almost all of them qualify as ''small'' businesses under the above special small business size standards.

12. *Marine Radio Equipment Manufacturers.* Some of the rules adopted herein may also affect small businesses that manufacture marine radio equipment. The Commission has not developed a definition of small entities applicable to marine radio equipment manufacturers. Therefore, the applicable definition is that for Wireless Communications Equipment Manufacturers. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: All such firms having 750 or fewer employees. According to Census Bureau data for 2002, there were a total of 1,041 establishments in this category that operated for the entire year. Of this total, 1,010 had employment of under 500, and an additional 13 had employment of 500 to 999. Thus, under this size standard, the majority of firms can be considered small.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

13. In the *Fourth R&O,* the Commission adopts two rule amendments that could potentially have a direct, significant economic impact on a substantial number of small entities. First, the Commission amends § 80.917 of the Commission's rules, 47 CFR 80.917, to require carriage of at least one VHF handheld marine radio by any small passenger vessel that does not carry a reserve power supply. This requirement could affect small entities that own or operate small passenger vessels which do not carry a reserve power supply, either in compliance with a pre-existing Commission requirement or voluntarily. Second, the Commission amends §§ 80.273 and 80.1101 of the Commission's rules, 47 CFR 80.273 and 80.1101, to incorporate by reference the currently applicable international standards for marine radar and other equipment. This could affect small entities that manufacture or use such equipment.

14. In the IRFA accompanying the *Third FNPRM,* the Commission specifically identified each of the above rule amendments as potentially affecting reporting, recordkeeping and other compliance requirements, and specifically requested comment on the economic impact of these changes.

Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

15. The RFA requires an agency to describe any significant alternatives that it has considered in developing its approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

16. Although the Commission received no comments specifically addressed to the IRFA for the *Third FNPRM,* the Commission considered all comments to the *Third FNPRM* addressing the impact of any proposed change on small entities and all suggestions for alternative measures that would have a less significant impact on small entities. Moreover, even where the Commission received no comments of this nature with regard to a particular new requirement, the Commission considered the potential impact of the requirement on small entities, and considered alternatives. As noted above, the Commission has identified two new requirements that may affect reporting, recordkeeping and other compliance requirements for small entities. The Commission discusses both of these new requirements adopted in the *Fourth R&O,* and relevant alternatives, below.

17. In determining to require the carriage of a VHF handheld radio transceiver on all small passenger vessels that do not carry a reserve power supply, the Commission found that such a requirement, which was supported by all commenters who addressed it, would enhance the safety of passengers and crew on such vessels by providing a means of communicating with search and rescue personnel in the event that an emergency situation, such as an on-board fire or the taking on of water, disrupts or disables the main power supply. The Commission also determined that there is no basis to exempt any class of small passenger vessel from the requirement to carry either a reserve power supply or at least one VHF handheld marine radio transceiver, or to otherwise take additional action to minimize the compliance costs of this requirement. In the IRFA accompanying the *Third FNPRM,* the Commission said that its ''understanding [was] that such handheld radio equipment can be purchased for under fifty dollars at retail, making it a far less expensive proposition for small vessel owners and operators than would expanding the reserve power supply requirement to all small passenger vessels, regardless of size.'' The Commission also said that, ''[n]otwithstanding the relative inexpensiveness of VHF handheld marine radios, and the important safety benefits that would accrue from imposing such a carriage requirement, we request that interested parties * * * address whether the costs of such a requirement would outweigh the safety benefits, and * * * suggest any alternatives, exemptions or phased-in implementation schedules that the Commission might adopt to reduce the compliance burden of such a requirement on small entities.'' No commenter has suggested that the Commission was incorrect in estimating the retail cost of VHF handheld marine radio transceivers as under fifty dollars. In fact, no commenter has suggested that the compliance costs of this new requirement would be onerous. Indeed, coupled with the Commission's earlier determination in the *Third Report and Order* in this proceeding, 73 FR 4475 (Jan. 25, 2008), regarding the appropriate scope of the reserve power supply requirement, the Commission believes that its action here benefits the small passenger vessel owners and operators that are subject to this new requirement to carry a VHF handheld marine radio transceiver insofar as it accords them a significantly less-costly alternative to carriage of a reserve power supply in order to meet their obligation to passengers and crew to have a means of maintaining communication with search and rescue personnel in the event of a disruption to the main power supply during a distress situation. The Commission is requiring compliance with the requirement for carriage of a VHF handheld marine radio transceiver (or a reserve power supply for those small passenger vessels that elect to install a reserve power supply voluntarily as an alternative) within one year after the effective date of this rule amendment, in keeping with the one-year transition period the Commission adopted in the *Third Report and Order* with respect to the reserve power supply requirement.

18. The Commission also has carefully considered the impact on small entities of its decision to incorporate by reference in Part 80 the currently applicable international standards for radar and other maritime equipment. In the IRFA accompanying the *Third FNPRM,* the Commission stated:

> We seek comment on the impact of such a revision on radar equipment manufacturers and on the owners and operators of vessels required to be fitted with radar equipment. Given that we contemplate amending our rules only to reflect the most up-to-date international standards for ship radar equipment, we question whether such an amendment would impose any new compliance burden on small entities, since they may already be required to, or have decided it is prudent to, manufacture and use equipment that conforms to those international standards. To the extent such an amendment would be deemed to create a new compliance burden, we ask interested parties whether and how that burden can be eliminated or mitigated for small entities, both small manufacturers and small owners and operators of vessels fitted with radar equipment. Commenters should consider the possibility of retaining the existing part 80 radar standards, incorporating by reference only some of the newer international radar standards, exempting certain entities from the requirement to comply with the newer international radar standards, and/or providing transition periods before compliance is required (so that, *e.g.,* radar equipment can still be certified based on

compliance with the current standards for a specified period of time) and grandfathering protection (to permit the continued manufacture, sale, importation, and use of radar equipment certified under the old standards, either for a specified period of years or indefinitely). Commenters are also invited to suggest alternatives other than those discussed here.

19. No commenter opposed this proposed rule amendment, and no commenter suggested that there was any need for the Commission to carve out any special provisions for small entities. In fact, nothing in the record suggests that these requirements will impose significant compliance costs on any entity. Instead, it appears that, although the incorporation by reference of the international standards will impose new part 80 requirements on certain vessels which have not been subject to Commission radar or other equipment standards to date, such vessels would have to meet the international radar and other equipment requirements when operating in international waters, irrespective of the part 80 rules, so the incorporation by reference of the international standards should not create a new compliance burden on the owners and operators of those vessels. Indeed, the commenters addressing this issue believe that the adoption of the international standards for domestic use will actually benefit manufacturers and users of the subject equipment because they will need to meet only a single set of standards, irrespective of where they operate. The absence of any comments opposing the incorporation by reference of any of these standards, or seeking relief for any small entities that may be newly subject to a requirement to comply with any of the standards, lends credence to the view that this rule change will not be burdensome to either vessel owners and operators or to manufacturers of equipment, whether or not they are small entities. In addition, we have accorded considerable flexibility to users of marine radar equipment, including small entities, by grandfathering all certified radar equipment installed prior to the effective date of these rule amendments, for the remainder of its useful life.

F. Report to Congress

20. The Commission will send a copy of the *Fourth R&O* in WT Docket No. 00–48, including the Final Regulatory Flexibility Analysis, in a report to be sent to Congress and the Congressional Budget Office pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the *Fourth R&O* in WT Docket No. 00–48, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the SBA. A copy of the *Fourth R&O* in WT Docket No. 00–48 and the Final Regulatory Flexibility Analysis (or summaries thereof) will also be published in the **Federal Register.**

List of Subjects in 47 CFR Parts 2 and 80

Communications equipment, Incorporation by reference, Radio, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Rule Changes

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR parts 2 and 80 as follows:

PART 2—FREQUENCY ALLOCATIONS AND RADIO TREATY MATTERS; GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, and 336, unless otherwise noted.

■ 2. Section 2.1093 is amended by revising paragraph (c) to read as follows:

§ 2.1093 Radiofrequency radiation exposure evaluation: Portable devices.

* * * * *

(c) Portable devices that operate in the Cellular Radiotelephone Service, the Personal Communications Service (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services, the Specialized Mobile Radio Service, the 4.9 GHz Band Service, the Wireless Medical Telemetry Service (WMTS) and the Medical Implant Communications Service (MICS), authorized under subpart H of part 22 of this chapter, parts 24, 25, 26, 27, 80 (ship earth station devices only) and 90 of this chapter, subparts H and I of part 95 of this chapter, and unlicensed personal communication service, unlicensed NII devices and millimeter wave devices authorized under subparts D and E, §§ 15.253, 15.255 and 15.257 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use. All other portable transmitting devices are categorically excluded from routine environmental evaluation for RF exposure prior to equipment authorization or use, except as specified in §§ 1.1307(c) and 1.1307(d) of this chapter. Applications for equipment authorization of portable transmitting devices subject to routine environmental evaluation must contain a statement confirming compliance with the limits specified in paragraph (d) of this section as part of their application. Technical information showing the basis for this statement must be submitted to the Commission upon request.

* * * * *

PART 80—STATIONS IN THE MARITIME SERVICES

■ 3. The authority citation for part 80 continues to read as follows:

Authority: Secs. 4, 303, 307(e), 309, and 332, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303, 307(e), 309, and 332, unless otherwise noted. Interpret or apply 48 Stat. 1064–1068, 1081–1105, as amended; 47 U.S.C. 151–155, 301–609; 3 UST 3450, 3 UST 4726, 12 UST 2377.

■ 4. Section 80.5 is amended by revising the definition of *Digital selective calling (DSC), Navigable waters,* and *On-board communication station* to read as follows:

§ 80.5 Definitions.

* * * * *

Digital selective calling (DSC). A synchronous system developed by the International Telecommunication Union Radiocommunication (ITU–R) Sector, used to establish contact with a station or group of stations automatically by means of radio. The operational and technical characteristics of this system are contained in ITU–R M.493–13 and ITU–R M.541–9 (both incorporated by reference, see § 80.7) (see subpart W of this part.)

* * * * *

Navigable waters. This term, as used in reference to waters of the United States, its territories and possessions, means the waters shoreward of the baseline of its territorial sea and internal waters as contained in 33 CFR 2.36.

* * * * *

On-board communication station. A low-powered mobile station in the maritime mobile service intended for use for internal communications on board a ship, or between a ship and its lifeboats and life-rafts during lifeboat drills or operations, or for communication within a group of vessels being towed or pushed, as well as for line handling and mooring instructions.

* * * * *

■ 5. Add § 80.7 to subpart A to read as follows:

§ 80.7 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Federal Communications Commission must publish notice of the change in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also it is available for inspection at the Federal Communications Commission, 445 12th Street, SW., Washington, DC (Reference Information Center), and is available from the sources listed below.

(b) The International Maritime Organization (IMO), 4 Albert Embankment, London SE1 7SR, United Kingdom; *http://www.imo.org;* Tel. +44 (0)20 7735 7611; Fax +44 (0)20 7587 3210; email: *info@imo.org.*

(1) IMO Resolution A.525(13) (''IMO Resolution A.525(13)''), ''Performance Standards for Narrow-band Direct Printing Telegraph Equipment for the Reception of Navigational and Meteorological Warnings and Urgent Information to Ships,'' including Annex, adopted 17 November 1983, IBR approved for §§ 80.905 and 80.1101.

(2) IMO Maritime Safety Committee (MSC) Resolution MSC.148(77) (''IMO Resolution MSC.148(77)''), ''Adoption of the Revised Performance Standards for Narrow-band Direct Printing Telegraph Equipment for the Reception of Navigational and Meteorological Warnings and Urgent Information to Ships (NAVTEX),'' adopted on 3 June 2003, IBR approved for §§ 80.905 and 80.1101.

(3) IMO Assembly Resolution A.662(16) (''IMO Resolution A.662(16)''), ''Performance Standards for Float-free Release and Activation Arrangements for Emergency Radio Equipment,'' adopted 19 October 1989, IBR approved for § 80.1101.

(4) IMO Assembly Resolution A.664(16) (''IMO Resolution A.664(16)''), ''Performance Standards for Enhanced Group Call Equipment,'' adopted 19 October 1989, IBR approved for § 80.1101.

(5) IMO Resolution A.694(17) (''IMO Resolution A.694(17)''), ''Recommendation on General Requirements for Shipborne Radio Equipment Forming part of the Global Maritime Distress and Safety System (GMDSS) and for Electronic Navigational Aids,'' adopted 6 November 1991, IBR approved for §§ 80.273 and 80.1101.

(6) IMO Resolution MSC.149(77) (''IMO Resolution MSC.149(77)''), ''Adoption of the Revised Performance Standards for Survival Craft Two-Way VHF Radiotelephone Apparatus,'' adopted on 3 June 2003, IBR approved for §§ 80.273 and 80.1101.

(7) IMO Assembly Resolution A.700(17), (''IMO Resolution A.700(17)''), ''Performance Standards for Narrow-band Direct-printing Telegraph Equipment for the Reception of Navigational and Meteorological Warnings and Urgent Information to Ships (MSI) by HF,'' adopted 6 November 1991, IBR approved for § 80.1101.

(8) IMO Assembly Resolution A.801(19) Appendix 13, Annex 5 (''IMO Resolution A.801(19)''), ''Criteria for Use When Providing Inmarsat Shore-Based Facilities for Use in the GMDSS,'' adopted 23 November 1995, IBR approved for § 80.1091.

(9) IMO Assembly Resolution A.802(19) (''IMO Resolution A.802(19)''), ''Performance Standards for Survival Craft Radar Transponders for Use in Search and Rescue Operations,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(10) IMO Resolution MSC.247(83) (''IMO Resolution MSC.247(83)''), ''Adoption of Amendments to Performance Standards for Survival Craft Radar Transponders for Use in Search and Rescue Operations,'' adopted on 8 October 2007, IBR approved for § 80.1101.

(11) IMO Assembly Resolution A.803(19) (''IMO Resolution A.803(19)''), ''Performance Standards for Shipborne VHF Radio Installations Capable of Voice Communication and Digital Selective Calling,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(12) IMO Resolution MSC.68(68) (''IMO Resolution MSC.68(68)''), ''Adoption of Amendments to Performance Standards for Shipborne Radiocommunications Equipment,'' adopted on 6 June 1997, IBR approved for § 80.1101.

(13) IMO Assembly Resolution A.804(19) (''IMO Resolution A.804(19)''), ''Performance Standards for Shipborne MF Radio Installations Capable of Voice Communication and Digital Selective Calling,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(14) IMO Assembly Resolution A.806(19) (''IMO Resolution A.806(19)''), ''Performance Standards for Shipborne MF/HF Radio Installations Capable of Voice Communication, Narrow-Band Direct Printing and Digital Selective Calling,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(15) IMO Assembly Resolution A.807(19) (''IMO Resolution A.807(19)''), ''Performance Standards for INMARSAT–C Ship Earth Stations Capable of Transmitting and Receiving Direct-Printing Communications,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(16) IMO Assembly Resolution A.808(19) (''IMO Resolution A.808(19)''), ''Performance Standards for Ship Earth Stations Capable of Two-Way Communications,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(17) IMO Assembly Resolution A.809(19) (''IMO Resolution A.809(19)''), ''Performance Standards for Survival Craft Two-Way VHF Radiotelephone Apparatus,'' including Annexes 1 and 2, adopted 23 November 1995, IBR approved for § 80.1101.

(18) IMO Assembly Resolution A.810(19) (''IMO Resolution A.810(19)''), ''Performance Standards for Float-free Satellite Emergency Position-indicating Radio Beacons (EPIRBs) Operating on 406 MHz,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1101.

(19) IMO Resolution MSC.56(66) (''IMO Resolution MSC.56(66)''), ''Adoption of Amendments to Recommendations on Performance Standards for Float-free Satellite Emergency Position-indicating Radio Beacons (EPIRBs) Operating on 406 MHz,'' adopted on 3 June 1996, IBR approved for § 80.1101.

(20) IMO Resolution MSC.120(74) (''IMO Resolution MSC.120(74)''), ''Adoption of Amendments to Performance Standards for Float-free Satellite Emergency Position-indicating Radio Beacons (EPIRBs) Operating on 406 MHz,'' adopted on 31 May 2001, IBR approved for § 80.1101.

(21) IMO Assembly Resolution A.811(19) (''IMO Resolution A.811(19)''), ''Performance Standards for a Shipborne Integrated Radiocommunication System (IRCS) When Used in the GMDSS,'' with Annex, adopted 23 November 1995, IBR approved for § 80.1083.

(22) IMO Assembly Resolution A.1001(25) (''IMO Resolution A.1001(25)''), ''Criteria for the Provision of Mobile Satellite Communication Systems in the Global Maritime Distress and Safety System (GMDSS),'' with

Annex, adopted 29 November 2007, IBR approved for § 80.1091.

(23) IMO Resolution MSC.74(69) (''IMO Resolution MSC.74(69)''), ''Adoption of New and Amended Performance Standards, Annex 3 Recommendation on Performance Standards for an Universal Shipborne Automatic Identification System (AIS),'' adopted 12 May 1998, IBR approved for § 80.1101.

(24) IMO Resolution MSC.80(70) (''IMO Resolution MSC.80(70)''), ''Adoption of New Performance Standards for Radiocommunication Equipment,'' with Annexes, adopted 8 December 1998, IBR approved for § 80.1101.

(25) IMO Resolution MSC.191(79) (''IMO Resolution MSC.191(79)''), ''Performance Standards for the Presentation of Navigation-Related Information on Shipborne Navigational Displays,'' adopted 6 December 2004, IBR approved for §§ 80.273 and 80.1101.

(26) IMO Resolution MSC.192(79) (''IMO Resolution MSC.192(79)''), ''Revised Recommendation on Performance Standards for Radar Equipment,'' adopted 6 December 2004, IBR approved for §§ 80.273 and 80.1101.

(27) IMO Circular MSC/Circ.1040 (''IMO Circular MSC/Circ.1040''), ''Guidelines on annual testing of 406 MHz satellite EPIRBs'' adopted 28 May 2002, IBR approved for § 80.1085.

(c) The International Telecommunication Union (ITU), Place des Nations, CH–1211, Geneva 20, Switzerland; *www.itu.int*; Voice: +41 22 730 5111; Fax: +41 22 733 7256; email: *itumail@itu.int*.

(1) ITU–R Recommendation M.476–5 (''ITU–R M.476–5''), ''Direct-Printing Telegraph Equipment in the Maritime Mobile Service,'' with Annex, 1995, IBR approved for §§ 80.219 and 80.225.

(2) ITU–R Recommendation M.492–6 (''ITU–R M.492–6''), ''Operational Procedures for the use of Direct-Printing Telegraph Equipment in the Maritime Mobile Service,'' with Annex, 1995, IBR approved for § 80.142.

(3) ITU–R Recommendation M.493–13, (''ITU–R M.493–13''), ''Digital Selective-calling System for Use in the Maritime Mobile Service,'' with Annexes 1, 2, 3, and 4 (10/2009), IBR approved for §§ 80.5, 80.179, 80.225, 80.1101, and 80.1113.

(4) ITU–R Recommendation M.540–2 (''ITU–R M.540–2''), ''Operational and Technical Characteristics for an Automated Direct-printing Telegraph System for Promulgation of Navigational and Meteorological Warnings and Urgent Information to Ships,'' including Annexes, 1990, IBR approved for §§ 80.905, 80.1101, and 80.1135.

(5) ITU–R Recommendation M.541–9 (''ITU–R M.541–9'') ''Operational Procedures for the Use of Digital Selective-Calling Equipment in the Maritime Mobile Service,'' with Annexes 1 through 5, 2004, IBR approved for §§ 80.5, 80.103, 80.179, 80.225, 80.359, 80.1101, 80.1113, and 80.1117.

(6) ITU–R Recommendation M.625–3 (''ITU–R M.625–3''), ''Direct-Printing Telegraph Equipment Employing Automatic Identification in the Maritime Mobile Service,'' with Annex, 1995, IBR approved for §§ 80.219, 80.225, 80.1125, 80.1127, 80.1131, and 80.1133.

(7) ITU–R Recommendation M.628–4 (''ITU–R M.628–4''), ''Technical Characteristics for Search and Rescue Radar Transponders,'' with Annexes, 2006, IBR approved for §§ 80.1101 and 80.1129.

(8) ITU–R Recommendation M.633–3 (''ITU–R M.633–3''), ''Transmission characteristics of a satellite emergency position-indicating radiobeacon (satellite EPIRB) system operating through a low polar-orbiting satellite system in the 406 MHz band,'' 2004, IBR approved for § 80.1101.

(9) ITU–R Recommendation M.824–3 (''ITU–R M.824–3''), ''Technical Parameters of Radar Beacons (RACONS),'' with Annexes, 2007, IBR approved for § 80.605.

(10) ITU–R Recommendation M.1177–3 (''ITU–R M.1177–3''), ''Techniques for measurement of unwanted emissions of radar systems,'' June 2003, IBR approved for §§ 80.273 and 80.1101.

(11) ITU–R Recommendation M.1371–3 (''ITU–R M.1371–3''), ''Technical characteristics for a universal shipborne automatic identification system using time division multiple access in the VHF maritime mobile band,'' with Annexes, 2007, IBR approved for § 80.1101.

(12) ITU–T Recommendation E.161 (''ITU–T E.161''), ''Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors: International Operation-Numbering Plan of the International Telephone Service: Arrangement of Digits, Letters and Symbols on Telephones and Other Devices that Can Be Used for Gaining Access to a Telephone Network'' (02/2001), IBR approved for § 80.1101.

(13) ITU–T Recommendation E.164.1 (''ITU–T E.164.1''), ''Series E: Overall Network Operation, Telephone Service, Service Operation and Human Factors: International Operation—Numbering Plan of the International Telephone Service: Criteria and Procedures for the Reservation, Assignment, and Reclamation of E.164 Country Codes and Associated Identification Codes (ICs)'' (09/2008), IBR approved for § 80.1101.

(d) The International Electrotechnical Commission (IEC), 3 Rue de Varembe, CH–1211, Geneva 20, Switzerland; *www.iec.ch*; phone: +41 22 919 02 11; fax: +41 22 919 03 00; email: *info@iec.ch*. (IEC publications can also be purchased from the American National Standards Institute (ANSI) through its NSSN operation (*www.nssn.org*), at Customer Service, American National Standards Institute, 25 West 43rd Street, New York NY 10036, telephone (212) 642–4900.)

(1) IEC 60092–101:1994+A1:1995 (''IEC 60092–101''), Edition 4.1, 2002–08, ''Electrical installations in ships—Part 101: Definitions and general requirements,'' IBR approved for § 80.1101.

(2) IEC 60533:1999(E) (''IEC 60533''), Second edition, 1999–11, ''Electrical and electronic installations in ships—Electromagnetic compatibility,'' IBR approved for § 80.1101.

(3) IEC 60945:2002 (''IEC 60945''), Fourth edition, 2002–08, ''Maritime navigation and radiocommunication equipment and systems–General requirements–Methods of testing and required test results,'' with Annexes, IBR approved for §§ 80.273 and 80.1101.

(4) IEC 61097–1:2007(E) (''IEC 61097–1''), Second edition, 2007–06, ''Global maritime distress and safety system (GMDSS)—Part 1: Radar transponder—Marine search and rescue (SART)—Operational and performance requirements, methods of testing and required test results,'' with Annexes, IBR approved for § 80.1101.

(5) IEC 1097–3:1994 (''IEC 61097–3''), First edition, 1994–06, ''Global maritime distress and safety system (GMDSS)—Part 3: Digital selective calling (DSC) equipment—Operational and performance requirements, methods of testing and required testing results,'' with Annexes, IBR approved for § 80.1101.

(6) IEC 61097–4 (''IEC 61097–4''), Edition 2.0, 2007–10, ''Global maritime distress and safety system (GMDSS)—Part 4: INMARSAT–C ship earth station and INMARSAT enhanced group call (EGC) equipment—Operational and performance requirements, methods of testing and required test results,'' IBR approved for § 80.1101.

(7) IEC 61097–6:2005(E) (''IEC 61097–6''), Second edition, 2005–12, ''Global maritime distress and safety system (GMDSS)—Part 6: Narrowband direct-printing telegraph equipment for the reception of navigational and meteorological warnings and urgent

information to ships (NAVTEX),'' IBR approved for § 80.1101.

(8) IEC 1097–7:1996 (''IEC 61097–7''), First edition, 1996–10, ''Global maritime distress and safety system (GMDSS)—Part 7: Shipborne VHF radiotelephone transmitter and receiver—Operational and performance requirements, methods of testing and required test results,'' IBR approved for § 80.1101.

(9) IEC 61097–8:1998(E) (''IEC 61097–8''), First edition, 1998–09, ''Global maritime distress and safety system (GMDSS)—Part 8: Shipborne watchkeeping receivers for the reception of digital selective calling (DSC) in the maritime MF, MF/HF, and VHF bands—Operational and Performance Requirements, Methods of Testing and Required Test Results,'' with Annexes, IBR approved for § 80.1101.

(10) IEC 61097–9:1997(E) (''IEC 61097–9''), First edition, 1997–12, ''Global maritime distress and safety system (GMDSS)—Part 9: Shipborne transmitters and receivers for use in the MF and HF bands suitable for telephony, digital selective calling (DSC) and narrow band direct printing (NBDP)—Operational and performance requirements, methods of testing and required test results,'' with Annexes, IBR approved for § 80.1101.

(11) IEC 61097–10:1999(E) (''IEC 61097–10''), First edition, 1999–06, ''Global maritime distress and safety system (GMDSS)—Part 10: INMARSAT–B ship earth station equipment—Operational and performance requirements, methods of testing and required test results,'' with Annexes, IBR approved for § 80.1101.

(12) IEC 1097–12:1996(E) (''IEC 61097–12''), First edition, 1996–11, ''Global maritime distress and safety system (GMDSS)—Part 12: Survival craft portable two-way VHF radiotelephone apparatus—Operational and performance requirements, methods of testing and required test results,'' IBR approved for § 80.1101.

(13) IEC 61097–13:2003(E) (''IEC 61097–13''), First edition, 2003–05, ''Global maritime distress and safety system (GMDSS)—Part 13: INMARSAT F77 ship earth station equipment—Operational and performance requirements, methods of testing and required test results,'' IBR approved for § 80.1101.

(14) IEC 61162–1:2007(E) (''IEC 61162–1''), Third edition, 2007–04, ''Maritime navigation and radiocommunication equipment and systems—Digital interfaces—Part 1: Single talker and multiple listeners,'' IBR approved for § 80.1101.

(15) IEC 61993–2:2001(E) (''IEC 61993–2''), First edition, 2001–12, ''Maritime navigation and radiocommunication equipment and systems—Automatic identification systems (AIS)—Part 2: Class A shipborne equipment of the universal automatic identification system (AIS)—Operational and performance requirements, methods of test and required test results,'' with Annexes, IBR approved for § 80.1101.

(16) IEC 62238:2003(E) (''IEC 62238''), First edition, 2003–03, ''Maritime navigation and radiocommunication equipment and systems—VHF radiotelephone equipment incorporating Class ''D'' Digital Selective Calling (DSC)—Methods of testing and required test results,'' IBR approved for § 80.225.

(17) IEC 62252:2004(E) (''IEC 62252''), First edition, 2004–07, ''Maritime navigation and radiocommunication equipment and systems—Radar for craft not in compliance with IMO SOLAS Chapter V—Performance requirements, methods of test and required test results,'' IBR approved for § 80.273.

(18) IEC 62287–1:2006(E) (''IEC 62287–1''), First edition, 2006–03, ''Maritime navigation and radiocommunication equipment and systems–Class B shipborne equipment of the Automatic Identification System–Part 1: Carrier–sense time division multiple access (CSTDMA) techniques,'' IBR approved for § 80.231.

(19) IEC 62388 (''IEC 62388''), Edition 1.0, 2007–12, ''Maritime navigation and radiocommunication equipment and systems–Shipborne radar–Performance requirements, methods of testing and required test results,'' IBR approved for §§ 80.273 and 80.1101.

(e) The International Organization for Standardization (ISO), 1, ch. De la Voie-Creuse, CP 56, CH–1211, Geneva 20, Switzerland; *www.iso.org*; Tel.: +41 22 749 01 11; Fax: +41 22 733 34 30; email: *central&iso.org*. (ISO publications can also be purchased from the American National Standards Institute (ANSI) through its NSSN operation (*www.nssn.org*), at Customer Service, American National Standards Institute, 25 West 43rd Street, New York NY 10036, telephone (212) 642–4900.)

(1) ISO Standard 3791 (''ISO Standard 3791''), ''Office Machines and Data Processing Equipment—Keyboard Layouts for Numeric Applications,'' First Edition 1976(E), IBR approved for § 80.1101.

(2) [Reserved]

(f) The Radio Technical Commission for Maritime Services (RTCM), 1800 N. Kent Street, Suite 1060, Arlington, VA 22209; *www.rtcm.org*; telephone (703) 527–2000; email *pubs@rtcm.org*.

(1) RTCM Paper 56–95/SC101–STD (''RTCM Paper 56–95/SC101–STD''), ''RTCM Recommended Minimum Standards for Digital Selective Calling (DSC) Equipment Providing Minimum Distress and Safety Capability,'' Version 1.0, August 10, 1995, IBR approved for § 80.225.

(2) RTCM 11000.2 (''RTCM 11000.2''), RTCM paper 77–2002/SC110–STD, ''RTCM Standard 11000.2 for 406 MHz Satellite Emergency Position-Indicating Radiobeacons (EPIRBs),'' Version 2.1, June 20, 2002, IBR approved for § 80.1061.

(3) RTCM 11020.1 (''RTCM 11020.1''), RTCM Paper 222–2009–SC110–STD), ''RTCM Standard 11020.0, Ship Security Alert Systems (SSAS) Using the Cospas-Sarsat System,'' October 9, 2009, IBR approved for § 80.277.

(g) COSPAS–SARSAT—International Satellite System for Search and Rescue, 700 de la Gauchetiere West, Suite 2450, Montreal, Quebec H3B 5 M2, Canada, telephone +1-(514) 954–6761, *www.cospas-sarsat.org*.

(1) COSPAS–SARSAT Standard C/S T.001 (''COSPAS–SARSAT Standard C/S T.001''), ''Specification for COSPAS–SARSAT 406 MHz Distress Beacons,'' Issue 3—Revision 10, October 2009, IBR approved for § 80.1061.

(2) COSPAS–SARSAT Standard C/S T.007 (''COSPAS–SARSAT Standard C/S T.007''), ''COSPAS–SARSAT 406 MHz Distress Beacon Type Approval Standard,'' Issue 4—Revision 4, October 2009, IBR approved for § 80.1061.

■ 6. Section 80.15 is amended by revising paragraph (e) to read as follows:

§ 80.15 Eligibility for station license.

* * * * *

(e) A 406.0–406.1 MHz EPIRB may be used by any ship required by U.S. Coast Guard regulations to carry an EPIRB or by any ship that is equipped with a VHF ship radio station.

* * * * *

■ 7. Section 80.103 is amended by revising paragraphs (a) and (c) and removing paragraph (e) to read as follows:

§ 80.103 Digital selective calling (DSC) operating procedures.

(a) Operating procedures for the use of DSC equipment in the maritime mobile service are as contained in ITU–R M.541–9 (incorporated by reference, see § 80.7), and subpart W of this part.

* * * * *

(c) DSC acknowledgment of DSC distress and safety calls must be made by designated coast stations and such acknowledgment must be in accordance with procedures contained in ITU–R M.541–9 (incorporated by reference, see § 80.7). Nondesignated public and

private coast stations must follow the guidance provided for ship stations in ITU–R M.541–9 (incorporated by reference, see § 80.7), with respect to DSC ''Acknowledgment of distress calls'' and ''Distress relays.'' (See subpart W of this part.)

* * * * *

■ 8. Section 80.142 is amended by revising paragraph (b) to read as follows:

§ 80.142 Ships using radiotelegraphy.

* * * * *

(b) *NB–DP operating procedure.* The operation of NB–DP equipment in the maritime mobile service must be in accordance with the operating procedures contained in ITU–R M.492–6 (incorporated by reference, see § 80.7).

* * * * *

■ 9. Section 80.148 is amended by revising paragraphs (a) and (b) to read as follows:

§ 80.148 Watch on 156.8 MHz (Channel 16).

* * * * *

(a) Where a ship station is operating only with handheld bridge-to-bridge VHF radio equipment under § 80.143(c) of this part; or

(b) For vessels subject to the Bridge-to-Bridge Act and participating in a Vessel Traffic Service (VTS) system when the watch is maintained on both the bridge-to-bridge frequency and a separately assigned VTS frequency.

■ 10. Section 80.151 is amended by revising paragraph (b) to read as follows:

§ 80.151 Classification of operator licenses and endorsements.

* * * * *

(b) The following licenses are issued by the Commission. The international classification of each license, if different from the license name, is given in parentheses. The listed alphanumeric designators are the codes by which the licenses are identified in the Commission's Universal Licensing System.

(1) RR. Restricted Radiotelephone Operator Permit (radiotelephone operator's restricted certificate).

(2) RL. Restricted Radiotelephone Operator Permit-Limited Use.

(3) MP. Marine Radio Operator Permit (radiotelephone operator's restricted certificate).

(4) PG. General Radiotelephone Operator License (radiotelephone operator's general certificate).

(5) DO. GMDSS Radio Operator's License (General Operator's Certificate).

(6) RG. Restricted GMDSS Radio Operator's License (Restricted Operator's Certificate).

(7) DM. GMDSS Radio Maintainer's License.

(8) DB. GMDSS Radio Operator/Maintainer License.

(9) T3. Third Class Radiotelegraph Operator's Certificate (radiotelegraph operator's special certificate).

(10) T2. Second Class Radiotelegraph Operator's Certificate.

(11) T1. First Class Radiotelegraph Operator's Certificate.

* * * * *

■ 11. Revise § 80.165 to read as follows:

§ 80.165 Operator requirements for voluntary stations.

MINIMUM OPERATOR LICENSE

Ship Morse telegraph	T2.
Ship direct-printing telegraph	MP.
Ship telephone, with or without DSC, more than 250 watts carrier power or 1,000 watts peak envelope power	PG.
Ship telephone, with or without DSC, not more than 250 watts carrier power or 1,000 watts peak envelope power	MP.
Ship telephone, with or without DSC, not more than 100 watts carrier power or 400 watts peak envelope power	
Above 30 MHz	None.[1]
Below 30 MHz	RP.
Ship earth station	RP.

[1] RP required for compulsory ships and international voyages.

■ 12. Section 80.179 is amended by revising paragraph (e)(1) to read as follows:

§ 80.179 Unattended operation.

* * * * *

(e) * * *

(1) The equipment must be using DSC in accordance with ITU–R M.493–13 and ITU–R M.541–9 (both incorporated by reference, see § 80.7), as modified by this section.

* * * * *

§ 80.205 [Amended]

■ 13. Section 80.205 is amended by removing and reserving footnote 13 from the table in paragraph (a).

§ 80.207 [Amended]

■ 14. Section 80.207 is amended by removing and reserving footnote 13 from the table in paragraph (d).

§ 80.209 [Amended]

■ 15. Section 80.209 is amended by removing and reserving footnote 6 from the table in paragraph (a).

* * * * *

■ 16. Section 80.219 is revised to read as follows:

§ 80.219 Special requirements for narrow-band direct-printing (NB–DP) equipment.

NB–DP and data transmission equipment installed in ship and coast stations before October 1, 1990, that operates on the frequencies in the 4,000–27,500 kHz bands must be capable of operation in accordance with the technical requirements of either ITU–R M.476–5 or ITU–R M.625–3 (both incorporated by reference, *see* § 80.7), and may be used indefinitely. Equipment installed on or after October 1, 1990, must be capable of operation in accordance with the technical requirements of ITU–R M.625–3, 1995 (incorporated by reference, see § 80.7). NB–DP and data transmission equipment are additionally permitted to utilize any modulation, so long as emissions are within the limits set forth in § 80.211(f) and the equipment is also capable of operation in accordance with ITU–R M.625–3 (incorporated by reference, see § 80.7).

■ 17. Section 80.225 is amended by revising the introductory text and paragraphs (a)(1)(i), (a)(1)(ii), (a)(2), (a)(3) and (c)(2) to read as follows:

§ 80.225 Requirements for selective calling equipment.

This section specifies the requirements for voluntary digital selective calling (DSC) equipment and selective calling equipment installed in ship and coast stations, and incorporates by reference ITU–R M.476–5; ITU–R M.493–13; ITU–R M.541–9; ITU–R M.625–3; RTCM Paper 56–95/SC101–STD; and IEC 62238 (all incorporated by reference, *see* § 80.7).

(a) * * *

(1) * * *

(i) RTCM Paper 56–95/SC101–STD and ITU–R M.493–13 (both incorporated

by reference, *see* § 80.7) (including only equipment classes A, B, D, and E); or

(ii) ITU–R M.493–13 and, in the case of Class D DSC equipment only, IEC 62238 (both incorporated by reference, *see* § 80.7).

(2) Beginning March 25, 2009, the Commission will not accept new applications (but will continue to process then-pending applications) for certification of non-portable DSC equipment that does not meet the requirements of ITU–R M.493–13 and, in the case of Class D DSC equipment only, IEC 62238 (both incorporated by reference, *see* § 80.7).

(3) Beginning March 25, 2012, the Commission will not accept new applications (but will continue to process then-pending applications) for certification of handheld, portable DSC equipment that does not meet the requirements of ITU–R M.493–13 and, in the case of Class D DSC equipment only, IEC 62238 (both incorporated by reference, *see* § 80.7).

* * * * *

(c) * * *

(2) Equipment used to perform a selective calling function during narrow-band direct-printing (NB–DP) operations in accordance with ITU–R M.476–5 or ITU–R M.625–3 or ITU–R M.493–13 (all incorporated by reference, *see* § 80.7), and

* * * * *

■ 18. Section 80.231 is amended by revising paragraph (a) to read as follows:

§ 80.231 Technical Requirements for Class B Automatic Identification System (AIS).

(a) Class B Automatic Identification System (AIS) equipment must meet the technical requirements of IEC 62287–1 (incorporated by reference, *see* § 80.7).

* * * * *

■ 19. Section 80.251 is amended by revising paragraph (a) to read as follows:

§ 80.251 Scope.

(a) This subpart gives the general technical requirements for certification of equipment used on compulsory ships. Such equipment includes automatic-alarm-signal keying devices, survival craft radio equipment, radar equipment and Ship Security Alert System (SSAS) equipment.

* * * * *

■ 20. Section 80.271 is amended by revising paragraph (a)(2) to read as follows:

§ 80.271 Technical requirements for portable survival craft radiotelephone transceivers.

(a) * * *

(2) The receiver must comply with the requirements in part 15, subpart B of this chapter and must have a sensitivity of not more than 2 microvolts;

* * * * *

■ 21. Section 80.273 is amended by revising the section heading and paragraphs (a) and (b) to read as follows:

§ 80.273 Radar standards.

(a) Radar installations on board ships that are required by the Safety Convention or the U.S. Coast Guard to be equipped with radar must comply with the following standards (all incorporated by reference, *see* § 80.7):

(1) IEC 60945;

(2) IEC 62388;

(3) IMO Resolution A.694(17), as revised by IMO Resolution MSC.149(77);

(4) IMO Resolution MSC.191(79);

(5) IMO Resolution MSC.192(79); and

(6) ITU–R M.1177–3.

(b) Radar equipment installed on voluntarily equipped vessels must comply with IEC 62252 (incorporated by reference, *see* § 80.7).

* * * * *

■ 22. Section 80.277 is amended by revising paragraph (a)(1) and removing and reserving paragraph (b) to read as follows:

§ 80.277 Ship Security Alert System (SSAS).

(a) * * *

(1) Equipment that complies with RTCM 11020.1 (incorporated by reference, *see* § 80.7); or

* * * * *

■ 23. Section 80.305 is amended by revising paragraph (b)(1) to read as follows:

§ 80.305 Watch requirements of the Communications Act and the Safety Convention.

* * * * *

(b) * * *

(1) If it is not carrying MF–DSC radio equipment, keep a continuous watch on 2182 kHz in the room from which the vessel is normally steered while at sea, whenever such station is not being used for authorized traffic. Such watch must be maintained by at least one officer or crewmember who may perform other duties relating to the operation or navigation of the vessel, provided such other duties do not interfere with the watch.

* * * * *

■ 24. Revise § 80.310 to read as follows:

§ 80.310 Watch required by voluntary vessels.

Voluntary vessels not equipped with DSC must maintain a watch on 2182 kHz and on 156.800 MHz (Channel 16) whenever the vessel is underway and the radio is not being used to communicate. Noncommercial vessels, such as recreational boats, may alternatively maintain a watch on 156.450 MHz (Channel 9) in lieu of VHF Channel 16 for call and reply purposes. Voluntary vessels equipped with VHF–DSC equipment must maintain a watch on 2182 kHz and on either 156.525 MHz (Channel 70) or VHF Channel 16 aurally whenever the vessel is underway and the radio is not being used to communicate. Voluntary vessels equipped with MF–HF DSC equipment must have the radio turned on and set to an appropriate DSC distress calling channel or one of the radiotelephone distress channels whenever the vessel is underway and the radio is not being used to communicate. Voluntary vessels equipped with a GMDSS-approved Inmarsat system must have the unit turned on and set to receive calls whenever the vessel is underway and the radio is not being used to communicate.

■ 25. Section 80.359 is amended by revising paragraph (b) to read as follows:

§ 80.359 Frequencies for digital selective calling (DSC).

* * * * *

(b) *Distress and safety calling.* The frequencies 2187.5 kHz, 4207.5 kHz, 6312.0 kHz, 8414.5 kHz, 12577.0 kHz, 16804.5 kHz and 156.525 MHz may be used for DSC by coast and ship stations on a simplex basis for distress and safety purposes, and may also be used for routine ship-to-ship communications provided that priority is accorded to distress and safety communications. The provisions and procedures for distress and safety calling are contained in ITU–R M.541–9 (incorporated by reference, *see* § 80.7), and § 80.103(c).

* * * * *

■ 26. Section 80.371 is amended by revising the second entry in the Coast transmit column of the table in paragraph (a) from ''[1]12514.0'' to ''[1]2514.0'' and revising paragraph (e) to read as follows:

§ 80.371 Public correspondence frequencies.

* * * * *

(a) * * *

WORKING FREQUENCY PAIRS IN THE 2000–4000 kHz BAND

Region	Carrier frequency (kHz)	
	Ship transmit	Coast transmit
* * * * *	*	*
	2118.0	[1] 2514.0
* * * * *	*	*

[1] Unlimited hours of use from December 15 to April 1 and day only from April 1 to December 15. Harmful interference must not be caused to any station in the Great Lakes region.

* * * * *

(e) Canada/U.S.A. channeling arrangement frequencies. The VHF frequencies assignable to ship and coast stations in the State of Washington and their usage limitations pursuant to the Canada/U.S.A. channeling arrangement are described in subpart B of this part.

■ 27. Section 80.373 is amended by revising paragraphs (b) introductory text, (b)(3), (b)(6), (f), and (g)(1) to read as follows:

§ 80.373 Private communications frequencies.

* * * * *

(b) Frequencies in the 2000–27500 kHz band for intership safety and other communications. This paragraph describes the geographic areas of operation and the frequencies and limitations in the band available for assignment for intership safety and operational simplex radiotelephone communications.

* * * * *

(3) Except for the frequencies 2093.0 kHz, 2214.0 kHz and 2670.0 kHz, the frequencies shown in paragraph (b)(1) of this section may be used on a non-interference basis to safety communications, for operational communications and, in the case of commercial transport ships and ships of municipal and state governments, for business communications.

* * * * *

(6) Navigational communications between ships and private coast stations may be exchanged on 2738.0 kHz and 2830.0 kHz. The frequencies 2214.0 kHz, 2738.0 kHz and 2830.0 kHz are assignable to private coast stations upon a showing that they need to communicate with commercial transport or Government ships. Private coast station applicants must show that public coast stations do not provide the required communications and harmful interference will not be caused to the intership use of these frequencies. The transmitter power must not exceed 150 watts. If 2214.0 kHz is authorized for ships, intership communication is also authorized. The geographic limitations to the frequencies 2738.0 kHz and 2830.0 kHz do not prohibit intership communication of less than 320 km (200 statute miles) when only one of the ship stations is within a permitted use geographic area.

* * * * *

(f) Frequencies in the 156–162 MHz band. The following tables describe the carrier frequencies available in the 156–162 MHz band for radiotelephone communications between ship and private coast stations. (**Note:** the letter ''A'' following the channel designator indicates simplex operation on a channel designated internationally as a duplex channel.)

FREQUENCIES IN THE 156–162 MHz BAND

Channel designator	Carrier frequency (MHz) ship transmit	Carrier frequency (MHz) coast transmit	Points of communication (intership and between coast and ship unless otherwise indicated)
Port Operations			
01A [1]	156.050	156.050	
63A [1]	156.175	156.175	
05A [2]	156.250	156.250	
65A	156.275	156.275	
66A	156.325	156.325	
12 [3]	156.600	156.600	
73	156.675	156.675	
14 [3]	156.700	156.700	
74	156.725	156.725	
75 [18]	156.775	156.775	
76 [18]	156.825	156.825	
77 [4]	156.875		Intership only.
20A [12]	157.000		Intership only.
Navigational (Bridge-to-Bridge) [5]			
67 [7]	156.375	156.375	
13 [6]	156.650	156.650	
Commercial			
01A [1]	156.050	156.050	
63A [1]	156.175	156.175	
07A	156.350	156.350	

FREQUENCIES IN THE 156–162 MHZ BAND—Continued

Channel designator	Carrier frequency (MHz) ship transmit	Carrier frequency (MHz) coast transmit	Points of communication (intership and between coast and ship unless otherwise indicated)
67 [7]	156.375		Intership only.
08	156.400		Do.
09	156.450	156.450	
10	156.500	156.500	
11 [3]	156.550	156.550	
72 [14]	156.625		Intership only.
18A	156.900	156.900	
19A	156.950	156.950	
79A	156.975	156.975	
80A	157.025	157.025	
88A [8]	157.425	157.425	
Digital Selective Calling			
70 [15]	156.525	156.525	
Noncommercial			
67 [14]	156.375		Intership only.
68 [17]	156.425	156.425	
09 [16]	156.450	156.450	
69	156.475	156.475	
71 [19]	156.575	156.575	
72	156.625		Intership only.
78A	156.925	156.925	
79A	156.975	156.975	Great Lakes only.
80A	157.025	157.025	Do.
Distress, Safety and Calling			
16	156.800	156.800	
Intership Safety			
06	156.300		a. Intership, or b. For SAR: Ship and aircraft for the U.S. Coast Guard.
Environmental			
15 [13]		156.750	Coast to ship only.
Maritime Control			
17 [9 10]	156.850	156.850	
Liaison and Safety Broadcasts, U.S. Coast Guard			
22A [11]	157.100	157.100	Ship, aircraft, and coast stations of the U.S. Coast Guard and at Lake Mead, Nev., ship and coast stations of the National Park Service, U.S. Department of the Interior.

[1] 156.050 MHz and 156.175 MHz are available for port operations and commercial communications purposes when used only within the U.S. Coast Guard designated Vessel Traffic Services (VTS) area of New Orleans, on the lower Mississippi River from the various pass entrances in the Gulf of Mexico to Devil's Swamp Light at River Mile 242.4 above head of passes near Baton Rouge.

[2] 156.250 MHz is available for port operations communications use only within the U.S. Coast Guard designated VTS radio protection areas of New Orleans and Houston described in § 80.383. 156.250 MHz is available for intership port operations communications used only within the area of Los Angeles and Long Beach harbors, within a 25-nautical mile radius of Point Fermin, California.

[3] 156.550 MHz, 156.600 MHz and 156.700 MHz are available in the U.S. Coast Guard designated port areas only for VTS communications and in the Great Lakes available primarily for communications relating to the movement of ships in sectors designated by the St. Lawrence Seaway Development Corporation or the U.S. Coast Guard. The use of these frequencies outside VTS and ship movement sector protected areas is permitted provided they cause no interference to VTS and ship movement communications in their respective designated sectors.

[4] Use of 156.875 MHz is limited to communications with pilots regarding the movement and docking of ships. Normal output power must not exceed 1 watt.

[5] 156.375 MHz and 156.650 MHz are available primarily for intership navigational communications. These frequencies are available between coast and ship on a secondary basis when used on or in the vicinity of locks or drawbridges. Normal output power must not exceed 1 watt. Maximum output power must not exceed 10 watts for coast stations or 25 watts for ship stations.

[6] On the Great Lakes, in addition to bridge-to-bridge communications, 156.650 MHz is available for vessel control purposes in established vessel traffic systems. 156.650 MHz is not available for use in the Mississippi River from South Pass Lighted Whistle Buoy "2" and Southwest Pass entrance Mid-channel Lighted Whistle Buoy to mile 242.4 above Head of Passes near Baton Rouge. Additionally it is not available for use in the Mississippi River-Gulf Outlet, the Mississippi River-Gulf Outlet Canal, and the Inner Harbor Navigational Canal, except to aid the transition from these areas.

[7] Use of 156.375 MHz is available for navigational communications only in the Mississippi River from South Pass Lighted Whistle Buoy "2" and Southwest Pass entrance Mid-channel Lighted Whistle Buoy to mile 242.4 above Head of Passes near Baton Rouge, and in addition over the full length of the Mississippi River-Gulf Outlet Canal from entrance to its junction with the Inner Harbor Navigational Canal, and over the full length of the Inner Harbor Navigational Canal from its junction with the Mississippi River to its entry to Lake Pontchartrain at the New Seabrook vehicular bridge.

[8] Within that portion of VHF Public Coast Station Areas (VPCSAs) 1 through 9 listed in the table in Section 80.371(c)(1)(ii) within 120 km (75 miles) of the United States/Canada border, in the area of the Great Lakes, the Saint Lawrence Seaway, and the Puget Sound and the Strait of Juan de Fuca and its approaches, Maritime VHF Channel 88A (157.425 MHz) is available for use for public correspondence communications, subject to prior coordination with Canada. Maritime VHF Channel 88B (162.025 MHz) is available only for Automatic Identification System communications. One hundred twenty kilometers (75 miles) from the United States/Canada border, 157.425 MHz is available for intership and commercial communications. Outside the Puget Sound area and its approaches and the Great Lakes, 157.425 MHz is available for communications between commercial fishing vessels and associated aircraft while engaged in commercial fishing activities.

[9] When the frequency 156.850 MHz is authorized, it may be used additionally for search and rescue training exercises conducted by state or local governments.

[10] The frequency 156.850 MHz is additionally available to coast stations on the Great Lakes for transmission of scheduled Coded Marine Weather Forecasts (MAFOR), Great Lakes Weather Broadcast (LAWEB) and unscheduled Notices to Mariners or Bulletins. F3C and J3C emissions are permitted. Coast stations on the Great Lakes must cease weather broadcasts which cause interference to stations operating on 156.800 MHz until the interference problem is resolved.

[11] The frequency 157.100 MHz is authorized for search and rescue training exercises by state or local government in conjunction with U.S. Coast Guard stations. Prior U.S. Coast Guard approval is required. Use must cease immediately on U.S. Coast Guard request.

[12] The duplex pair for channel 20 (157.000/161.600 MHz) may be used for ship to coast station communications.

[13] Available for assignment to coast stations, the use of which is in accord with an agreed program, for the broadcast of information to ship stations concerning the environmental conditions in which vessels operate, i.e., weather; sea conditions; time signals; notices to mariners; and hazards to navigation.

[14] Available only in the Puget Sound and the Strait of Juan de Fuca.

[15] The frequency 156.525 MHz is to be used exclusively for distress, safety and calling using digital selective calling techniques. No other uses are permitted.

[16] The frequency 156.450 MHz is available for intership, ship and coast general purpose calling by noncommercial vessels, such as recreational boats and private coast stations.

[17] The frequency 156.425 MHz is assigned by rule to private coast stations in Alaska for facsimile transmissions as well as voice communications.

[18] The frequencies 156.775 and 156.825 MHz are available for navigation-related port operations or ship movement only, and all precautions must be taken to avoid harmful interference to channel 16. Transmitter output power is limited to 1 watt for ship stations, and 10 watts for coast stations.

[19] 156.575 MHz is available for port operations communications use only within the U.S. Coast Guard designated VTS radio protection area of Seattle (Puget Sound) described in § 80.383. Normal output power must not exceed 1 watt. Maximum output power must not exceed 10 watts.

(g)(1) On-board communications: This section describes the carrier frequency pairs assignable for on-board mobile radiotelephony communications. The center of the on-board repeater antenna must not be located more than 3 meters (10 feet) above the ship's working deck. These frequencies are available on a shared basis with stations in the Industrial/Business Radio Pool.

FREQUENCIES FOR ON-BOARD COMMUNICATIONS

Channel	Carrier frequency (MHz)	
	On-board mobile station	On-board repeater station[1]
1	467.750	457.525
2	467.775	457.550
3	467.800	457.575
4	467.825	457.600

[1] These frequencies may also be assigned to mobile stations for single frequency simplex operation.

* * * * *

■ 28. Section 80.375 is amended by revising paragraphs (d)(1) and (d)(2)(v) and removing paragraph (d)(2)(vi) to read as follows:

§ 80.375 Radiodetermination frequencies.

* * * * *

(d) *Radiodetermination frequency bands above 2400 MHz.* (1) The radiodetermination frequency bands assignable to ship and shore stations including ship and shore radar and transponder stations are as follows: 2450–2500 MHz; 2900–3100 MHz; 5460–5650 MHz; and 9300–9500 MHz.

* * * * *

(2) * * *

(v) The use of the 5460–5650 MHz band for radionavigation is limited to shipborne radar.

* * * * *

§ 80.511 [Removed]

■ 29. Remove § 80.511.

■ 30. Section 80.605 is amended by revising paragraphs (b) and (c) to read as follows:

§ 80.605 U.S. Coast Guard coordination.

* * * * *

(b) Coast station transponders (i.e., radar beacons, or racons) operating in the band 2900–3100 or 9300–9500 MHz shall meet the requirements of ITU–R M.824–3 (incorporated by reference, see § 80.7). Applications for certification of these transponders must include a description of the technical characteristics of the equipment including the scheme of interrogation and the characteristics of the transponder response, and test results demonstrating the device meets each applicable requirement of this ITU–R recommendation.

(c) The use of ship station transponders in the band 2900–3100 or 9300–9500 MHz other than those described in §§ 80.1085(a)(3) and 80.1095(b) is prohibited.

§ 80.854 [Amended]

■ 31. Section 80.854 is amended by removing paragraph (c) and by redesignating paragraphs (d) through (f) as paragraphs (c) through (e).

■ 32. Section 80.905 is amended by removing paragraph (a)(4)(vii), redesignating paragraphs (a)(4)(viii) and (a)(4)(ix) as paragraphs (a)(4)(vii) and (a)(4)(viii), and by revising paragraphs (a)(3)(iii)(B), (a)(3)(v), (a)(3)(vi), (a)(4)(v), (a)(4)(vi), and newly redesignated paragraph (a)(4)(vii) to read as follows:

§ 80.905 Vessel radio equipment.

(a) * * *

(3) * * *

(iii) * * *

(B) If operated in an area within the coverage of an INMARSAT maritime mobile geostationary satellite in which continuous alerting is available, a GMDSS-approved Inmarsat ship earth station.

* * * * *

(v) Be equipped with a NAVTEX receiver conforming to the following performance standards: IMO Resolution A.525(13), as revised by IMO Resolution MSC.148(77) and ITU–R M.540–2 (all incorporated by reference, *see* § 80.7);

(vi) Be equipped with a Category I 406–406.1 MHz satellite emergency position-indicating radiobeacon (EPIRB) meeting the requirements of § 80.1061; and

* * * * *

(4) * * *

(v) Be equipped with a NAVTEX receiver conforming to the following performance standards: IMO Resolution A.525(13), as revised by IMO Resolution MSC.148(77) and ITU–R M.540–2 (all incorporated by reference, *see* § 80.7);

(vi) Be equipped with a Category I 406–406.1 MHz satellite emergency position-indicating radiobeacon (EPIRB) meeting the requirements of § 80.1061;

* * * * *

■ 33. Section 80.917 is amended by revising paragraph (a), and by adding paragraph (h) to read as follows:

§ 80.917 Reserve power supply.

(a) Any small passenger vessel the keel of which was laid after March 1, 1957, must have a reserve power supply located on the same deck as the main wheel house or at least one deck above the vessel's main deck, unless the main power supply is so situated, if—

(1) The vessel is of more than 100 gross tons; or

(2) Beginning March 25, 2009:

(i) The vessel carries more than 150 passengers or has overnight accommodations for more than 49 persons; or

(ii) The vessel operates on the high seas or more than three miles from shore on Great Lakes voyages.

* * * * *

(h) Beginning January 2, 2013, any small passenger vessel that does not carry a reserve power supply must carry at least one VHF handheld radiotelephone.

■ 34. Section 80.1053 is revised to read as follows:

§ 80.1053 Prohibition on certification, manufacture, importation, sale or use of Class A, Class B, Class S, and INMARSAT–E EPIRBs.

The manufacture, importation, or sale in the United States of Class A, Class B, Class S, or INMARSAT–E EPIRBs is prohibited. New Class A, Class B, Class S, or INMARSAT–E EPIRBs will no longer be certified by the Commission.

§ 80.1055 [Removed]

■ 35. Remove § 80.1055.

§ 80.1059 [Removed]

■ 36. Remove § 80.1059.

■ 37. Section 80.1061 is amended by revising paragraphs (a), (c) introductory text, and (c)(1)(ii) to read as follows:

§ 80.1061 Special requirements for 406.0–406.1 MHz EPIRB stations.

(a) Notwithstanding the provisions in paragraph (b) of this section, 406.0–406.1 MHz EPIRBs must meet all the technical and performance standards contained in the Radio Technical Commission for Maritime Services document entitled RTCM 11000.2 (incorporated by reference, *see* § 80.7), and must also comply with the standards specified in § 80.1101(c)(5).

* * * * *

(c) Prior to submitting a certification application for a 406.0–406.1 MHz radiobeacon, the radiobeacon must be certified by a test facility recognized by one of the COSPAS–SARSAT Partners that the equipment satisfies the design characteristics associated with the measurement methods described in COSPAS–SARSAT Standard C/S T.001 (incorporated by reference, see § 80.7), and COSPAS–SARSAT Standard C/S T.007 (incorporated by reference, *see* § 80.7). Additionally, the radiobeacon must be subjected to the environmental and operational tests associated with the test procedures described in Appendix A of RTCM Standard 11000.2 (incorporated by reference, see § 80.7), by a test facility accepted by the U.S. Coast Guard for this purpose. Information regarding accepted test facilities may be obtained from Commandant (CG–5214), U.S. Coast Guard, 2100 2nd St SW., Mail Stop 7126, Washington, DC 20593–7126, *http://cgmix.uscg.mil/EQLabs/EQLabsSearch.aspx*.

(1) * * *

(ii) Copies of the certificate and test data obtained from the test facility recognized by a COSPAS/SARSAT Partner showing that the radiobeacon complies with the COSPAS/SARSAT design characteristics associated with the measurement methods described in the COSPAS–SARSAT Standard C/S T.001 and COSPAS–SARSAT Standard C/S T.007, and RTCM 11000.2 (all incorporated by reference, *see* § 80.7);

* * * * *

§ 80.1063 [Removed]

■ 38. Remove § 80.1063.

■ 39. Section 80.1074 is amended by revising paragraph (b) to read as follows:

§ 80.1074 Radio maintenance personnel for at-sea maintenance.

* * * * *

(b) The following licenses qualify personnel as GMDSS radio maintainers to perform at-sea maintenance of equipment specified in this subpart. For the purposes of this subpart, no order is intended by this listing or the alphanumeric designator.

(1) DM: GMDSS Maintainer's License;

(2) DB: GMDSS Operator's/Maintainer's License.

* * * * *

§ 80.1077 [Amended]

■ 40. Section 80.1077 is amended by removing the entry in the table for ''INMARSAT–E EPIRBs [12], 1626.5–1645.5 MHz (Earth-to-space)'' and by removing footnote 12.

■ 41. Section 80.1083 is amended by revising paragraph (d) to read as follows:

§ 80.1083 Ship radio installations.

* * * * *

(d) Shipborne Integrated Radiocommunication System (IRCS) may be utilized to integrate all GMDSS equipment into a standard operator's console. Such installation must be certified in accordance with § 80.1103 and meet the requirements of IMO Resolution A.811(19) (incorporated by reference, *see* § 80.7).

* * * * *

■ 42. Section 80.1085 is amended by revising paragraphs (a)(6)(i) and (iii) to read as follows:

§ 80.1085 Ship radio equipment–General.

* * * * *

(a) * * *

(6) * * *

(i) Capable of transmitting a distress alert through the polar orbiting satellite service operating in the 406.0–406.1 MHz band (406.0–406.1 MHz EPIRB); and

* * * * *

(iii) Examined and tested annually in accordance with the IMO standard, IMO

Circular MSC/Circ.1040 (incorporated by reference, *see* § 80.7). *See* § 80.1105(k).

* * * * *

■ 43. Section 80.1087 is amended by revising paragraph (a)(2) to read as follows:

§ 80.1087 Ship radio equipment–Sea area A1.

* * * * *

(a) * * *

(2) Through the polar orbiting satellite service on 406.0–406.1 MHz (this requirement may be fulfilled by the EPIRB required by § 80.1085(a)(6), either by installing the EPIRB close to, or by allowing remote activation from, the position from which the ship is normally navigated); or

* * * * *

■ 44. Section 80.1089 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 80.1089 Ship radio equipment—Sea areas A1 and A2.

* * * * *

(a) * * *

(3) * * *

(i) Through the polar orbiting satellite service on 406.0–406.1 MHz (this requirement may be fulfilled by the EPIRB required by § 80.1085(a)(6), either by installing the EPIRB close to, or by allowing remote activation from, the position from which the ship is normally navigated); or

* * * * *

■ 45. Section 80.1091 is amended by revising paragraphs (a)(4)(i) and (iii), removing paragraph (b)(3)(ii), and redesignating paragraph (b)(3)(iii) as (b)(3)(ii).

The revisions read as follows:

§ 80.1091 Ship radio equipment—Sea areas A1, A2, and A3.

(a) * * *

(4) * * *

(i) Through the polar orbiting satellite service on 406.0–406.1 MHz (this requirement may be fulfilled by the EPIRB required by § 80.1085(a)(6), either by installing the EPIRB close to, or by allowing remote activation from, the position from which the ship is normally navigated); or

* * * * *

(iii) Through the INMARSAT geostationary satellite service, by an additional ship earth station.

Note to paragraph (a)(4)(iii): For ships subject to this subpart, sailing only in domestic waters, alternative satellite system fitting may be considered. However, the satellite system fitted must comply with all features of the INMARSAT system for its intended function. These are shown in IMO Resolution A.801(19) and in IMO Resolution A.1001(25) (both incorporated by reference, *see* § 80.7). In any case, the alternative satellite system must provide continuous coverage for all sea areas in which the ship intends to sail.

* * * * *

■ 46. Section 80.1101 is amended by revising paragraphs (b) and (c) and removing paragraph (d).

The revisions read as follows:

§ 80.1101 Performance standards.

* * * * *

(b) All equipment specified in this subpart must meet the general requirements for shipboard equipment in conformity with performance specifications listed in this paragraph, which are incorporated by reference. (*See* § 80.7).

(1) IMO Resolution A.694(17), as revised by IMO Resolution MSC.149(77)

(2) ITU–T E.161.

(3) ITU–T E.164.1.

(4) IEC 60092–101.

(5) IEC 60533.

(6) IEC 60945.

(7) ISO Standard 3791.

(c) The equipment specified in this subpart must also conform to the appropriate performance standards listed in paragraphs (c)(1) through (12) of this section, which are incorporated by reference (*see* § 80.7), and must be tested in accordance with the applicable IEC testing standards listed in paragraph (c)(13) of this section, which are also incorporated by reference. (*See* § 80.7).

(1) NAVTEX receivers:

(i) IMO Resolution A.525(13), as revised by IMO Maritime Safety Committee (MSC) Resolution MSC.148(77).

(ii) ITU–R M.540–2.

(2) VHF radio equipment:

(i) IMO Resolution A.803(19), as amended by IMO Resolution MSC.68(68).

(ii) ITU–R M.493–13.

(iii) ITU–R M.541–9.

(3) MF radio equipment:

(i) IMO Resolution A.804(19), as amended by IMO Resolution MSC.68(68).

(ii) ITU–R M.493–13.

(iii) ITU–R M.541–9.

(4) MF/HF radio equipment:

(i) IMO Resolution A.806(19), as amended by IMO Resolution MSC.68(68).

(ii) ITU–R M.493–13.

(iii) ITU–R M.541–9.

(iv) IMO Resolution A.700(17).

(5) 406.0–406.1 MHz EPIRBs:

(i) IMO Resolution A.810(19), as amended by IMO Resolution MSC.56(66) and IMO Resolution MSC.120(74).

(ii) IMO Resolution A.662(16).

(iii) ITU–R M.633–3.

(iv) The 406.0–406.1 MHz EPIRBs must also comply with § 80.1061.

(6) 9 GHz radar transponders:

(i) IMO Resolution A.802(19), as amended by IMO Resolution MSC.247(83).

(ii) ITU–R M.628–4.

(7) Two-Way VHF radiotelephone:

(i) IMO Resolution A.809(19), as revised by IMO Resolution MSC.149(77).

(ii) IMO Resolution MSC.80(70).

(8) INMARSAT Ship Earth Station Capable of Two-Way Communications: IMO Resolution A.808(19).

(9) INMARSAT–C SES: IMO Resolution A.807(19), as amended by IMO Resolution MSC.68(68).

(10) INMARSAT EGC: IMO Resolution A.664(16).

(11) Shipboard radar:

(i) IEC 60945.

(ii) IEC 62388 Edition 1.0 (2007–12).

(iii) IMO Resolution A.694(17).

(iv) IMO Resolution MSC.191(79).

(v) IMO Resolution MSC.192(79).

(vi) ITU–R M.1177–3.

(12) Automatic Identification Systems (AIS):

(i) ITU–R M.1371–3.

(ii) IMO Resolution MSC.74(69).

(iii) IEC 61162–1.

(iv) IEC 61993–2 .

(13) Standards for testing GMDSS equipment:

(i) IEC 61097–1.

(ii) IEC 61097–3.

(iii) IEC 61097–4.

(iv) IEC 61097–6.

(v) IEC 61097–7.

(vi) IEC 61097–8.

(vii) IEC 61097–9.

(viii) IEC 61097–10.

(ix) IEC 61097–12.

(x) IEC 61097–13.

■ 47. Add § 80.1107 to Subpart W under the undesignated center heading, ''Equipment Requirements for Ship Stations,'' to read as follows:

§ 80.1107 Test of radiotelephone station.

Unless the normal use of the required radiotelephone station demonstrates that the equipment is operating, a test communication on a required or working frequency must be made each day the ship is navigated. When this test is performed by a person other than the master and the equipment is found to be defective, the master must be promptly notified.

■ 48. Section 80.1113 is amended by revising paragraph (b) to read as follows:

§ 80.1113 Transmission of a distress alert.

* * * * *

(b) The format of distress calls and distress messages must be in accordance with ITU–R M.493–13 and ITU–R M.541–9 (both incorporated by reference, *see* § 80.7), as specified in § 80.1101.

* * * * *

■ 49. Section 80.1117 is amended by revising paragraph (a) to read as follows:

§ 80.1117 Procedure for receipt and acknowledgement of distress alerts.

(a) Normally, distress calls received using digital selective calling are only acknowledged using a DSC acknowledgement by a coast station. Ships should delay any acknowledgement in order to give sufficient time for a coast station to acknowledge the call. In cases where no acknowledgement has been heard and no distress traffic has been heard, the ship should transmit a distress alert relay to the coast station. Upon advice from the Rescue Coordination Center, the ship may transmit a DSC acknowledgement call to stop it from being repeated. Acknowledgement by digital selective calling of receipt of a distress alert in the terrestrial services must comply with ITU–R M.541–9 (incorporated by reference, *see* § 80.7).

* * * * *

■ 50. Section 80.1125 is amended by revising paragraph (b) to read as follows:

§ 80.1125 Search and rescue coordinating communications.

* * * * *

(b) Error correction techniques, in accordance with ITU–R M.625–3 (incorporated by reference, *see* § 80.7), as specified in § 80.1101, must be used for distress traffic by direct-printing telegraphy. All messages must be preceded by at least one carriage return, a line feed signal, a letter shift signal and the distress signal MAYDAY.

* * * * *

■ 51. Section 80.1127 is amended by revising paragraph (c) to read as follows:

§ 80.1127 On-scene communications.

* * * * *

(c) The preferred frequencies in radiotelephony for on-scene communications are 156.8 MHz and 2182 kHz. The frequency 2174.5 kHz may also be used for ship-to-ship on-scene communications using narrow-band direct-printing telegraphy in the forward error correcting mode in accordance with ITU–R M.625–3 (incorporated by reference, *see* § 80.7), as specified in § 80.1101.

* * * * *

■ 52. Section 80.1129 is amended by revising paragraph (d) to read as follows:

§ 80.1129 Locating and homing signals.

* * * * *

(d) The 9 GHz locating signals must be in accordance with ITU–R M.628–4 (incorporated by reference, *see* § 80.7), as specified in § 80.1101.

■ 53. Section 80.1131 is amended by revising paragraph (j) to read as follows:

§ 80.1131 Transmissions of urgency communications.

* * * * *

(j) Error correction techniques, in accordance with ITU–R M.625–3 (incorporated by reference, *see* § 80.7), as specified in § 80.1101, must be used for urgency messages by direct-printing telegraphy. All messages must be preceded by at least one carriage return, a line feed signal, a letter shift signal, and the urgency signal PAN PAN.

* * * * *

■ 54. Section 80.1133 is amended by revising paragraph (g) to read as follows:

§ 80.1133 Transmission of safety communications.

* * * * *

(g) Error correction techniques, in accordance with ITU–R M.625–3 (incorporated by reference, *see* § 80.7), as specified in § 80.1101, must be used for safety messages by direct-printing telegraphy. All messages must be preceded by at least one carriage return, a line feed signal, a letter shift signal, and the safety signal SECURITE.

* * * * *

■ 55. Section 80.1135 is amended by revising paragraph (b) to read as follows:

§ 80.1135 Transmission of maritime safety information.

* * * * *

(b) The mode and format of the transmissions mentioned in this section is in accordance with ITU–R M.540–2 (incorporated by reference, *see* § 80.7) as specified in § 80.1101.

* * * * *

[FR Doc. 2011–27587 Filed 11–1–11; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 110819519–1640–02]

RIN 0648–BB22

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

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement the management actions described in a regulatory amendment to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) prepared by the Gulf of Mexico Fishery Management Council (Council). This final rule increases the 2011 commercial quota for red grouper, and thereby increases the 2011 commercial quota for shallow water grouper (SWG), sets the commercial quota for red grouper and SWG from 2012 to 2015 and subsequent fishing years, and increases the red grouper recreational bag limit from two to four fish within the current four-fish grouper aggregate bag limit. The increase in the recreational bag limit will allow the recreational sector to more effectively harvest the increase in the recreational allocation established in the regulatory amendment. The intended effect of this final rule is to help prevent overfishing of red grouper while achieving optimum yield (OY) by increasing the red grouper harvest consistent with the findings of the recent 2010 re-run of the stock assessment for this species using updated information.

DATES: This rule is effective November 2, 2011.

ADDRESSES: Electronic copies of the regulatory amendment, which includes an environmental assessment and a regulatory impact review, may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sf/GrouperSnapperandReefFish.htm.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, Southeast Regional Office, NMFS, *telephone:* (727) 824–5305, *email: Peter.Hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico (Gulf) is managed under the FMP. The FMP

was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On September 21, 2011, NMFS published a proposed rule for the 2011 red grouper regulatory amendment and requested public comment (76 FR 58455). The proposed rule and the regulatory amendment outline the rationale for the actions contained in this final rule. A summary of the actions implemented by this final rule is provided below.

This final rule increases the commercial quota and the recreational allocation for Gulf red grouper and thereby increases the Gulf red grouper total allowable catch (TAC). This final rule increases the Gulf red grouper 2011 commercial quota from 4.32 million lb (1.96 million kg) to 5.23 million lb (2.82 million kg). This rule also sets the Gulf red grouper commercial quotas for 2012 to 2015 at 5.37 million lb (2.37 million kg) for 2012, 5.53 million lb (2.44 million kg) for 2013, 5.63 million lb (2.51 million kg) for 2014, and 5.72 million lb (2.59 million kg) for 2015, and subsequent fishing years. However, these increases in the red grouper commercial quota are contingent upon the TAC not being exceeded in the previous fishing year (regardless of which sector is responsible for any overage). Increases in the Gulf red grouper commercial quotas from 2012 to 2015 will correspondingly increase the SWG quota to 6.21 million lb (2.82 million kg) for 2012, 6.37 million lb (2.89 million kg) for 2013, 6.47 million lb (2.93 million kg) for 2014, and 6.56 million lb (2.98 million kg) for 2015, and subsequent fishing years. Increases in the SWG quota are contingent upon the red grouper TAC or gag TAC not being exceeded in the previous fishing year.

This rule also increases the recreational allocation of Gulf red grouper for 2011 from 1.36 million lb (0.62 million kg) to 1.65 million lb (0.75 million kg). The recreational allocation for 2012 to 2015 would be 1.70 million lb (0.78 million kg) for 2012, 1.74 million lb (0.79 million kg) for 2013, 1.78 million lb (0.81 million kg) for 2014, and 1.80 million lb (0.82 million kg) for 2015, and subsequent fishing years.

Given the increase in the recreational allocation and that the recreational sector's harvest has been less than catch targets in recent years, a relaxation of recreational management measures is warranted. This final rule increases the Gulf red grouper recreational bag limit from two to four fish. Amendment 32 to the FMP, currently under development, would establish an adaptive management approach for this new bag limit through an accountability measure. Under Amendment 32, if the red grouper recreational ACL is exceeded, the bag limit would be reduced for the subsequent year by one fish (with a two-fish bag limit as the lowest bag limit allowable under this accountability measure).

Comments and Responses

NMFS received seven letters on the proposed rule; one from an industry organization and six from individuals. Three of the letters supported the proposed rule, and are not addressed here. Four letters opposed some or all of the management measures. These letters contained two distinct comments to the rule, which are addressed below.

Comment 1: Two comments from for-hire operators indicated they would prefer maintaining the current two-fish bag limit if the February 1 to March 31 seasonal closure could be lifted. The commenters stated that the current 2-month closure limits their ability to market fishing trips.

Response: Because the red grouper closed season for the 2011 fishing year has already passed, the Council only evaluated increasing the recreational bag limit to allow the recreational sector to more fully harvest its increased allocation and achieve OY specifically for the 2011 fishing year. If the bag limit was not increased, then the ability of the recreational sector to harvest its allocation for the 2011 fishing year would be reduced. The current February 1 through March 31 seasonal closure for SWG, which includes red grouper, was implemented through Amendment 30B to the FMP (April 16, 2009, 74 FR 17603). The current closure was implemented to co-manage gag and red grouper and constrain the recreational gag harvest while simultaneously allowing the stock to increase and allow the red grouper harvest to be harvested as close to OY as possible. As the gag stock rebuilds, the Council may examine management alternatives to the current closed season.

Comment 2: Two comments, one from the for-hire sector and one from the commercial sector, suggested the increases in the red grouper recreational bag limit and quota were too large. The for-hire captain supported a three-red grouper bag limit, and both commenters supported a reduced quota increase.

Response: The Council evaluated bag limit analyses from Amendment 30B to the FMP, which indicated the increase in the recreational sector's allocation could support a four-fish bag limit. However, to ensure this bag limit increase does not lead to overfishing, the Council has submitted for approval by the Secretary of Commerce an accountability measure (AM) in Amendment 32 to the FMP that would decrease the recreational bag limit if the recreational annual catch limit (ACL) is exceeded in a fishing year. Additional recreational AMs implemented through Amendment 30B and proposed in Amendment 32 will allow for recreational seasonal closures should landings indicate the recreational sector's ACL is projected to be met or exceeded.

The rerun of the 2009 update assessment for red grouper supports the 910,000 lb (412,769 kg) increase in the commercial quota. This quota is less than the current ACL for the commercial sector for red grouper. The commercial harvest of red grouper is managed under the Gulf grouper-tilefish individual fishing quota (IFQ) program. The IFQ program functions as an AM for the commercial sector because the program closely monitors commercial landings and IFQ participants are limited to their specific IFQ allocation each fishing year. Therefore, it is unlikely the commercial ACL would be exceeded during a fishing year.

Classification

The Regional Administrator, Southeast Region, NMFS has determined that this final rule is necessary for the conservation and management of red grouper in the Gulf of Mexico and is consistent with the Magnuson-Stevens Act and other applicable laws.

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

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

NMFS finds good cause under 5 U.S.C. 553(d) to waive the delay in effective date for this rule. Delaying the effectiveness of this final rule is unnecessary and contrary to the public interest. This rule increases the 2011 commercial quota for red grouper, which in turn increases the 2011

commercial quota for SWG and the red grouper recreational bag limit to four fish. These measures will benefit commercial and recreational fishermen, and will not have any adverse affects on the grouper stocks in the Gulf of Mexico. Additionally, the immediate effectiveness of this final rule will allow fishermen to more effectively harvest the increase in the red grouper and SWG quota and red grouper recreational bag limit established in the regulatory amendment during the current fishing season. Delaying implementation of these measures could result in red grouper fishermen not having the opportunity to achieve OY from the stock, because the sectors would have insufficient time to harvest the quota increase before the fishing year's end. A delay would thus diminish the social and economic benefits for red grouper fishermen this rule provides, and undermine the purpose of the rule itself. Finally, this rule creates no new duties, obligations, or requirements for the regulated community that would necessitate delaying this rule's effectiveness to allow them to come into compliance with it. Indeed, parties regulated by this rule can continue to conduct their operations without modification even after this rule is in effect. Thus, delaying the rule's effectiveness is unnecessary and contrary to the public interest.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: October 28, 2011.

John Oliver

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.39, the first sentence in paragraph (b)(1)(ii) is revised to read as follows:

§ 622.39 Bag and possession limits.

* * * * *

(b) * * *

(1) * * *

(ii) Groupers, combined, excluding goliath grouper and Nassau grouper—4 per person per day, but not to exceed 1 speckled hind or 1 warsaw grouper per vessel per day, or 2 gag per person per day. * * *

* * * * *

■ 3. In § 622.42, two sentences are added after the first sentence in the introductory text and paragraphs (a)(1)(iii)(A) and (C) are revised to read as follows:

§ 622.42 Quotas.

* * * Annual quota increases are contingent on the total allowable catch for the applicable species not being exceeded in the previous fishing year. If the total allowable catch is exceeded in the previous fishing year, the RA will file a notification with the Office of the **Federal Register** to maintain the quota for the applicable species from the previous fishing year for following fishing years, unless the best scientific information available determines maintaining the quota from the previous year is unnecessary. * * *

(a) * * *

(1) * * *

(iii) * * *

(A) *SWG combined.* (*1*) For fishing year 2011—6.07 million lb (2.75 million kg).

(*2*) For fishing year 2012—6.21 million lb (2.82 million kg).

(*3*) For fishing year 2013—6.37 million lb (2.89 million kg).

(*4*) For fishing year 2014—6.47 million lb (2.93 million kg).

(*5*) For fishing year 2015 and subsequent fishing years—6.56 million lb (2.98 million kg).

* * * * *

(C) *Red grouper.* (*1*) For fishing year 2011—5.23 million lb (2.82 million kg).

(*2*) For fishing year 2012—5.37 million lb (2.37 million kg).

(*3*) For fishing year 2013—5.53 million lb (2.44 million kg).

(*4*) For fishing year 2014—5.63 million lb (2.51 million kg).

(*5*) For fishing year 2015 and subsequent fishing years—5.72 million lb (2.59 million kg).

* * * * *

[FR Doc. 2011–28409 Filed 10–28–11; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 76, No. 212
Wednesday, November 2, 2011

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

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

6 CFR Part 5

[Docket No. DHS–2011–0103]

Privacy Act of 1974: Implementation of Exemptions; Department of Homeland Security U.S. Customs and Border Protection DHS/CBP–003 Credit/Debit Care Data System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Homeland Security is giving concurrent notice of a newly established system of records pursuant to the Privacy Act of 1974 for the ''Department of Homeland Security/U.S. Customs and Border Protection–003 Credit/Debit Care Data System of Records'' and this proposed rulemaking. In this proposed rulemaking, the Department proposes to exempt portions of the system of records from one or more provisions of the Privacy Act because of criminal, civil, and administrative enforcement requirements.

DATES: Comments must be received on or before December 2, 2011.

ADDRESSES: You may submit comments, identified by docket number DHS–2011–0103, by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (703) 483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Laurence E. Castelli (202) 325–0280), CBP Privacy Officer, Office of International Trade, U.S. Customs and Border Protection, Mint Annex, 799 Ninth Street, NW., Washington, DC 20229. For privacy issues please contact: Mary Ellen Callahan (703) 235–0780), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Customs and Border Protection (CBP) proposes to establish a new DHS system of records notice titled, ''DHS/CBP–003 Credit/Debit Card Data System of Records.''

This system collects, uses, and maintains records related to any credit and debit card transactions with CBP. CBP is providing notice to the public regarding the collection, use, and dissemination of any credit and debit card transaction information provided to CBP. Many programs administered by CBP require an individual or business to provide payment for various purposes, including services, applications, fees, and duties, among others. As CBP expands methods of payment, many of these transactions will permit use of credit and debit cards, which will require the collection of the card data, disseminating that data to process the transaction, and maintaining the data for recordkeeping purposes. Information from this system will be shared with the Department of Treasury, banks, and credit and debit card processors as necessary. The data will not be used for law enforcement or intelligence purposes unless the individual's underlying transaction becomes associated with a law enforcement or intelligence action.

The purpose of this system is to provide payment processing and recordkeeping of credit and debit card transactions with CBP. Authority for maintenance of this system is given by The Homeland Security Act of 2002, Public Law 107–296; 5 U.S.C. 301; 8 U.S.C. 1101, *et seq.;* 19 U.S.C. 1, *et seq.;* Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act), (Pub. L. 110–53); and the Travel Promotion Act (Pub. L. 111–145). This newly established system will allow CBP to collect credit and/or debit card payment information from individuals providing payment to CBP for services, applications, fees, duties, and other official activities. Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions. All routine uses proposed are compatible with the purpose for which the information was collected and CBP's mission.

Consistent with DHS's information sharing mission, information stored in the Credit/Debit Card Data system of record may be shared with other DHS components, as well as appropriate Federal, State, local, foreign, or international or tribal government agencies. This sharing will only take place after DHS determines that the receiving component or agency has a need to know the information to carry out national security, law enforcement, immigration, intelligence, or other functions consistent with the routine uses set forth in this system of records notice.

Additionally, the Department of Homeland Security is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act, concurrent with this system of records elsewhere in the **Federal Register**. DHS

is not exempting any data in the system regarding an individual's credit or debit card transaction. This system, however, may contain records or information pertaining to the accounting of disclosures made from this system to other law enforcement or intelligence agencies (federal, state, local, foreign, international or tribal) in accordance with the published routine uses or statutory basis for disclosure under 5 U.S.C. 552a(b). For the accounting of these disclosures only, in accordance with 5 U.S.C. 552a(j)(2), and (k)(2), DHS will claim exemptions for these records or information.

II. Privacy Act

The Privacy Act embodies fair information practice principles in a statutory framework governing the means by which the U.S. government collects, maintains, uses, and disseminates personally identifiable information. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass U.S. citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors.

The Privacy Act allows government agencies to exempt certain records from the access and amendment provisions. If an agency claims an exemption, however, it must issue a Notice of Proposed Rulemaking to make clear to the public the reasons why a particular exemption is claimed.

DHS is claiming exemptions from certain requirements of the Privacy Act for DHS/CBP–003 CDCDS System of Records. Some information in DHS/CBP–003 CDCDS System of Records relates to official DHS law enforcement and immigration activities; specifically, records or information pertaining to the accounting of disclosures made from this system to other law enforcement or intelligence agencies (Federal, state, local, foreign, international or tribal) in accordance with the published routine uses or statutory basis for disclosure under 5 U.S.C. 552a(b). These exemptions are needed to protect information relating to DHS activities from disclosure to subjects or others related to these activities. Specifically, the exemptions are required to preclude subjects of these activities from frustrating these processes and to avoid disclosure of activity techniques. Disclosure of information to the subject of the inquiry could also permit the subject to avoid detection or apprehension.

The exemptions proposed here are standard law enforcement and national security exemptions exercised by a large number of federal law enforcement and intelligence agencies. In appropriate circumstances, where compliance would not appear to interfere with or adversely affect the law enforcement purposes of this system and the overall law enforcement process, the applicable exemptions may be waived on a case by case basis.

A notice of system of records for DHS/CBP–0 CDCDS System of Records is also published in this issue of the **Federal Register**.

List of Subjects in 6 CFR Part 5

Freedom of information; Privacy.

For the reasons stated in the preamble, DHS proposes to amend Chapter I of Title 6, Code of Federal Regulations, as follows:

PART 5—DISCLOSURE OF RECORDS AND INFORMATION

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

Authority: 6 U.S.C. 101 *et seq.;* Pub. L. 107–296, 116 Stat. 2135; 5 U.S.C. 301. Subpart A also issued under 5 U.S.C. 552. Subpart B also issued under 5 U.S.C. 552a.

2. Add at the end of Appendix C to Part 5, the following new paragraph ''1'':

Appendix C to Part 5—DHS Systems of Records Exempt From the Privacy Act

* * * * *

63. The DHS/CBP–003 CDCDS System of Records consists of electronic and paper records and will be used by DHS and its components. The DHS/CBP–003 CDCDS System of Records is a repository of information held by DHS in connection with its several and varied missions and functions, including, but not limited to the enforcement of civil and criminal laws; investigations, inquiries, and proceedings thereunder; national security and intelligence activities.. The DHS/CBP–003 CDCDS System of Records contains information that is collected by, on behalf of, in support of, or in cooperation with DHS and its components and may contain personally identifiable information collected by other Federal, State, local, tribal, foreign, or international government agencies. The Secretary of Homeland Security has exempted this system from the following provisions of the Privacy Act, subject to limitations set forth in 5 U.S.C. 552a(c)(3) and (4), (e)(8), and (g) pursuant to 5 U.S.C. 552a(j)(2) and (k)(2). Exemptions from these particular subsections are justified, on a case-by-case basis to be determined at the time a request is made, for the following reasons:

(a) From subsection (c)(3) and (4) (Accounting for Disclosures) because release of the accounting of disclosures could alert the subject of an investigation of an actual or potential criminal, civil, or regulatory violation to the existence of that investigation and reveal investigative interest on the part of DHS as well as the recipient agency. Disclosure of the accounting would therefore present a serious impediment to law enforcement efforts and/or efforts to preserve national security. Disclosure of the accounting would also permit the individual who is the subject of a record to impede the investigation, to tamper with witnesses or evidence, and to avoid detection or apprehension, which would undermine the entire investigative process.

(b) From subsection (e)(8) (Notice on Individuals) because compliance would interfere with DHS's ability to obtain, serve, and issue subpoenas, warrants, and other law enforcement mechanisms that may be filed under seal and could result in disclosure of investigative techniques, procedures, and evidence.

(c) From subsection (g)(1) (Civil Remedies) to the extent that the system is exempt from other specific subsections of the Privacy Act.

Dated: October 3, 2011.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–28400 Filed 11–1–11; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF ENERGY

10 CFR Parts 609 and 950

RIN 1990–AA38

Modification of Regulatory Provisions Requiring Credit Rating or Assessments in Accordance With Section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act

AGENCY: Office of the General Counsel, Department of Energy (DOE).

ACTION: Proposed rule; request for comment.

SUMMARY: Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Act), the Department of Energy (DOE) has reviewed DOE regulations that require the use of an assessment of the credit-worthiness of a security or money market instrument. DOE has identified regulatory provisions that may be subject to the Act's requirement to remove any references to or requirements in such regulations regarding credit ratings. The regulations DOE identified are

regulations implementing the loan guarantee program created by Title XVII of the Energy Policy Act of 2005 and regulations implementing the standby support program for certain nuclear plant delays promulgated pursuant to section 638 of the Energy Policy Act of 2005. DOE provided a report of its review to Congress as required by the Act and, as a result of this review, proposes to modify these regulatory provisions to remove provisions that would require applicants or sponsors to provide a credit rating or other credit assessment to DOE.

DATES: Comments on these proposed procedures must be postmarked by December 2, 2011.

ADDRESSES: Interested parties may submit comments, identified by Regulation Identifier Number (RIN) 1990–AA38, by any of the following methods:

1. *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
2. *Email: 1990-AA38@hq.doe.gov.* Include RIN 1990–AA38 in the subject line of the message.
3. *Postal Mail:* Office of the General Counsel, U.S. Department of Energy, Room 6A–245, 1000 Independence Avenue SW., Washington, DC 20585–0121. Please submit one signed paper original and include RIN 1990–AA38 on your submission.
4. *Hand Delivery/Courier:* Office of the General Counsel, U.S. Department of Energy, Room 6A–245, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–5281. Please submit one signed paper original and include RIN 1990–AA38 on your submission.

FOR FURTHER INFORMATION CONTACT: Samuel Walsh, Office of the General Counsel, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0121; phone: (202) 586–6732; email: *1990-AA38@hq.doe.gov*. Include RIN 1990–AA38 in the subject line of the message.

SUPPLEMENTARY INFORMATION: Section 939A(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Act), Public Law 111–203, requires Federal agencies, including DOE, to review (1) any regulation issued by such agency that requires the use of an assessment of the credit-worthiness of a security or money market instrument; and (2) any reference to or requirements in such regulations regarding credit ratings. Subsequent to such review, section 939A(b) requires Federal agencies to modify any such regulations to remove any references to or requirements of reliance on credit ratings and to substitute an appropriate standard of credit-worthiness. To the extent feasible, Federal agencies must seek to establish uniform standards of credit-worthiness, taking into account the regulated entities and the purposes for which such entities would rely on the established standard of credit-worthiness. Section 939A(c) also requires Federal agencies to submit a report to Congress describing any regulatory modifications at the conclusion of its review.

DOE submitted a report to Congress on July 20, 2011, describing the results of its review and the regulatory changes DOE was considering. These changes consist of revisions to DOE regulations implementing the loan guarantee program created by Title XVII of the Energy Policy Act of 2005 (10 CFR 609.6, 609.8 and 609.9) and its regulations implementing the standby support program for certain nuclear plant delays promulgated pursuant to section 638 of the Energy Policy Act of 2005 (10 CFR 950.10). In today's proposed rule, DOE proposes changes to these regulatory provisions to references to or requirements of reliance on credit ratings. DOE believes that the remaining provisions in both 10 CFR part 609 and 10 CFR part 950 provide an appropriate standard of creditworthiness for potential applicants and sponsors. DOE's Loan Programs Office currently conducts an internal risk analysis pursuant to its policies and procedures. This analysis is independent of any third-party rating and does not require the submission of a credit rating or credit assessment. For the standby support program, a potential sponsor would still be required to submit a detailed business plan that includes intended financing for the project including the credit structure and all sources and uses of funds for the project, and the projected cash flows for all debt obligations of the advanced nuclear facility which would be covered under the Standby Support Contract.

Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

This proposed rule has been determined to be not significant for purposes of E.O. 12866.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a final regulatory flexibility analysis (FRFA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site (*www.gc.doe.gov).*

DOE has reviewed today's proposed rule under the Regulatory Flexibility Act and certifies that, if adopted, the rule would not have a significant impact on a substantial number of small entities. DOE believes that it is unlikely that any entities wishing to contract with DOE to offer standby support for the specified nuclear plant delays under 10 CFR part 950 are considered small entities. The SBA considers a firm engaged in nuclear power generation (NAICS Code 221113) to be a small business if, including its affiliates, the firm is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and its total electric output for the preceding fiscal year did not exceed 4 million megawatt hours. Because nuclear reactors cost on average $4–6 billion per reactor to construct and likely exceed the 4 million megawatt hours per year threshold, DOE believes that nuclear firms who would engage with DOE in standby support activities are not small entities. DOE recognizes that some applicants for assistance under 10 CFR part 609 may be small businesses according to SBA size standards. DOE believes, however, that the impact of the proposed rule on both nuclear standby support providers and applicants for assistance would not be significant. The proposed rule would delete from the regulations any requirements to provide a credit rating or other credit assessment to DOE as part of any application, which is expected to decrease the burden on applicants. In addition to reducing regulatory burden, this proposal would save nuclear standby support providers and applicants for assistance the cost of a credit rating, which is determined based on negotiations between the applicant and the rating agency.

C. Review Under the Paperwork Reduction Act

This proposed rule contains collection-of-information requirements subject to review and approval by OMB

under the Paperwork Reduction Act (PRA). This requirement has been submitted to OMB for approval. Public reporting burden for submission of the required information for the Loan Guarantee Program is estimated to average 12 hours per response. These burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Public comment is sought regarding: Whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including through the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information for the Loan Guarantee Program to Alvin Leong at *Alvin.leong@hq.doe.gov* and Chad Whiteman at *Chad_S._Whiteman@omb.eop.gov*.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act

In this proposed rule, DOE proposes to delete requirements to provide a credit rating or other credit assessment as part of an application for financial assistance or an application to enter into a conditional agreement to provide standby support for certain nuclear plant delays. DOE has determined that proposed change falls within the categorical exclusion found at paragraph A5 of Appendix A to Subpart D, 10 CFR part 1021, which applies to amending an existing rule or regulation that does not change the environmental effect of the rule or regulation being amended. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has considered today's proposed rule in accordance with EO 13132 and its policy and determined that this proposed rule, if adopted, would not preempt State law or have any federalism impacts. No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. 61 FR 4729 (February 7, 1996). Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. For proposed regulatory actions likely to result in a rule that may cause expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish estimates of the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) UMRA also requires Federal agencies to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate.'' In addition, UMRA requires an agency plan for giving notice and opportunity for timely input to small governments that may be affected before establishing a requirement that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. (This policy is also available at *http://www.gc.doe.gov*). Today's proposed rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

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

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights,'' 53 FR 8859 (March 18, 1988), that this regulation would not result in any takings which might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed today's notice under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

DOE has concluded that today's regulatory action, which would delete requirements to provide a credit rating or other credit assessment as part of an application for financial assistance or an application to enter into a conditional agreement to provide standby support for certain nuclear plant delays, is not a significant energy action because the proposed standards are not likely to have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects for the proposed rule.

L. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the bulletin is to enhance the quality and credibility of the Government's scientific information. DOE has determined that today's proposed rule does not contain any influential or highly influential scientific information that would be subject to the peer review requirements of the OMB Bulletin.

Approval of the Office of the Secretary

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

List of Subjects

10 CFR Part 609

Administrative practice and procedure, Energy, Loan programs, Reporting and recordkeeping requirements.

10 CFR Part 950

Government contracts, Nuclear safety.

Issued in Washington, DC, on October 25, 2011.

David Frantz,

Director of the Origination Division of the Loan Programs Office.

John Kelly,

Deputy Assistant Secretary for Nuclear Reactor Technologies.

For the reasons stated in the preamble, DOE proposes to amend Part 609 of Chapter II and Part 950 of Chapter III of Title 10, Code of Federal Regulations, to read as set forth below:

PART 609—LOAN GUARANTEES FOR PROJECTS THAT EMPLOY INNOVATIVE TECHNOLOGIES

1. The authority citation for part 609 continues to read as follows:

Authority: 42 U.S.C. 7254, 16511–16514.

§ 609.6 [Amended]

2. Section 609.6 is amended by:

a. Removing paragraphs (b)(21);

b. Redesignating paragraphs (b)(22) through (b)(29) as (b)(21) through (b)(28).

3. In § 609.8 revise paragraph (a) to read as follows:

§ 609.8 Term sheets and conditional commitments.

(a) DOE, after review and evaluation of the Application, additional information requested and received by DOE, and information obtained as the result of meeting with the Applicant and the Eligible Lender or other Holder, may offer to an Applicant and the Eligible Lender or other Holder detailed terms and conditions that must be met, including terms and conditions that must be met by the Applicant and the Eligible Lender or other Holder.

* * * * *

§ 609.9 [Amended]

4. Section 609.9 is amended by:

a. Removing paragraph (f);

b. Redesignating paragraph (g) as paragraph (f).

PART 950—STANDBY SUPPORT FOR CERTAIN NUCLEAR PLANT DELAYS

5. The authority citation for Part 950 continues to read as follows:

Authority: 42 U.S.C. 2201, 42 U.S.C. 7101 *et seq.,* and 42 U.S.C. 16014.

6. Section 950.10 is amended by revising paragraph (b)(3) to read as follows:

§ 950.10 Conditional agreement.

* * * * *

(b) * * *

(3) A detailed business plan that includes intended financing for the project including the credit structure and all sources and uses of funds for the project, and the projected cash flows for all debt obligations of the advanced nuclear facility which would be covered under the Standby Support Contract;

* * * * *

[FR Doc. 2011–28242 Filed 11–1–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1167; Directorate Identifier 2011–NM–058–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A319 and A320 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the

products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

> One operator has reported a torn out aspirator following scheduled (for on-ground testing purposes) deployment of the Left Hand (LH) OWS [off-wing escape slide].
>
> Investigations have revealed that the aspirator of the off-wing ramp/slide system interferes with the extrusion lip of the OWS enclosure during the initial stage of the deployment sequence.
>
> This condition, if not corrected, could result in both LH and Right Hand (RH) off-wing exits being unserviceable which, during an emergency, would impair the safe evacuation of occupants, possibly resulting in personal injuries.

* * * * *

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by December 19, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, 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.

For service information identified in this proposed AD, contact Airbus, Airworthiness Office—EAS, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; *telephone* +33 5 61 93 36 96; fax +33 5 61 93 44 51; *email account.airworth-eas@airbus.com; Internet http://www.airbus.com.*You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call (425) 227–1221.

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 regulatory 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 FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1405; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1167; Directorate Identifier 2011–NM–058–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2010–0210, dated October 21, 2010; corrected October 27, 2010 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> One operator has reported a torn out aspirator following scheduled (for on-ground testing purposes) deployment of the Left Hand (LH) OWS [off-wing escape slide].
>
> Investigations have revealed that the aspirator of the off-wing ramp/slide system interferes with the extrusion lip of the OWS enclosure during the initial stage of the deployment sequence.
>
> This condition, if not corrected, could result in both LH and Right Hand (RH) off-wing exits being unserviceable which, during an emergency, would impair the safe evacuation of occupants, possibly resulting in personal injuries.
>
> For the reasons described above, this [EASA] AD requires the modification of the OWS enclosures on both sides.

* * * * *

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Airbus has issued Service Bulletin A320–25–1649, dated February 16, 2010. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 694 products of U.S. registry. We also estimate that it would take about 14 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $0 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $825,860, or $1,190 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. 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 a regulatory 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 AD:

Airbus: Docket No. FAA–2011–1167; Directorate Identifier 2011–NM–058–AD.

Comments Due Date

(a) We must receive comments by December 19, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; and Model A320–111, –211, –212, –214, –231, –232, and –233 airplanes; certificated in any category; all manufacturer serial numbers; except for airplanes delivered with Airbus Modification 30088 on which off-wing escape slides (OWS) having part numbers (P/N) D31865–111 and P/N D31865–112 are installed.

Subject

(d) Air Transport Association (ATA) of America Code 25: Equipment/Furnishings.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

One operator has reported a torn out aspirator following scheduled (for on-ground testing purposes) deployment of the Left Hand (LH) OWS [off-wing escape slide].

Investigations have revealed that the aspirator of the off-wing ramp/slide system interferes with the extrusion lip of the OWS enclosure during the initial stage of the deployment sequence.

This condition, if not corrected, could result in both LH and Right Hand (RH) off-wing exits being unserviceable which, during an emergency, would impair the safe evacuation of occupants, possibly resulting in personal injuries.

* * * * *

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Actions

(g) Within 36 months after the effective date of this AD, modify both left-hand and right-hand OWS enclosures, in accordance with the instructions in Airbus Service Bulletin A320–25–1649, dated February 16, 2010.

Parts Installation

(h) As of the effective date of this AD, no person may install an OWS having P/N D31865–109, P/N D31865–110, P/N D31865–209, or P/N D31865–210 on any airplane.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows:

(1) The MCAI specifies that certain parts may not be installed after doing the modification. However, this AD specifies that those parts may not be installed as of the effective date of this AD.

(2) The applicability of the MCAI is limited to manufacturer serial numbers (MSN) equipped with Air Cruisers/Aerazur P/N D31865–109; P/N D31865–110; P/N D31865–209; or P/N D31865–210 OWS; however, this AD is applicable to all MSNs with the exception of airplanes delivered with Airbus Modification 30088 on which OWS having P/Ns D31865–111 and P/N D31865–112 are installed.

(3) Although the applicability of the MCAI includes Model A318 series airplanes, the airplane models identified in the effectivity of Airbus Service Bulletin A320–25–1649, dated February 16, 2010, are limited to Model A319 and Model A320 series airplanes. Therefore, the applicability of this AD does not include Model A318 series airplanes.

Other FAA AD Provisions

(i) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Sanjay Ralhan, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; *telephone* (425) 227–1405; *fax* (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(j) Refer to MCAI EASA Airworthiness Directive 2010–0210, dated October 21, 2010, corrected October 27, 2010; and Airbus Service Bulletin A320–25–1649, dated February 16, 2010; for related information.

Issued in Renton, Washington, on October 21, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–28368 Filed 11–1–11; 8:45 a.m.]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1188; Directorate Identifier 2008–SW–46–AD]

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron, Inc. (Bell) Model 204B, 205A, 205A–1, 205B, and 212 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes superseding four existing airworthiness directives (ADs) for the specified Bell model helicopters. Two of the existing ADs require an initial and repetitive inspection of certain part-numbered main rotor yokes installed on Bell Model 204B, 205A–1, and 212 helicopters. Two other existing ADs also establish a retirement life of 3,600 hours time-in-service (TIS) for certain part-numbered main rotor yokes installed on the Bell Model 204, 205 series, and 212 series helicopters. Those ADs were prompted by reports of cracks in the main rotor yoke (yoke). This action would retain the requirements of the existing ADs and would apply these inspections and retirement lives to additional part-numbered yokes. This action would also increase the inspection frequency for certain yokes installed on a Bell Model 205B or 212 helicopter and would require replacing any unairworthy yoke. This proposal is prompted by the need to expand the applicability to include yokes produced under a Parts Manufacturing Approval (PMA) whose design approval was based on identicality with the affected Bell yoke parts and a recent discovery of a cracked yoke. The actions specified by the proposed AD are intended to prevent cracking of a yoke, failure of the yoke, and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before January 3, 2012.

ADDRESSES: Use one of the following addresses to submit comments on this proposed AD:

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

You may get the service information identified in this proposed AD from Bell Helicopter Textron, Inc., P.O. Box 482, Fort Worth, TX 76101, telephone (817) 280–3391, fax (817) 280–6466, or at *http://www.bellcustomer.com/files/*.

FOR FURTHER INFORMATION CONTACT: Michael Kohner, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Certification Office, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5170, fax (817) 222–5783.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to submit any written data, views, or arguments regarding this proposed AD. Send your comments to the address listed under the caption **ADDRESSES**. Include the docket number ''FAA–2011–1188, Directorate Identifier 2008–SW–46–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed rulemaking. Using the search function of our docket web site, you can find and read the comments to any of our dockets, including the name of the individual who sent or signed the comment. You may review the DOTs complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Examining the Docket

You may examine the docket that contains the proposed AD, any comments, and other information 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 Docket Operations office (telephone (800) 647–5527) is located in Room W12–140 on the ground floor of the West Building at the street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

Discussion

On September 13, 1979, we issued AD 79–20–05, Docket No. 79–ASW–25, Amendment 39–3572 (44 FR 55556, September 27, 1979) for Bell Model 204B, 205A–1, and 212 helicopters. That AD requires an initial and repetitive inspection at 2,400-hour intervals and corrosion protection and sealing of the yoke, P/N 204–011–102, of the main rotor hub assembly (hub), P/N 204–012–101. We issued Amendment 39–3626, November 21, 1979 (44 FR 70123, December 6, 1979) and Amendment 39–3662 January 3, 1980 (45 FR 6922, January 31, 1980) to AD 79–20–05. The amendments to the AD deleted references to the radius in the bottom of the pillow block bushing holes because the cracks did not initiate there. The cracks originated in the side of the hole near the top or through the center section of the yoke adjacent to the data plate.

On August 26, 1981, we issued AD 81–19–01, Amendment 39–4207, Docket 81–ASW–38 (46 FR 45595, September 14, 1981) for Bell Model 212 series helicopters. We also issued AD 81–19–02, Amendment 39–4208, Docket 81–ASW–40 (46 FR 45595, September 14, 1981) for Bell Model 204 and 205 series helicopters. These ADs established a retirement life of 3,600 hours TIS for certain yokes installed on these model helicopters. These yokes previously did not have a retirement life. AD 81–19–01 also reduced the yoke retirement life below 3,600 hours TIS for those yokes installed on Model 212 helicopters used in external load operations involving more than four lifts per hour by requiring the operators to log additional hours for these type operations against the retirement life of the yoke. These ADs were prompted by three field reports of cracked yokes. These ADs were intended to establish retirement lives to prevent yoke failure and subsequent loss of control of the helicopter.

On March 4, 1993, we issued AD 93–05–01, Amendment 39–8507, Docket No. 92–ASW–13 (58 FR 13700, March 15, 1993), for the Bell Model 212 helicopters to require repetitive inspections of yoke, P/N 204–011–102

(all dash numbers). That action was prompted by 12 reports of cracking at the pillow block holes on yokes installed on Model 212 helicopters. That AD was intended to detect corrosion pitting and a crack in the pillow block bolt bushing holes of the yoke and to prevent failure of the main rotor system and subsequent loss of control of the helicopter.

After issuing ADs 79–20–05, 81–19–01, and 81–19–02, Bell has introduced a replacement stainless steel yoke, P/N 212–011–102. Bell issued Alert Service Bulletins (ASBs) Nos. 204–92–36, 205–92–51, and 212–92–80, all dated October 23, 1992. The ASBs specify replacing the yoke, P/N 204–011–102 (all dash numbers), by December 31, 1993. These ASBs also specify replacing the yoke with yoke, P/N 212–011–102–105 or –109, depending on the helicopter configuration. The replacement stainless steel yokes have improved design characteristics addressing the corrosion problems and are not subject to any heavy lift cycle counting required for previous yokes installed on the Model 205B and 212 helicopters.

The FAA also issued PMAs to Air Services International (ASI) for yokes, P/N ASI–4011–102, and to Arizona Aeroparts International (AAI) for yokes, P/N AAI–4011–102, both based on identicality with the Bell-manufactured yoke, P/N 204–011–102. The yokes manufactured under the PMAs are eligible for installation on Bell Model 204B, 205A, 205A–1, and 212 helicopters.

Transport Canada recently contacted the FAA about a PMA yoke, P/N AAI–4011–102–125, manufactured by AAI. A Canadian operator reported this part was no longer supported by the PMA-manufacturer. The Canadian operator was trying to determine if the inspections in the existing ADs applicable to the Bell yoke, P/N 204–011–102, needed to be performed on the PMA-manufactured yokes as well. Both of these PMA companies have gone out of business. There is no longer an FAA-approved PMA holder for these PMA yokes. This results in no continued operational safety oversight of the PMA parts by the manufacturer that produced the parts that were sold to operators. Because the PMA yokes are identical to the Bell parts, these yokes are susceptible to the same cracking conditions found in the same Bell part-numbered yokes.

This AD action proposes to give operators credit for the accumulated operating time on yokes, P/N 204–011–102 (all dash numbers), previously determined and recorded by following ADs 81–19–01 or 81–19–02; or the applicable Bell Model 204B, 205A–1, 205B, or 212 maintenance manuals, which results in equal or higher accumulated factored hours TIS. However, these values must be included for previously accumulated service time in the calculations of the accumulated total factored hours TIS. Any additional factored hours TIS would be determined for each yoke using the hours TIS factors in the proposed AD.

This proposal is prompted by the need to expand the applicability to include yokes produced under a PMA whose design approval was based on identicality with the affected Bell yoke parts and also a recent discovery of a cracked yoke on a Bell Model 212 helicopter.

The previously described unsafe condition is likely to exist or develop on other helicopters of these same type designs. We estimate 25 to 30 of the yokes manufactured under a PMA may still be installed on helicopters operating in the U.S. Therefore, the proposed AD would supersede the previously issued ADs and would require:

- For helicopters with yoke, *P/N AAI–4011–102 (all dash numbers) and ASI–4011–102 (all dash numbers),* installed, within 100 hours TIS, unless accomplished previously, creating a component history card or equivalent record for each yoke; determining the model for each helicopter on which the yoke has been installed from the time the yoke had zero hours TIS; calculating the factored hours TIS for each type of operation and rate of external load lifts and takeoffs for each hour TIS accumulated on each yoke; and recording the accumulated total factored hours TIS on the component history card or equivalent record for each yoke. Continuing to factor the hours TIS for each yoke and recording the additional factored hours TIS on the component history card or equivalent record. Tracking these factored hours TIS is only for the purpose of establishing a retirement life and not to be counted against the hours TIS used to track inspection intervals.
- For helicopters with yoke, *P/N 204–011–102 (all dash numbers),* installed, before further flight, unless accomplished previously:
  - ○ Calculating the total factored hours TIS on the yoke for hours TIS accumulated *before* the effective date of this AD using the same requirements as ADs 81–19–01 and 81–19–02, which establishes the starting point for the new factoring of hours TIS contained in this AD.
  - ○ Calculating and recording the factored hours TIS on the yoke for hours TIS accumulated *after* the effective date of this AD using the same requirements as used for calculating the total factored hours TIS in this AD for yokes, P/N AAI–4011–102 (all dash numbers) and ASI–4011–102 (all dash numbers).
- Revising the Airworthiness Limitations section of the applicable maintenance manuals or the Instructions for Continued Airworthiness (ICAs) by establishing or continuing a retirement life of 3,600 Total Factored Hours TIS for each yoke.
- Recording a life limit of 3,600 Total Factored Hours TIS for each yoke on the component history card or equivalent record.
- Within 100 hours TIS or 600 hours TIS since the last magnetic particle inspection (MPI) of the yoke, whichever occurs later, and thereafter at intervals not to exceed 600 hours TIS, for any yoke installed on any Model 205B or 212 helicopter:
  - ○ Removing the yoke from the hub. Using a 5-power or higher magnifying glass, visually inspecting each pillow block bushing hole, spindle radius, and center section web for any corrosion or mechanical damage.
  - ○ Performing an MPI of each yoke for a crack.
- Within 100 hours TIS or 2,400 hours TIS since the last MPI of the yoke, whichever occurs later, and thereafter at intervals not to exceed 2,400 hours TIS, for any yoke installed on any Model 204B, 205A, or 205A–1 helicopter:
  - ○ Removing the yoke from the hub. Using a 5-power or higher magnifying glass, visually inspect each pillow block bushing hole, spindle radius, and center section web for any corrosion or mechanical damage.
  - ○ Performing an MPI of each yoke for a crack.
- Before further flight, replacing each yoke with an airworthy yoke if:
  - ○ The yoke has 3,600 or more Total Factored Hours TIS;
  - ○ The Total Factored Hours TIS for the yoke is unknown and cannot be determined;
  - ○ The yoke has any corrosion or mechanical damage that exceeds any of the maximum repair damage limits; or
  - ○ The yoke has a crack.

We estimate that this proposed AD would affect about 15 helicopters of U.S. registry and would take about:

- 3 work hours to review the helicopter records and determine the total factored hours TIS (the cost of tracking the total factored flight hours will be negligible),
- 35 work hours to remove the yoke from the helicopter and do a visual inspection and MPI, and

• 32 work hours to replace a yoke, at an average labor rate of $85 per work hour per helicopter.

• Required parts would cost about $40,157 per helicopter.

Based on these figures, we estimate the total cost of the proposed AD on U.S. operators to be $48,450, assuming 15 helicopters have a yoke installed requiring a review of the helicopter records and to determine the hours TIS with one visual inspection and MPI, and no yoke needs to be replaced. If we assume all the yokes in the fleet are replaced, the total cost would be about $643,155.

Regulatory Findings

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

For the reasons discussed above, I certify that the 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); and

3. 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 a draft economic evaluation of the estimated costs to comply with this proposed AD. See the AD docket to examine the draft economic evaluation.

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.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. Section 39.13 is amended by removing Amendments 39–8507 (58 FR 13700, March 15, 1993); 39–4208 (46 FR 45595, September 14, 1981); 39–4207 (46 FR 45595, September 14, 1981); 39–3662 (45 FR 6922, January 31, 1980); 39–3626 (44 FR 70123, December 6, 1979); and 39–3572 (44 FR 55556, September 27, 1979); and by adding a new airworthiness directive (AD) to read as follows:

Bell Helicopter Textron, Inc (Bell): Docket No. FAA–2011–1188; Directorate Identifier 2008–SW–46–AD. Supersedes AD 93–05–01, Amendment 39–8507, Docket No. 92–ASW–13; AD 81–19–02, Amendment 39–4208, Docket No. 81–ASW–40; AD 81–19–01, Amendment 39-4207, Docket No. 81–ASW–38; and AD 79–20–05, Amendments 39–3662, 39–3626, and 39–3572, Docket No. 79–ASW–25.

Applicability: Model 204B, 205A, 205A–1, 205B, and 212 helicopters, with a main rotor yoke (yoke), part number (P/N) AAI–4011–102 (all dash numbers), ASI–4011–102 (all dash numbers), or 204–011–102 (all dash numbers), installed, certificated in any category.

Compliance: Required as indicated.

To prevent cracking of a yoke, failure of a yoke, and subsequent loss of control of the helicopter, do the following:

(a) For helicopters with yoke, *P/N AAI–4011–102 (all dash numbers) and ASI–4011–102 (all dash numbers),* installed, within 100 hours time-in-service (TIS), unless accomplished previously:

(1) Create a component history card or equivalent record for each yoke.

(2) Determine the model for each helicopter on which the yoke has been installed from the time the yoke had zero hours TIS.

(3) In accordance with the rate per hour categories shown in Table 1 of this AD, categorize the accumulated ''Unfactored Hours TIS'' on each yoke by determining the types of operation AND the rate per hour of external load lifts and takeoffs for each hour TIS accumulated on each yoke. One external load lift occurs each time the helicopter picks up an external load and drops it off. For determining the proper rate per hour category for external load operations, any external load lift in which the helicopter achieves a vertical altitude difference of greater than 200 feet indicated altitude between the pickup and drop-off point counts as two external load lifts.

TABLE 1—FACTORED HOURS TIS FOR A YOKE

Helicopter model	Types of operation	Rate per hour of external load lifts and takeoffs	Unfactored hours TIS	Hours TIS factor	Factored hours TIS on yoke (unfactored hours TIS × hours TIS factor)
Yokes installed on any Model 204B, 205A, or 205A–1 helicopter.	All Operations	All	120	1	120
Yokes installed on any Model 205B or 212 helicopter.	External Load Operations [1].	1 to 5	105	1	105
		5.1 to 8		1.5	
		8.1 to 12		2	
		12.1 to 18		3	
		18.1 to 32	170	5	850
		32.1 to 48		7	
		48.1 or above		9	
		Unknown	50	7	350

TABLE 1—FACTORED HOURS TIS FOR A YOKE—Continued

Helicopter model	Types of operation	Rate per hour of external load lifts and takeoffs	Unfactored hours TIS	Hours TIS factor	Factored hours TIS on yoke (unfactored hours TIS × hours TIS factor)
	Internal Load Operations.	All Takeoffs	2,025	1	2,025
Total Factored Hours TIS on Yoke (Summation of the Factored Hours TIS).					3,450

[1] For the purposes of this AD, an external load operation occurs each time a helicopter picks up an external load and drops it off. Any external load lift in which the helicopter achieves a vertical altitude difference of greater than 200 feet indicated attitude between the pick-up and drop-off point counts as two external load lifts in determining the proper rate per hour category.

Note 1: The number of unfactored hours TIS and factored hours TIS contained in Table 1 of this AD are examples and presented for illustration purposes only.

(4) By reference to Table 1 of this AD, enter the ''Unfactored Hours TIS'' for each category as determined by paragraph (a)(3) of this AD. Calculate the ''Factored Hours TIS'' by multiplying the ''Unfactored Hours TIS'' by the ''Hours TIS Factor.'' Determine the accumulated ''Total Factored Hours TIS'' on each yoke by adding the factored hours TIS for each type of operation and helicopter model. Tracking the Total Factored Hours TIS is only for establishing a retirement life and not for tracking inspection intervals.

(5) Record the accumulated Total Factored Hours TIS on the component history card or equivalent record for each yoke.

(6) Continue to factor the hours TIS for each yoke by following paragraph (a)(2) through (a)(4) of this AD, and record the additional factored hours TIS on the component history card or equivalent record.

(b) For helicopters with yoke, *P/N 204–011–102 (all dash numbers),* installed, before further flight, unless accomplished previously:

(1) For hours TIS accumulated *before* the effective date of this AD, calculate and record the Total Factored Hours TIS as follows:

(i) For the Model 212 helicopters, 1 hour TIS in which passenger or internal cargo was carried equals 1 factored hour TIS; 1 hour TIS where more than 4 external load lifts occurred equals 5 factored hours TIS.

(ii) For the Model 204 and 205 series helicopters, 1 hour TIS equals 1 factored hour TIS.

Note 2: Paragraph (b)(1) gives credit to the operators for compliance with ADs 81–19–01 and 81–19–02 in establishing the starting point for the new factoring of hours TIS contained in this AD.

Note 3: The accumulated Total Factored Hours TIS for yoke, P/N 204–011–102 (all dash numbers), calculated in accordance with the applicable Bell Model 204B, 205A–1, 205B, or 212 maintenance manuals, which results in an equal or higher accumulated Total Factored Hours TIS is an acceptable alternative to meeting the factoring requirements of AD 81–19–01 (contained in Bell ASB 212–81–23, dated June 22, 1981, for the Model 212 helicopters) and AD 81–19–02 (contained in Bell ASBs 204–81–11 and 205–81–16, both dated June 22, 1981, for the Model 204 and 205 series helicopters).

(2) For hours TIS accumulated after the effective date of this AD, calculate and record the factored hours TIS on the yoke in accordance with the requirements of paragraphs (a)(1) thorough (a)(6) of this AD.

(c) Revise the Airworthiness Limitations section of the applicable maintenance manuals or the Instructions for Continued Airworthiness (ICAs) by establishing a new retirement life of 3,600 Total Factored Hours TIS for each yoke, P/N AAI–4011–102 (all dash numbers), ASI–4011–102 (all dash numbers), or 204–011–102 (all dash numbers), by making pen and ink changes or inserting a copy of this AD into the Airworthiness Limitations section of the maintenance manual or ICAs.

(d) Unless accomplished previously, record a life limit of 3,600 Total Factored Hours TIS for each yoke, P/N AAI–4011–102 (all dash numbers), ASI–4011–102 (all dash numbers), or 204–011–102 (all dash numbers), on the component history card or equivalent record.

(e) Within 100 hours TIS or 600 hours TIS since the last magnetic particle inspection (MPI) of the yoke, whichever occurs later, and thereafter at intervals not to exceed 600 hours TIS, for any yoke installed on any Model 205B or 212 helicopter:

(1) Remove the yoke from the main rotor hub assembly (hub). Using a 5-power or higher magnifying glass, visually inspect each pillow block bushing hole, spindle radius, and center section web for any corrosion or mechanical damage.

(2) Perform an MPI of each yoke for a crack.

Note 4: MPI procedures are contained in Bell Standard Practices Manual BHT–ALL–SPM.

(f) Within 100 hours TIS or 2,400 hours TIS since the last MPI of the yoke, whichever occurs later, and thereafter at intervals not to exceed 2,400 hours TIS, for any yoke installed on any Model 204B, 205A, or 205A–1 helicopter:

(1) Remove the yoke from the hub. Using a 5-power or higher magnifying glass, visually inspect each pillow block bushing hole, spindle radius, and center section web for any corrosion or mechanical damage.

(2) Perform an MPI of each yoke for a crack.

(g) Before further flight, replace each yoke with an airworthy yoke if:

(1) The yoke has 3,600 or more Total Factored Hours TIS; or

(2) The Total Factored Hours TIS for the yoke is unknown and cannot be determined; or

(3) The yoke has any corrosion or mechanical damage that exceeds any of the maximum repair damage limits; or

Note 5: The applicable Bell Component and Repair Overhaul Manual contains the maximum repair damage limitations.

(4) The yoke has a crack.

(h) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Rotorcraft Certification Office, FAA, ATTN: Michael Kohner, Aviation Safety Engineer, Rotorcraft Directorate, 2601 Meacham Blvd., Fort Worth, Texas 76137, telephone (817) 222–5170, fax (817) 222–5783, for information about previously approved alternative methods of compliance.

(i) Special flight permits may only be issued under 14 CFR 21.197 and 21.199 for the purpose of operating the helicopter to a location where the MPI requirements of paragraphs (e) or (f) of this AD can be performed.

(j) The Joint Aircraft System Component (JASC) Code is 6220: Main Rotor Head Issued in Fort Worth, Texas, on October 21, 2011.

Lance T. Gant,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2011–28361 Filed 11–1–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1212; Directorate Identifier 2011–CE–034–AD]

RIN 2120–AA64

Airworthiness Directives; Cirrus Design Corporation Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Cirrus Design Corporation (Cirrus) Model SR22T airplanes. This proposed AD was prompted by reports of partial loss of engine power due to a dislodged rubber gasket/seal being ingested into the turbocharger. This proposed AD would require inspection and modification of the air box flange welds and slots and installation of induction system air box seals as applicable. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by December 19, 2011.

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

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

For service information identified in this proposed AD, contact Cirrus Design Corporation, 4515 Taylor Circle, Duluth, Minnesota 55811–1548, phone: (218) 788–3000; fax: (218) 788–3525; email: *fieldservice@cirrusaircraft.com;* Internet: *http://www.cirrusaircraft.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Michael Downs, Propulsion Engineer, Chicago ACO, FAA, O'Hare Lake Office Center, 2300 East Devon Ave., Des Plaines, Illinois 60018; phone: (847) 294–7870; fax: (847) 294–7834; email: *michael.downs@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1212; Directorate Identifier 2011–CE–034–AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

We received two reports of partial loss of engine power due to dislodged rubber gaskets/seals being ingested into one of the two turbochargers. The gasket/seal is located between the air-box mounting base and the turbochargers. Once the gasket/seal is ingested into a turbocharger the engine will experience a partial loss of power as the turbocharger fails to perform its function. A complete loss of power could occur if metal debris from the failing turbocharger migrates into the engine oil system and damages other engine components. Examination by Cirrus of other Cirrus Model SR22T airplanes showed early evidence of the gasket/seal starting to dislodge on at least one other airplane.

This condition, if not corrected, could result in engine failure.

Relevant Service Information

We reviewed Cirrus Design Corporation SR22T Service Bulletin SB 2X–71–17 R1, dated September 30, 2011. The service information describes procedures for replacement of the air box seals.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require inspection and modification of the air box flange welds and slots and installation of air box seals and adhesive with materials better suited for the high-temperature environment encountered in close proximity to the turbocharger.

Costs of Compliance

We estimate that this proposed AD affects 67 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement of the induction system air box seals and extension of air box flange slots.	2.5 work-hours × $85 per hour = $212.50.	$139	$351.50	$23,550.50

According to the manufacturer, all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701:

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

Regulatory Findings

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Cirrus Design Corporation: Docket No. FAA–2011–1212; Directorate Identifier 2011–CE–034–AD.

(a) Comments Due Date

We must receive comments by December 19, 2011.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following model and serial number airplanes, certificated in any category:

(1) *Group 1 Airplanes:* Cirrus Design Corporation Model SR22T airplanes, serial numbers 0001 through 0169, except 0004, 0019, 0027, 0047, 0097, 0126, 0127, 0135, 0138, 0139, 0144, 0154, 0155, 0157, 0158, 0159, 0160, 0161, and 0163.

(2) *Group 2 Airplanes:* Cirrus Design Corporation Model SR22T airplanes, serial numbers 0004, 0019, 0027, 0047, 0097, 0126, 0127, 0135, 0138, 0139, 0144, 0155, 0157, 0158, 0160, and 0161. These airplanes had the reinforced silicone fiberglass seals installed at the factory but the box flange welds and slots may be incorrectly modified. Therefore, this AD still applies to these airplanes.

(d) Subject

Joint Aircraft System Component (JASC) Code 7160, Engine Air Intake.

(e) Unsafe Condition

This AD was prompted by reports of partial loss of engine power due to a dislodged rubber gasket/seal being ingested into the turbocharger. We are issuing this AD to inspect and modify the air box flange welds and slots and install induction system air box seals as applicable.

(f) Compliance

Comply with this AD following Cirrus Design Corporation SR22T Service Bulletin SB 2X–71–17 R1, dated September 30, 2011, within the compliance times specified, unless already done.

(g) Actions

(1) *Group 1 Airplanes:* Within the next 10 hours time-in-service (TIS) after the effective date of this AD, inspect the air box flange welds and slots, make modifications as necessary, and replace the induction air box seals with reinforced silicone fiberglass seals part number 29486–001.

(2) *Group 2 Airplanes:* Within the next 10 hours TIS after the effective date of this AD, inspect the air box flange welds and slots and, as necessary, make modifications.

Note: Credit will be given for actions required in paragraphs (g)(1) and (g)(2) of this AD if already done before the effective date of this AD following Cirrus Design Corporation SR22T Service Bulletin SB 2X–71–17, dated July 21, 2011.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Chicago Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(i) Related Information

(1) For more information about this AD, contact Michael Downs, Propulsion Engineer, Chicago ACO, FAA, O'Hare Lake Office Center, 2300 East Devon Ave., Des Plaines, Illinois 60018; phone: (847) 294–7870; fax: (847) 294–7834; email: *michael.downs@faa.gov.*

(2) For service information identified in this AD, contact Cirrus Design Corporation, 4515 Taylor Circle, Duluth, Minnesota 55811–1548, phone: (218) 788–3000; fax: (218) 788–3525; email: *fieldservice@cirrusaircraft.com;* Internet: *http://www.cirrusaircraft.com.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on October 27, 2011.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–28382 Filed 11–1–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–1166; Directorate Identifier 2010–NM–169–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Model Mystere-Falcon 50 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

The Maintenance Procedure (MP) 57–607, related to non destructive check of the flap tracks 2 and 5, has been introduced thru revision 4 (01/2009) of section 5–10 of the Recommended Maintenance Schedules chapter of the Aircraft Maintenance Documentation.

After the implementation of this MP cracks have been detected in service.

* * * * *

Cracking of the flap tracks could lead to flap asymmetry and loss of control of the airplane. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by December 19, 2011.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Dassault Falcon Jet, P.O. Box 2000, South Hackensack, New Jersey 07606; telephone (201) 440–6700; Internet *http://www.dassaultfalcon.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call (425) 227–1221.

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 regulatory 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 FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2011–1166; Directorate Identifier 2010–NM–169–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2010–0080, dated April 29, 2010 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

The Maintenance Procedure (MP) 57–607, related to non destructive check of the flap tracks 2 and 5, has been introduced thru revision 4 (01/2009) of section 5–10 of the Recommended Maintenance Schedules chapter of the Aircraft Maintenance Documentation.

After the implementation of this MP cracks have been detected in service.

* * * * *

Cracking of the flap tracks could lead to flap asymmetry and loss of control of the airplane. The required actions include revising the maintenance program to include Dassault Aviation, Falcon 50/50EX Maintenance Manual, Non-Destructive Check of Flap Tracks 2 and 5, 57–607, dated January 2009 (commonly referred to as Dassault Falcon 50/50EX Maintenance Procedure 57–607, Non-Destructive Check of Flap Tracks 2 and 5, of Chapter 5–40 Airworthiness Limitations, of the Dassault Falcon 50/50EX Maintenance Manual, Revision 21, dated June 2011). You may obtain further information by examining the MCAI in the AD docket.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 250 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $21,250, or $85 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. 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 a regulatory 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 AD:

Dassault Aviation: Docket No. FAA–2011–1166; Directorate Identifier 2010–NM–169–AD.

Comments Due Date

(a) We must receive comments by December 19, 2011.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Dassault Aviation Model Mystere-Falcon 50 airplanes, all serial numbers, certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 57: Wings.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

The Maintenance Procedure (MP) 57–607, related to non destructive check of the flap tracks 2 and 5, has been introduced thru revision 4 (01/2009) of section 5–10 of the Recommended Maintenance Schedules chapter of the Aircraft Maintenance Documentation.

After the implementation of this MP cracks have been detected in service.

* * * * *

Cracking of the flap tracks could lead to flap asymmetry and loss of control of the airplane.

Compliance

(f) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Actions

(g) Within 30 days after the effective date of the AD, revise the maintenance program to include Dassault Aviation, Falcon 50/50EX Maintenance Manual, Non-Destructive Check of Flap Tracks 2 and 5, 57–607, dated January 2009 (commonly referred to as Dassault Falcon 50/50EX Maintenance Procedure 57–607, Non-Destructive Check of Flap Tracks 2 and 5, of Chapter 5–40 Airworthiness Limitations, of the Dassault Falcon 50/50EX Maintenance Manual, Revision 21, dated June 2011). The initial compliance time for doing the check is prior to the accumulation of 7,900 total flight cycles or within 600 flight cycles after the effective date of this AD, whichever occurs later.

No Alternative Actions or Intervals

(h) After accomplishing the revision required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

FAA AD Differences

Note 1: This AD differs from the MCAI and/or service information as follows:

No difference.

Other FAA AD Provisions

(i) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to *Attn:* Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; *phone:* (425) 227-–1137; fax: (425) 227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

Related Information

(j) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2010–0080, dated April 29, 2010; and Dassault Aviation, Falcon 50/50EX Maintenance Manual, Non-Destructive Check of Flap Tracks 2 and 5, 57–607, dated January 2009 (commonly referred to as Dassault Falcon 50/50EX Maintenance Procedure 57–607, Non-Destructive Check of Flap Tracks 2 and 5, of Chapter 5–40 Airworthiness Limitations, of the Dassault Falcon 50/50EX Maintenance Manual, Revision 21, dated June 2011); for related information.

Issued in Renton, Washington, on October 21, 2011.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2011–28362 Filed 11–1–11; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 902

[SATS No. AK–007–FOR; Docket ID OSM–2011–0017]

Alaska Regulatory Program

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

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

SUMMARY: We are announcing receipt of a proposed amendment to the Alaska regulatory program (hereinafter, the ''Alaska program'') under the Surface Mining Control and Reclamation Act of 1977 (''SMCRA'' or ''the Act''). Alaska intends to revise its rules to be consistent with the corresponding Federal regulations and to conform to the drafting manual for the State of Alaska.

This document gives the times and locations that the Alaska program and proposed amendment to that program are available for your inspection, the comment period during which you may

submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., m.d.t. December 2, 2011. If requested, we will hold a public hearing on the amendment on November 28, 2011. We will accept requests to speak until 4 p.m., m.d.t. on November 17, 2011.

ADDRESSES: You may submit comments by either of the following two methods:

- *Federal eRulemaking Portal: www.regulations.gov.* This proposed rule has been assigned Docket ID: OSM–2011–0017. If you would like to submit comments through the Federal eRulemaking Portal, go to *www.regulations.gov* and follow the instructions.
- *Mail/Hand Delivery/Courier:* Kenneth Walker, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, Colorado 80201–3050.

For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''III. Public Comment Procedures'' in the **SUPPLEMENTARY INFORMATION** section of this document.

In addition to viewing the docket and obtaining copies of documents at *www.regulations.gov,* you may review copies of the Alaska program, this amendment, a listing of any public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may also receive one free copy of the amendment by contacting OSM's Denver Office.

Kenneth Walker, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, Colorado, (303) 293–5012, *kwalker@osmre.gov.*

Russell Kirkham, Manager, Alaska Coal Regulatory Program, Division of Mining, Land and Water, Department of Natural Resources, 550 West 17th Avenue, Suite 920, Anchorage, Alaska 99501–3650, (907) 269–8650, *russell.kirkham@alaska.gov.*

FOR FURTHER INFORMATION CONTACT: Kenneth Walker, Telephone: (303) 293–5012. Internet: *kwalker@osmre.gov.*

SUPPLEMENTARY INFORMATION:

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

I. Background on the Alaska Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Alaska program on March 23, 1983. You can find background information on the Alaska program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Alaska program in the March 23, 1983, **Federal Register** (48 FR 12274). You can also find later actions concerning Alaska's program and program amendments at 30 CFR 902.15 and 902.16.

II. Description of the Proposed Amendment

By letter dated September 8, 2011, Alaska sent us a proposed amendment to its program (Administrative Record Document ID No. OSM–2011–0017 under SMCRA (30 U.S.C. 1201 *et seq.*). Alaska sent the amendment to include changes made at its own initiative and in response to the required program amendment at 30 CFR 902.16(a)(14). The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

The provisions of the Alaska program that Alaska proposes to revise are: 11 Alaska Annotated Code (AAC) 90.043(b), concerning water quality analyses; 11 AAC 90.045(a), (b), (c), and (d), concerning description of geology; 11 AAC 90.057(a), (b), and (c), concerning fish and wildlife information; 11 AAC 90.085(a) and (e), concerning a plan for protection of hydrologic balance; 11 AAC 90.089(a)(1), concerning construction plans for ponds, impoundments, dams, and embankments; 11 AAC 90.101(a) through (f), concerning a subsidence control plan and the definition of material damage; 11 AAC 90.173(b), concerning eligibility for assistance under the small operator assistance program; 11 AAC 90.179(a) and (b), concerning data collection that would be covered by the small operator assistance program; 11 AAC 90.185(a), concerning applicant liability under the small operator assistance program; 11 AAC 90.201(d), concerning the requirement to file a reclamation bond; 11 AAC 90.211(a), concerning bond release procedures and criteria; 11 AAC 90.321(d), (e), and (f), concerning replacement of water supplies affected by underground mining activities; 11 AAC 90.323(a), concerning water quality standards; 11 AAC 90.323(b), concerning sediment control measures; 11 AAC 90.325(b) and (c) and 11 AAC 90.327(b), concerning stream channel diversions; 11 AAC 90.331(d), concerning sedimentation ponds; 11 AAC 90.331(e), concerning removal of siltation structures; 11 AAC 90.331(h), concerning the design of other treatment facilities; 11 AAC 90.336(a), (b), (f), and (g), concerning impoundment design and construction; 11 AAC 90.337(a), concerning impoundment inspection; 11 AAC 90.345(e), concerning requirements for surface water monitoring; 11 AAC 90.349, concerning discharges of water or coal mine waste into an underground mine working; 11 AAC 90.375(f) and (g), concerning public notice of blasting; 11 AAC 90.391(n) and (t), concerning disposal of excess spoil or coal mine waste; 11 AAC 90.395(a), concerning general requirements for coal mine waste; 11 AAC 90.397(a), concerning inspections of disposal areas for excess spoil, underground development waste or coal processing waste; 11 AAC 90.401(a), (b), (d), (e), and (f), concerning construction plans for coal mine waste refuse piles; 11 AAC 90.407(c) and (f), concerning coal mine waste dams or embankments; 11 AAC 90.423(h), concerning protection of fish and wildlife; 11 AAC 90.443(a), (k), (l), and (m), concerning requirements for backfilling and grading; 11 AAC 90.444(a) and (b), concerning requirements for backfilling and grading where there is thick or thin overburden; 11 AAC 90.447(c), concerning requirements for auger mining; 11 AAC 90.457(c), concerning standards for revegetation success on areas to be developed for fish and wildlife habitat, recreation, undeveloped land, or forest products; 11 AAC 90.461(b), (g), (h), (i), (j), (k), and (l), concerning subsidence control; 11 AAC 90.491(f), concerning the requirements for construction and maintenance of roads; 11 AAC 90.601(h), (i) and (j), concerning inspections of abandoned sites; 11 AAC 90.629(a), concerning procedures for assessment conference; 11 AAC 90.631(a), concerning violations and requests for a public hearing; 11 AAC 90.635(a) and (b), concerning when an

individual civil penalty may be assessed; 11 AAC 90.637(a) and (b), concerning the amount of individual civil penalty; 11 AAC 90.639(a), (b), and (c), concerning procedures for assessment of an individual civil penalty; 11 AAC 90.641(a), (b), (c), and (d), concerning payments of an individual civil penalty; 11 AAC 90.652 through 11 AAC 90.669, concerning requirements for incidental mining of coal; 11 AAC 90.701(a), (b), and (c), concerning the filing of a petition to designate lands as unsuitable for surface coal mining operations; 11 AAC 90.901(a), concerning the applicability of Alaska's rules to all coal exploration and surface coal mining and reclamation operations; 11 AAC 90.911(125), concerning the definition of ''community or institutional building;'' 11 AAC 90.911(126), concerning the definition of ''cumulative impact area;'' 11 AAC 90.911(128), concerning the definition of ''other minerals;'' 11 AAC 90.911(129), concerning the definition of ''other treatment facility;'' 11 AAC 90.911(130), concerning the definition of ''precipitation event;'' 11 AAC 90.911(133), concerning the definition of ''registered professional engineer;'' 11 AAC 90.911(134), concerning the definition of ''registered professional land surveyor;'' and 11 AAC 90.911(135), concerning the definition of ''siltation structure.''

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Alaska program.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final regulations will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed above (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available in the electronic docket for this rulemaking at *www.regulations.gov*. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., m.d.t. on November 17, 2011. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT.** We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold the hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at a public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public; if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSM for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 902

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 14, 2011.

Allen D. Klein,

Director, Western Region.

[FR Doc. 2011–28436 Filed 11–1–11; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

[SATS No. WV–118–FOR; Docket ID OSM–2011–0009]

West Virginia Regulatory Program

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

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

SUMMARY: We are announcing receipt of a proposed amendment to the West Virginia permanent regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). On May 2, 2011, the West Virginia Department of Environmental Protection (WVDEP) submitted a program amendment to OSM that includes both statutory and regulatory revisions. That portion of the amendment dealing with changes to West Virginia's Surface Mining Reclamation Regulations is the subject of this notice.

DATES: We will accept written comments on this amendment until

4 p.m. EDT, on December 2, 2011. If requested, we will hold a public hearing on the amendment on November 28, 2011. We will accept requests to speak until 4 p.m. EDT, on November 17, 2011.

ADDRESSES: You may submit comments by any of the following two methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* The proposed rule has been assigned Docket ID OSM–2011–0009. If you would like to submit comments through the Federal eRulemaking Portal, go to *http://www.regulations.gov* and follow the instructions.
- *Mail/hand Delivery:* Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301.

Please include the rule identifier (WV–118–FOR) with your written comments.

Instructions: All submissions received must include the agency Docket ID (OSM–2011–0009) for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see ''IV. Public Comment Procedures'' in the **SUPPLEMENTARY INFORMATION** section of this document. You may also request to speak at a public hearing by any of the methods listed above or by contacting the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Docket: The proposed rule and any comments that are submitted may be viewed over the internet at *http://www.regulations.gov.* Look for Docket ID OSM–2011–0009. In addition, you may review copies of the West Virginia program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may also receive one free copy of this amendment by contacting OSM's Charleston Field Office listed below.

Mr. Roger W. Calhoun, Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street, East, Charleston, West Virginia 25301, Telephone: (304) 347–7158, *Email: chfo@osmre.gov.*

West Virginia Department of Environmental Protection, 601 57th Street, SE., Charleston, West Virginia 25304, *Telephone:* (304) 926–0490.

In addition, you may review a copy of the amendment during regular business hours at the following locations:

Morgantown Area Office, Office of Surface Mining Reclamation and Enforcement, 604 Cheat Road, Suite 150, Morgantown, West Virginia 26508, *Telephone:* (304) 291–4004. (By Appointment Only).

Beckley Area Office, Office of Surface Mining Reclamation and Enforcement, 313 Harper Park Drive, Suite 3, Beckley, West Virginia 25801, *Telephone:* (304) 255–5265.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Charleston Field Office, Telephone: (304) 347–7158. *Email: chfo@osmre.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the West Virginia Program
II. Description of the Amendment
III. Description of West Virginia's Proposed Action
IV. Public Comment Procedures
V. Procedural Determinations

I. Background on the West Virginia Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, ''* * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the West Virginia program on January 21, 1981. You can find background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the West Virginia program in the January 21, 1981, **Federal Register** (46 FR 5915). You can also find later actions concerning West Virginia's program and program amendments at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Description and Submission of the Amendment

By letter dated April 25, 2011, and received by OSM on May 2, 2011 (Administrative Record Number WV–1561), the WVDEP submitted an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). The proposed amendment consists of both statutory and regulatory revisions. However, this notice only addresses that portion of the amendment that concerns revisions to West Virginia's Surface Mining Reclamation Regulations at Code of State Regulations (CSR) Title 38, Series 2.

Enrolled Committee Substitute for Senate Bill No. 121 (SB 121) passed the West Virginia Legislature on March 18, 2011, and was signed by the Governor on March 30, 2011. SB 121 authorized WVDEP to promulgate several revisions to its Surface Mining Reclamation Regulations. SB 121 authorizes regulatory revisions which codifies an Emergency Rule filed on December 2009 which relates to trust funds and annuities; clarifies the format and information necessary for complete application submittal and clarification on the renewal process to take into account WVDEP's electronic permit filing processes; modifies the provision that an approved person must be capable and maintain the capability of submitting maps, plans and all other technical data in an electronic format proscribed by the Secretary; modifies the provision that pre-subsidence surveys shall be confidential and only used for evaluating damage relating to subsidence; clarifies that bonding for a permit in inactive status shall remain in effect for the life of the operation; and modifies the provision that the Secretary shall provide email notice of the issuance of a show cause order to members of the public who have subscribed to the Secretary's email notification service and otherwise provide notice to any person whose citizen complaint has resulted in the issuance of any violation that led to the issuance of a show cause order.

III. Description of West Virginia's Proposed Action

1. Permit Application Requirements—CSR 38–2–3.1.c.4

The State proposes adding the words ''if available'' before ''MSHA number'' to require the submission of the MSHA number by the applicant if it is available. This proposed State revision falls under the Federal provisions at 30 CFR 778.12(c) and sections 507, 508, 510, and 515 of SMCRA.

2. Permit Application Requirements—CSR 38–2–3.1.d

The State is proposing to add the language ''either in the application or in an electronic database accessible to the agency which has been updated within three months of submittal'' after the word ''List'' to indicate the kinds of ownership or control information that is to be included in the permit application. This proposed State revision falls under the Federal provisions at 30 CFR 778.12 and sections 507, 508, 510, and 515 of SMCRA.

3. Permit Application Requirements—CSR 38–2–3.1.k

The State is proposing to add the language ''either in the application or in an electronic database accessible to the agency which has been updated within three months of submittal'' after ''List'' to indicate the kinds of violation information that is to be included in the permit application. This proposed State revision falls under the Federal provisions at 30 CFR 778.12 and 778.14 and sections 507, 508, 510, and 515 of SMCRA.

4. Advertisement of Permit—CSR 38–2–3.2.a

The State is proposing to add the word ''technically'' and removing the word ''administratively'' before ''complete'' to indicate that a permit application must be technically complete, not administratively complete, to begin the advertisement. This proposed State revision falls under the Federal provisions at 30 CFR 773.6 and sections 506, 507, and 513 of SMCRA.

5. Maps for Permit—CSR 38–2–3.4.b

The State is proposing to add the language ''in a format proscribed by the Secretary and either be'' on paper 30 by 42 inches after the word ''submitted'' and ''or, if electronic, be capable of being printed on paper of this size.'' after the word ''less'' to allow for the submission of paper or electronic maps in a format prescribed by the Secretary. This proposed State revision falls under the Federal provisions at 30 CFR 779.24 and 783.24 and sections 506 and 507 of SMCRA.

6. Subsidence Control Plan—CSR 38–2–3.12.a.2.B

The State is proposing to add new language in this subsection that will provide ''All surveys'' of the condition of all non-commercial buildings or residential dwellings and structures related thereto ''shall be confidential and only used for evaluating damage relating to subsidence. The Secretary shall develop a procedure for assuring surveys shall remain confidential.'' This proposed State revision falls under the Federal provisions at 30 CFR 784.20 and sections 507(a), 508(a), 510(b), 515(b), and 516 of SMCRA.

7. Certifications by Professional Surveyors—CSR 38–2–3.15.a; 3.15.b.1; 4.2.a.7; 4.10.a.1; 4.12; 5.4.d.2; 5.4.d.3; 5.4.e.1; 5.4.e.3; 7.5.b.11; 7.5.g.1.A; 7.5.g.2.A

Throughout the regulations the words ''licensed land'' have been deleted and the word ''professional'' added before ''surveyor'' to clarify that surveyors certified and licensed in West Virginia are considered to be professional surveyors. The proposed State revisions fall under the Federal provisions at 30 CFR 780.14(c), 780.25, 780.37, 784.23, 784.16, 784.24, 816/817.46(b), 816/817.49(a)(11), and 816/817.151 and sections 507(b)(14) and 515(b)(10)(B)(ii) of SMCRA.

8. Approved Persons—CSR 38–2–3.15.b.3

The State is proposing to add new language at the end of the paragraph to read: ''Furthermore, any person seeking an approval must be capable and maintain the capability of submitting maps, plans and all other technical data in an electronic format proscribed by the Secretary.'' Although there are no specific Federal requirements governing approved persons, these proposed revisions fall under the provisions at 30 CFR 780.14(c) and sections 507(b)(14) and 515(b)(10)(B)(ii) of SMCRA.

9. Bonding: Trust Fund or Annuity—CSR 38–2–11.3.f

All of subsection 11.3.f is new and can be viewed in its entirety at *http://www.regulations.gov.* Under the proposed rule, a permittee, with the approval of the Secretary, may establish a trust fund, annuity or both to guarantee treatment of long-term postmining pollutional discharges in lieu of posting a bond. The trust fund or annuity will be subject to certain conditions. The proposed revisions fall under the Federal provisions at 30 CFR 800.4, 800.11, 800.13, 800.14, 800.16, and 800.17, and sections 509 and 519 of SMCRA.

10. Inactive Status Procedures—CSR 38–2–14.11.h

Under the proposed rule, the Secretary may grant inactive status for a term longer than those set forth currently in (e), (f), and now (g). This will allow the Secretary to grant inactive status for coal refuse sites to exceed a period of 10 years. New language is also being added to provide that ''Bonding in this manner shall remain in effect for the life of the operation.'' This will require the permittee of an operation that receives inactive status approval to furnish and maintain a full-cost reclamation bond for the life of the operation. These proposed revisions fall under the Federal provisions at 30 CFR 816 and 817.131 and sections 509, 510, and 515 of SMCRA.

11. Show Cause Orders—CSR 38–2–20.4.a

The State is proposing to add new language to provide that ''The Secretary shall provide email notice of the issuance of a show cause order to members of the public who have subscribed to the Secretary's email notification service and otherwise provide notice to any person whose citizen's complaint has resulted in the issuance of any violation that led to the issuance of the show cause order.'' This is to ensure that citizens who subscribe to the Secretary's email notification system get notified of all show cause orders, and any citizen whose complaint resulted in an enforcement action that led to a show cause notice is also notified. These proposed revisions fall under the Federal provisions at 30 CFR 843.14 and sections 521, 525, and 526 of SMCRA.

IV. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the West Virginia program.

Written Comments

Send your written comments to OSM at one of the addresses given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We may not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see **DATES**) or sent to an address other than those listed above (see **ADDRESSES**).

Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m. (local time), on November 17, 2011. If you are disabled and need special accommodations to attend a

public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If there is limited interest in participation in a public hearing, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the Administrative Record.

V. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSM for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 27, 2011.

Thomas D. Shope,

Regional Director, Appalachian Region.

[FR Doc. 2011–28441 Filed 11–1–11; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2010–0391; FRL–9485–9]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Attainment Plan for the Pennsylvania Portion of the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware 1997 Fine Particulate Matter Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Pennsylvania State Implementation Plan (SIP), which was submitted to EPA on April 12, 2010 to demonstrate attainment of the 1997 annual fine particulate matter ($PM_{2.5}$) national ambient air quality standard (NAAQS) for the Pennsylvania portion of the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware (PA-NJ-DE) nonattainment area (Philadelphia area). This plan (herein called the ''attainment plan'') includes the Pennsylvania portion of the Philadelphia area's attainment demonstration and motor vehicle emission budgets (MVEBs) used for transportation conformity purposes. The attainment demonstration includes an analysis of reasonably available control measures (RACM) and reasonably available control technology (RACT), a base year emissions inventory, and contingency measures. The requirement for a reasonable further progress (RFP) plan is not required because Pennsylvania projected that attainment of the 1997 $PM_{2.5}$ NAAQS would have occurred in the Pennsylvania portion of the Philadelphia area by the attainment date, April 2010. This action is being taken in accordance with the Clean Air Act (CAA) and the Clean Air Fine Particulate Implementation Rule ($PM_{2.5}$ Implementation Rule) issued by EPA on April 25, 2007.

DATES: Written comments must be received on or before December 2, 2011.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2010–0391 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: fernandez.cristina@epa.gov.*

C. *Mail:* EPA–R03–OAR–2010–0391, Cristina Fernandez, Associate Director, Office of Air Planning Program, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R03–OAR–2010–0391. EPA'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 whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.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 *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, 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 electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814–2182, or by email at *quinto.rose@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

The following is provided to aid in locating information in this preamble.

I. What action is EPA proposing to take?
II. What is the background for EPA's proposed action?
A. Designation History
B. Clean Air Fine Particle Implementation Rule
C. Attaining Data Determination and Finding of Attainment
III. What is included in the Pennsylvania attainment plan?
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A. Attainment Demonstration
1. Pollutants Addressed
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B. Motor Vehicle Emissions Budgets
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VI. Statutory and Executive Order Reviews

I. What action is EPA proposing to take?

EPA is proposing to approve Pennsylvania's SIP submission, which was submitted by the Pennsylvania Department of Environmental Protection (PADEP) to EPA on April 12, 2010 to demonstrate attainment of the 1997 annual $PM_{2.5}$ NAAQS for the Pennsylvania portion of the Philadelphia area (herein called the state's ''$PM_{2.5}$ attainment plan''). This $PM_{2.5}$ attainment plan includes Pennsylvania's attainment demonstration and MVEBs used for transportation conformity purposes. The attainment demonstration includes a base year emissions inventory, an analysis of RACM/RACT, and contingency measures. RFP plan is not required because the Pennsylvania portion of the Philadelphia area demonstrated that attainment of the 1997 annual $PM_{2.5}$ NAAQS occurred by the attainment date, April 2010.

EPA has determined that the Pennsylvania's $PM_{2.5}$ attainment plan meets the applicable requirements of the CAA, as described in the $PM_{2.5}$ Implementation Rule issued by EPA on April 25, 2007 (72 FR 20586). EPA's analysis and findings are discussed in this proposed rulemaking. In addition, technical support documents (TSDs) for this proposal are available online at *www.regulations.gov*, Docket No. EPA–R03–OAR–2010–0391. These TSDs provide additional explanation on EPA's analysis supporting this proposal.

II. What is the background of EPA's proposed action?

A. Designation History

On July 18, 1997 (62 FR 36852), EPA established the 1997 $PM_{2.5}$ NAAQS, including an annual standard of 15.0 micrograms per cubic meter ($\mu g/m^3$) based on a 3-year average of annual mean $PM_{2.5}$ concentrations and a 24-hour (or daily) standard of 65 $\mu g/m^3$ based on a 3-year average of the 98th percentile of 24-hour concentrations. EPA established these standards based on significant evidence and numerous health studies demonstrating that serious health effects are associated with exposures to $PM_{2.5}$.

Following promulgation of a new or revised NAAQS, EPA is required by the CAA to designate areas throughout the United States as attaining or not attaining the NAAQS; this designation process is described in section 107(d)(1) of the CAA. In 1999, EPA and State Air Quality Agencies initiated the monitoring process for the 1997 $PM_{2.5}$ NAAQS and by January 2001, established a complete set of air quality monitors. On January 5, 2005 (70 FR 944), EPA promulgated initial air quality designations for the 1997 $PM_{2.5}$ NAAQS, which became effective on April 5, 2005, based on air quality monitoring data for calendar years 2001–2003.

On April 14, 2005 (70 FR 19844), EPA promulgated a supplemental rule amending the Agency's initial designations, with the same effective date (April 5, 2005) as 70 FR 944. As a result of this supplemental rule, $PM_{2.5}$ nonattainment designations are in effect for 39 areas, comprising 208 counties within 20 states (and the District of Columbia) nationwide, with a combined population of about 88 million. The Pennsylvania portion of the Philadelphia area, which is the subject of this rulemaking, is included in the list of areas not attaining the 1997 annual $PM_{2.5}$ NAAQS. The Pennsylvania portion of the Philadelphia area consists of the following counties: Bucks, Chester, Delaware, Montgomery, and Philadelphia.

It should be noted that on November 13, 2009 (74 FR 58688), EPA revised the existing designation tables in 40 CFR part 81.339 to clarify that the 1997 designations were for both the annual $PM_{2.5}$ NAAQS and the 24-hour $PM_{2.5}$ NAAQS. The Pennsylvania portion of the Philadelphia area was designated unclassifiable/attainment for the 24-hour $PM_{2.5}$ NAAQS.

B. Clean Air Fine Particle Implementation Rule

On April 25, 2007 (72 FR 20586), EPA issued the $PM_{2.5}$ Implementation Rule for the 1997 $PM_{2.5}$ NAAQS. The ''$PM_{2.5}$ Implementation Rule'' describes the CAA framework and requirements for developing SIPs for areas designated nonattainment for the 1997 $PM_{2.5}$ NAAQS. An attainment plan must include a demonstration that a nonattainment area will meet the applicable NAAQS within the timeframe provided in the statute. This demonstration must include modeling (40 CFR 51.1007) that is performed in accordance with EPA modeling guidance (EPA–454/B–07–002, April 2007). It must also include supporting technical analyses and descriptions of all relevant adopted Federal, State, and local regulations and control measures that have been adopted in order to provide attainment of the 1997 $PM_{2.5}$ NAAQS by the proposed attainment date.

For the 1997 $PM_{2.5}$ NAAQS, an attainment plan must show that a nonattainment area will attain the 1997 $PM_{2.5}$ NAAQS as expeditiously as practicable, but within five years of designation (i.e. attainment date of April 2010 based on air quality data for 2007 through 2009). If the area is not expected to meet the NAAQS by April 2010, a state may request to extend the attainment date by one to five years based on the severity of the nonattainment problem or the feasibility of implementing control measures (CAA section 172(a)(2)) in the specific area. For EPA to approve an extension of the attainment date beyond 2010, the state must provide an analysis to support the request and demonstrate that the attainment date is as expeditious as practicable for the area given the facts and circumstances of the area and

consistent with the statutory criteria for an extension.

For each nonattainment area, the state must demonstrate that it has adopted all RACM, including all RACT for the appropriate emissions sources, needed to provide for attainment of the $PM_{2.5}$ standards in the specific nonattainment area ''as expeditiously as practicable.'' The $PM_{2.5}$ Implementation Rule provided guidance for making these RACM/RACT determinations (*See,* Section IV.A.4 below). Any measures that are necessary to meet these requirements that are not already Federally promulgated or in an EPA-approved part of the state's SIP must be submitted as part of a state's attainment demonstration. Any state measures must meet the applicable statutory and regulatory requirements, and in particular, must be Federally enforceable.

The $PM_{2.5}$ Implementation Rule also included guidance on pollutants that states must address in their attainment plans. The CAA (section 302(g)) authorizes EPA to regulate criteria pollutants and their precursors. In the case of $PM_{2.5}$, the main chemical precursors are sulfur dioxide (SO_2), nitrogen oxides (NO_X), ammonia (NH_3), and volatile organic compounds (VOCs). The effect of reducing emissions of precursor pollutants that contribute to $PM_{2.5}$ concentrations varies by area, however, depending on $PM_{2.5}$ composition, emission levels, and other area-specific factors. For this reason, the $PM_{2.5}$ Implementation Rule provided guidance recommending that states elect direct $PM_{2.5}$ emissions and the precursor that would be most effective for attaining the NAAQS within the specific area, based upon an appropriate technical demonstration.

In accordance with the $PM_{2.5}$ Implementation Rule, direct $PM_{2.5}$ emissions means ''solid particles emitted directly from an air emissions source or activity, or gaseous emissions or liquid droplets from an air emissions source or activity which condense to form particulate matter at ambient temperatures. Direct $PM_{2.5}$ emissions include elemental carbon, directly emitted organic carbon (OC), directly emitted sulfate (SO_4), directly emitted nitrate (NO_3), and other inorganic particles (including but not limited to crustal material, metals, and sea salt).''

The $PM_{2.5}$ Implementation Rule requires all states to address SO_2 as a $PM_{2.5}$ attainment plan precursor and to evaluate SO_2 for possible control measures in all $PM_{2.5}$ nonattainment areas. States are required to address NO_X as a $PM_{2.5}$ attainment plan precursor and evaluate reasonable controls for NO_X in all $PM_{2.5}$ attainment plans, unless the state and EPA make a finding that NO_X emissions from sources in the state do not significantly contribute to $PM_{2.5}$ concentrations in the relevant nonattainment area.

Although current scientific information shows that certain VOC emissions are precursors to the formation of secondary organic aerosol, and significant progress has been made in understanding the role of gaseous organic material in the formation of organic particular matter (PM), this relationship remains complex. Further research and technical tools are needed to better characterize emissions inventories for specific VOC compounds and to determine the extent of the contribution of specific VOC compounds to organic PM mass. Because of these factors, the $PM_{2.5}$ Implementation Rule did not require states to address VOCs as $PM_{2.5}$ attainment plan precursors and evaluate them for control measures, unless the state or EPA makes a finding that VOCs significantly contribute to a $PM_{2.5}$ nonattainment problem in the specific area or to other downwind air quality concerns.

The $PM_{2.5}$ Implementation Rule also describes the formation of particles related to NH_3 emissions, which is a complex, nonlinear process. Though recent studies have improved our understanding of the role of NH_3 in aerosol formation, ongoing research is needed to better describe the relationships between NH_3 emissions, PM concentrations, and related impacts. Also, area-specific data is needed to evaluate the effectiveness of reducing NH_3 emissions on reducing $PM_{2.5}$ concentrations in different areas, and to determine where NH_3 decreases may increase the acidity of particles and precipitation. For these reasons, in the $PM_{2.5}$ Implementation Rule, NH_3 is presumed not to be a $PM_{2.5}$ attainment plan precursor, meaning that the state is not required to address NH_3 in its attainment plan or evaluate sources of NH_3 emissions for reduction measures, unless the state or EPA makes a finding that NH_3 significantly contributes to a $PM_{2.5}$ nonattainment problem in the area or to other downwind air quality concerns.

The presumptive inclusion of NO_X, and the presumptive exclusion of VOC and NH_3 as attainment plan precursors can be reversed based on an acceptable technical demonstration for a particular nonattainment area by the state or EPA. Such a demonstration should include information from multiple sources, including results of speciation data analyses, air quality modeling studies, chemical tracer studies, emission inventories, or special intensive measurement studies to evaluate specific atmospheric chemistry in an area (*See,* the $PM_{2.5}$ Implementation Rule for more information).

The $PM_{2.5}$ Implementation Rule also provided guidance for the other elements of a state's attainment plan, including, but not limited to, emission inventories, contingency measures, and MVEBs used for transportation conformity purposes.

There are, however, three aspects of the $PM_{2.5}$ Implementation Rule for which EPA received petitions requesting reconsideration. These pertain to the presumption or advance determination that compliance with the requirements of the Clean Air Interstate Rule (CAIR) automatically satisfies the requirements for RACT or RACM for NO_X or SO_2 emissions from electric generating unit (EGU) sources participating in regional cap and trade programs; the suggestion in the preamble that the economic feasibility element of a RACT determination for EGUs should include consideration of whether the cost of a measure is reasonable in light of the benefits; and the policy described in the preamble of allowing certain emissions reductions from outside the nonattainment area to be credited as meeting the RFP requirement. EPA is granting these petitions and intends to undertake rulemaking to change these aspects of the $PM_{2.5}$ Implementation Rule. The attainment plan for the Pennsylvania portion of the Philadelphia area did not rely on any of these aspects of the rule.

C. Attaining Data Determination and Finding of Attainment

The data in Table 1 indicates that the Pennsylvania portion of the Philadelphia area is meeting the 1997 annual $PM_{2.5}$ NAAQS. In addition, Table 2 shows that the Philadelphia area continues to attain the 1997 annual $PM_{2.5}$ NAAQS by 2010. More detailed information can be found in the TSD entitled, ''Technical Support Document for the Modeling Portion of the Commonwealth of Pennsylvania's Fine Particulate Matter State Implementation Plan,'' dated October 11, 2011, available on line at *www.regulations.gov*, Docket No. EPA–R03–OAR–2010–0391. However, this action does not determine that the Pennsylvania portion of the Philadelphia area has attained the 1997 annual $PM_{2.5}$ NAAQS and the information is included here only to support Pennsylvania's demonstration that the Pennsylvania portion of the Philadelphia area could meet the attainment date of April 5, 2010, and

continues to attain based on the most recent data available. EPA plans to take action to formally determine the Pennsylvania portion of the Philadelphia area's attainment of the 1997 annual $PM_{2.5}$ NAAQS in a separate action.

TABLE 1—2009 ANNUAL AVERAGED $PM_{2.5}$ DESIGN VALUE

County	Site name	Site No.	Design value (μg/m³)
Bucks	Bristol	420170012	12.1
Chester	New Garden	420290100	12.4
Delaware	Chester	420450002	13.3
Montgomery	Norristown	420910013	11.3
Philadelphia	AMS Lab	421010004	12.9
Philadelphia	NE Airport	421010024	11.9
Philadelphia	Broad Street	421010047	13.5
Philadelphia	Elmwood	421010136	12.7

TABLE 2—2008–2010 MONITORED ANNUAL DESIGN VALUES

County	Site name	Site No.	Design value (μg/m³)		
			2008	2009	2010
Bucks	Bristol	420170012	12.6	12.2	11.3
Chester	New Garden	420290100	13.4	13.9	13.8
Delaware	Chester	420450002	14.1	13.7	13.1
Montgomery	Norristown	420910013	12.3	11.7	10.5
Philadelphia	AMS Lab	421010004	13.4	12.5	11.5
Philadelphia	NE Airport	421010024	12.4	11.5	10.5
Philadelphia	Broad Street	421010047	14.5	13.0	11.9
Philadelphia	Elmwood	421010136	13.2	13.3	.....

III. What is included in the Pennsylvania attainment plan?

In accordance with section 172(c) of the CAA and the $PM_{2.5}$ Implementation Rule, the attainment plan submitted on April 12, 2010 by PADEP for the Pennsylvania portion of the Philadelphia area included: (1) An emissions inventory for the plan's base year (2002); (2) an attainment demonstration; and (3) MVEBs for the attainment year. The attainment demonstration includes: (a) Technical analyses that locate, identify, and quantify sources of emissions contributing to violations of the 1997 annual $PM_{2.5}$ NAAQS; (b) analyses of future year emissions reductions and air quality improvements expected to result from national and local programs from new measures to meet RACM/RACT; (c) adopted emission reduction measures with schedules for implementation; and (d) contingency measures for NO_X and SO_2 to be implemented if the area did not meet RFP or did not attain the standard by the attainment date.

To analyze future year emissions reductions and air quality improvements, Pennsylvania used local, regional, and national modeling analyses that have been developed to support Federal and local emission reduction programs. This modeling was performed in accordance with EPA's ''Guidance on the Use of Models and Other Analyses for Determining Attainment of Air Quality Goals for Ozone, $PM_{2.5}$, and Regional Haze'' (EPA–454/B–07–002, April 2007).

IV. What is EPA's analysis of the Pennsylvania attainment plan submittal?

A. Attainment Demonstration

1. Pollutants Addressed

In accordance with policies described in the $PM_{2.5}$ Implementation Rule, Pennsylvania's $PM_{2.5}$ attainment plan evaluates emissions of direct $PM_{2.5}$, SO_2, and NO_X in the Pennsylvania portion of the Philadelphia area. Because of uncertainties regarding NH_3 emission inventories and the efficacy of ammonia control technologies as noted earlier in this notice, the final rule sets forth the presumption that NH_3 is not a $PM_{2.5}$ precursor and that the states are not required to address NH_3 in their attainment plan. Similarly, VOC emissions are presumed not to be an attainment plan precursor because of uncertainties regarding the role of VOC in secondary organic aerosol formation. Pennsylvania's attainment plan does not reverse this presumption.

2. Emissions Inventory Requirements

States are required under section 172(c)(3) of the CAA to develop emissions inventories of point, area, onroad mobile, and nonroad mobile sources for their attainment demonstrations. These inventories provide a detailed accounting of all emissions and emission sources by precursor or pollutant. In addition, inventories are used to model air quality to demonstrate that attainment of the 1997 $PM_{2.5}$ NAAQS as expeditiously as practicable, and if an attainment extension beyond 2010 is needed to support the need for such an extension. Emissions inventory guidance was provided in the April 1999 document ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter NAAQS and Regional Haze Regulations'' (EPA–454/R–99–006), which was updated in November 2005 (EPA–454/R–05–001). Emissions reporting requirements were provided in the 2002 Consolidated Emissions Reporting Rule (CERR) (67 FR 39602). On December 17, 2008 (73 FR 76539), EPA promulgated the Air Emissions Reporting Requirements (AERR) to update emissions reporting requirements in the CERR, and to harmonize, consolidate and simplify data reporting by states.

In accordance with the AERR and the November 2005 guidance, the $PM_{2.5}$ Implementation Rule required states to submit inventory information on directly emitted $PM_{2.5}$ and $PM_{2.5}$ precursors and any additional inventory

information needed to support an attainment demonstration.

The SIP base year inventory is the primary inventory from which other inventories (3-year cycle inventories, RFP inventories, modeling inventories) are derived. The CAA calls for state, local, and tribal agencies to ensure that the base year inventory is comprehensive, accurate, and current for all actual emissions (EPA–454/R–05–001). The base year inventory includes emissions estimates from stationary point and nonpoint sources, onroad mobile sources, and nonroad mobile sources. For the $PM_{2.5}$ NAAQS, the pollutants to be inventoried are primary emissions (including condensables) of PM_{10} and $PM_{2.5}$, and emissions of SO_2, NH_3, VOC, and NO_X, and are reported as actual annual weekday emissions. The State Air Agencies defined 2002 as the base year inventory. The pollutants inventoried for the Pennsylvania portion of Philadelphia area included PM_{10}, $PM_{2.5}$, SO_2, NH_3, VOC, and NO_X. Information on the manmade sources of direct PM and its potential precursors, SO_2, NH_3, VOC, and NO_X was compiled for:

Stationary sources (or point sources), which are sources for which PADEP collects individual emissions-related information, generally represent major stationary sources but may be smaller. The point source data for 2002 is derived from the Air Information Management System/environment, Facility, Application, Compliance Tracking System (AIMS/eFACTS). The AIMS/eFACTS database is comprised of sources identified and inventoried by PADEP's regional and central offices through permitting, field inspections, and surveys.

Area sources, which are industrial, commercial, and residential sources too small or too numerous to be handled individually, include, but are not limited, to commercial and residential open burning, architectural and industrial maintenance coatings applications and clean-up, consumer product use, and vehicle refueling at service stations. Where there is overlap between stationary point sources and stationary area sources, the area source values are adjusted to remove any double counting. PADEP's inventory contained estimations of emissions by multiplying an emission factor by an indicator or activity level for each category at the county level. These emissions are calculated on an annual basis since the activity data are generally available on an annual basis. Area source estimates were provided by source classification code (SCC).

Highway vehicles, which include passenger cars and light-duty trucks, other trucks, buses, and motorcycles, are onroad mobile source emissions inventory that was developed using the most current version of EPA's highway mobile source emissions model MOBILE6.2. PADEP also used PPSUITE, an enhanced version of the Post Processor for Air Quality software systems used for previous inventory submissions in Pennsylvania. The Pennsylvania Department of Transportation (PennDOT) provided estimates of vehicles miles traveled (VMT) by vehicle type and roadway type. PADEP provided sample MOBILE6.2 input files and estimates for review.

Nonroad sources, which encompass a diverse collection of engines, including, but not limited to, outdoor power equipment, recreational vehicles, farm and construction machinery, lawn and garden equipment, industrial equipment, recreational marine vessels, commercial marine vessels, locomotives, ships, and aircraft were estimated using the EPA NONROAD 2005 model.

The emissions inventory for the base year, 2002, was developed in accordance with EPA guidance, ''Emissions Inventory Guidance for Implementation of Ozone and Particulate Matter National Ambient Air Quality Standards and Regional Haze Regulations, EPA–454/R–05–001, August 2005, updated November 2005.'' Table 3 summarizes the emissions for 2002.

TABLE 3—2002 ANNUAL EMISSIONS

[Tons per year]

Philadelphia area 2002	$PM_{2.5}$	PM_{10}	SO_2	NOx	VOC	NH_3
Stationary Point Sources	2139	3430	23745	22124	8183	256
Area Sources	10020	55224	13153	13029	59227	4821
Highway Vehicle Sources	1033	1492	1920	63476	33974	2614
Nonroad Sources	1535	1611	1640	21619	21589	14
Total	14727	61758	40459	120248	122973	7705

The review and evaluation of the methods used for the emissions inventory submitted by Pennsylvania are found in the attainment plan submittal (section III) and a TSD entitled ''Technical Support Document for the Pennsylvania portion of the Philadelphia-Wilmington, PA-NJ-DE $PM_{2.5}$ Noanattainment Area: State Implementation Plan Attainment Demonstration and Base Year Inventory,'' dated October 11, 2011, available on line at *www.regulations.gov,* Docket No. EPA–R03–OAR–2010–0391. EPA is proposing to approve the 2002 base year emissions inventory for the Pennsylvania portion of the Philadelphia area as meeting the requirements of section 172(c)(3) of the CAA.

$PM_{2.5}$ is comprised of filterable and condensable emissions. Condensable particulate matter (CPM) can comprise a significant percentage of direct $PM_{2.5}$ emissions from certain sources, and are required to be included in national emission inventories based on emission factors. Test Methods 201A and 202 are available for source-specific measurement of condensable emissions. However, the $PM_{2.5}$ Implementation Rule acknowledged that there were issues and concerns related to availability and implementation of these test methods as well as uncertainties in existing data for condensable $PM_{2.5}$. In recognition of these concerns, EPA established a transition period during which EPA could assess possible revisions to available test methods and to allow time for states to update emissions inventories as needed to address direct $PM_{2.5}$, including condensable emissions. Because of the time required for this assessment, EPA recognized that states would be limited in how to effectively address CPM emissions, and established a period of transition, up to January 1, 2011, during which state submissions for $PM_{2.5}$ were not required to address CPM emissions. Amendments to these test methods were proposed on March 25, 2009 (74 FR 12969), and finalized on December 21,

2010 (75 FR 80118). The amendments to Method 201A added a particle-sizing device for $PM_{2.5}$ sampling, and the amendments to Method 202 revised the sample collection and recovery procedures of the method to reduce the formation of reaction artifacts that could lead to inaccurate measurements of CPM emissions.

The period of transition for establishing emissions limits for condensable direct $PM_{2.5}$ ended on January 1, 2011. $PM_{2.5}$ submissions made during the transition period are not required to address CPM emissions; however, states must address the control of direct $PM_{2.5}$ emissions, including condensable emissions, with any new action taken after this January 1, 2011. Pennsylvania submitted the Pennsylvania portion of the Philadelphia area attainment plan prior to January 1, 2011 and did not consider condensables.

In July 2008, EarthJustice filed a petition requesting reconsideration of EPA's transition period for CPM emissions provided in the $PM_{2.5}$ Implementation Rule. In January 2009, EPA decided to allow states that have not previously addressed CPM to continue to exclude CPM for Prevention of Significant Deterioration (PSD) permitting during the transition period. Today's action reflects a review of Pennsylvania's submittal based on current EPA guidance as described in the $PM_{2.5}$ Implementation Rule.

3. Modeling

All attainment demonstrations must include modeling that is performed in accordance with EPA's ''Guidance on the Use of Models and Other Analyses for Demonstrating Attainment of Air Quality Goals for Ozone, $PM_{2.5}$, and Regional Haze'' (EPA–454/B–07–002, April 2007). Modeling may be based on national (*e.g.,* EPA), regional (*e.g.,* Ozone Transport Commission), local modeling, or a combination thereof, if appropriate. A brief description of modeling used to support Pennsylvania's attainment demonstration follows. More detailed information can be found in the TSD entitled, ''Technical Support Document for the Modeling Portion of the Commonwealth of Pennsylvania's Fine Particulate Matter State Implementation Plan,'' dated October 11, 2011, available on line at *www.regulations.gov,* Docket number EPA–R03–OAR–2011–0391. The Philadelphia area's attainment plan addressed the following components of a modeled attainment demonstration.

a. Conceptual Description of the Problem

A conceptual model describes how weather patterns affect the formation and transport of $PM_{2.5}$, accounting for emissions and photochemistry. A conceptual model for the Philadelphia area's attainment plan is described in a document prepared by the Northeast States for Coordinated Air Use Management (NESCAUM), ''The Nature of the Fine Particle and Regional Haze Air Quality Problems in the Mid-Atlantic Northeast Visibility Union (MANE–VU) Region: A Conceptual Description (NESCAUM), November 2006,'' for use by the Ozone Transport Commission (OTC) member states which provides the conceptual description of $PM_{2.5}$ issues in the OTC states and is consistent with EPA's guidance.

b. The Model Used in the Attainment Demonstration

By agreement of OTC, the New York State Department of Environmental Conservation (NYSDEC) ran the Community Multi-scale Air Quality Model (CMAQ) for the states in the northeast ozone transport region that includes Pennsylvania. EPA agrees CMAQ is appropriate for this modeling demonstration. The inputs of the model are described in section V of the attainment plan submittal.

c. Meteorological Time Periods Used in the Modeling

Since the Philadelphia area's attainment demonstration used a resource intensive photochemical grid model, EPA accepts the use of single, recent representative year to be used for an annual simulation. Two factors were used in selecting 2002 as the representative year. The observed annual mean concentrations of $PM_{2.5}$ are close to the 3-year observed design value at all, or most monitoring sites, and the pattern of quarterly mean values is similar to the pattern of quarterly mean concentrations averaged over 3 years.

d. Meteorological Data Used in the Air Quality Model

The OTC modeling committee decided to use a prognostic meteorological model that provides life-like meteorological inputs to the photochemical grid model. The Pennsylvania State University/National Center for Atmospheric Research Mesoscale Meteorological Model (MM5) version 3.6 was chosen for the modeling analysis. The MM5 model provides a reasonable representation of weather conditions at the surface and aloft.

e. Domain of the Model, Horizontal/Vertical Resolution and the Initial and Boundary Conditions

The modeling domain extends from Maine to Florida and out in the Atlantic Ocean on the east and west to the Mississippi River. The size of the modeling domain was made large enough to include all emission sources that affect $PM_{2.5}$ concentration in the northeastern United States. Even this boundary is defined by a larger photochemical modeling domain that covers much of North America. Over the northeastern United States, the model used 12 kilometer grid cells. The Pennsylvania portion of the Philadelphia area is included in the 12 kilometer grid cell area. The OTC Modeling Committee used a 12-kilometer grid size for the areas in and near its states to provide a fine enough grid resolution to adequately capture the PM patterns experienced in the ozone transport region (OTR). Outside the local areas the grid resolution used in the modeling is 36 kilometers. The selection of model domains and horizontal grid resolution was deemed acceptable to EPA.

Vertical resolution is the number of layers and the size of each layer in the model. The layers in the photochemical grid model were set up to be compatible with the model that produced weather conditions for the photochemical grid model. The vertical resolution used in the modeling exercise followed EPA's modeling guidance and therefore adequately represents the atmosphere where $PM_{2.5}$ is emitted, forms and is transported.

f. Emissions Used in the Air Quality Model

The emissions data for 2002 were generated by individual states within the OTR and assembled and processed through Mid-Atlantic Northeast Visibility Union (MANE–VU), a Regional Planning Organization (RPO). These emissions were then processed by NYSDEC using the sparse matrix operator kernel emissions (SMOKE) emissions processor to provide CMAQ compatible inputs. The 2002 emissions for the non-OTR areas within the modeling domain were obtained from the corresponding RPOs and were processed using SMOKE, in manner similar to that of the OTR emissions. The OTR states, through MANE–VU, contracted MACTEC Federal Programs (called Contractor) to develop 2009, 2012 and 2018 inventories based on 2002 inventories that the states had previously developed for the base-year model work. The Contractor, in

consultation with the states, developed the necessary growth and control factors and applied to the 2002 inventory.

g. Base Case Run Model Performance Evaluation

NYSDEC performed a model evaluation for the OTC to determine how well CMAQ reproduced the 2002 $PM_{2.5}$ concentrations. CMAQ was employed to simulate $PM_{2.5}$ for the calendar year 2002. A review of $PM_{2.5}$ and its individual species was conducted for the study domain. Several observations were made with respect to model performance: (1) Approximately 80–90 percent of organic mass (OM) is in the primary fraction; (2) CMAQ captures seasonal variation in SO_4 well; (3) CMAQ appears to overestimate primary $PM_{2.5}$ components, especially during colder months; and (4) CMAQ appears to underestimate secondary OM during the summer.

These issues are not of great regulatory concern since attainment tests are based on the application of relative response factors. Therefore, the regional and local model performance is acceptable for $PM_{2.5}$. While there are some differences between the spatial data between sub-regions, there is nothing to suggest a tendency for the model to respond in a systematically different manner between regions. Examination of the statistical metrics by sub-region confirms the absence of significant performance problems arising in one area but not in another, building confidence that the CMAQ modeling system is operating consistently across the full OTC domain. This confidence in the modeling results allows for the modeling system to be used to support the attainment plan to meet the 1997 annual $PM_{2.5}$ NAAQS.

h. 2009 Control Case Modeling and Modeled Attainment Test

As previously mentioned, the Pennsylvania portion of the Philadelphia area has an attainment date of April 5, 2010. The $PM_{2.5}$ NAAQS include an annual standard of 15 μg/m³ based on the 3-year average of annual mean $PM_{2.5}$ concentrations. The purpose of a modeling assessment is to determine if control strategies currently being implemented (''on the books'') will lead to attainment of the annual average NAAQS for $PM_{2.5}$ by 2009. The modeling is applied in a relative sense, similar to the 8-hour ozone attainment test. However, the $PM_{2.5}$ attainment test is more complicated and reflects the fact that $PM_{2.5}$ is a mixture. In the test, ambient $PM_{2.5}$ is divided into major components, with a separate relative response factor (RRF) and Future Design Value (FDV) calculated for each of the $PM_{2.5}$ components. Since the attainment test is calculated on a per species basis, the attainment test for $PM_{2.5}$ is referred to as the Speciated Modeled Attainment Test (SMAT).

Table 4 presents the results of the annual SMAT results for the Philadelphia area. The SMAT results demonstrate that the projected average annual arithmetic mean $PM_{2.5}$ concentration calculated at each Federal Reference Method (FRM) monitor attains the annual $PM_{2.5}$ NAAQS. Specifically, all calculations are less than15 μg/m³. Table 4 presents the results of the annual SMAT results for a suite of regional modeling runs conducted by OTC each representing OTB/OTW—''On the Books, On the Way'' control measures. All runs demonstrate compliance with the annual $PM_{2.5}$ NAAQS.

TABLE 4—ANNUAL SMAT RESULTS FOR PHILADELPHIA-WILMINGTON, PA-NJ-DE $PM_{2.5}$ NONATTAINMENT AREA ON-THE-BOOKS-ON-THE-WAY CONTROL MEASURES

AIRS ID	Site name	County	State	2000–2004 Baseline design value				2009
				Q1	Q2	Q3	Q4	DVF
420170012	Bristol	Bucks	PA	14.14	13.69	14.73	13.85	12.1
420290100	New Garden	Chester	PA	14.39	14.73	16.36	13.76	12.4
420450002	Chester	Delaware	PA	15.07	15.96	16.34	13.74	13.3
420910013	Norristown	Montgomery	PA	12.68	13.62	13.96	12.34	11.3
421010004	AMS Lab	Philadelphia	PA	15.99	14.01	15.95	13.82	12.9
421010024	NE Airport	Philadelphia	PA	13.58	13.63	14.95	12.96	11.9
421010047	Broad Street	Philadelphia	PA	16.59	16.45	15.80	15.37	13.5
421010136	Elmwood	Philadelphia	PA	15.70	14.20	15.27	12.99	12.7
100031003	Bellefonte	New Castle	DE	14.87	15.16	15.50	13.13	12.6
100031007	Lums Pond	New Castle	DE	13.16	14.37	16.05	10.66	11.3
100031012	Newark	New Castle	DE	15.27	14.91	16.53	13.14	12.6
100032004	MLK	New Castle	DE	16.41	15.40	17.61	14.04	13.3
340070003	Camden	Camden	NJ	13.99	14.54	15.76	12.47	12.3
340071007	Pennsauken	Camden	NJ	13.99	14.00	14.75	13.59	12.3
340155001	Gibbstown	Gloucester	NJ	13.92	13.43	15.08	11.39	11.7

In summary, the basic photochemical grid modeling, presented in the Philadelphia area attainment plan, used the methods recommended in EPA's modeling guidance. When EPA's attainment test is applied to the modeling results, the 2009 annual-average $PM_{2.5}$ design value is predicted to be 13.5μg/m³ in the Philadelphia area. Therefore, based on EPA's modeled attainment test, the Pennsylvania portion of the Philadelphia area reached attainment of the annual average $PM_{2.5}$ standard in 2009 before the attainment date of April 5, 2010.

i. Supplemental Analyses and Weight of Evidence (WOE) Determination

EPA's modeling guidance states that additional analyses are recommended to determine if attainment will be likely, even if the modeled attainment test is ''passed.'' The guidance recommends supplementary analyses in all cases. EPA's modeling guidance describes how to use a photochemical grid model and additional analytical methods to complete a WOE analysis to estimate if emissions control strategies will lead to attainment. A WOE analysis is a supporting analysis that helps to determine if the results of the photochemical modeling system are correctly (or not correctly) predicting future air quality.

All models, including the CMAQ model have inherent uncertainties. Over or under prediction may result from uncertainties associated with emission inventories, meteorological data, and representation of $PM_{2.5}$ chemistry in the

model. Therefore, EPA modeling guidance provides for other evidence to address these model uncertainties so that proper assessment of the probability to attain the applicable standards can be made. EPA modeling guidance states that those modeling analyses that show that attainment with the NAAQS will be reached in the future with some margin of safety (*i.e.,* estimated concentrations below 14.5 μg/m³ for annual $PM_{2.5}$ and 62 μg/m³ for 24-hour $PM_{2.5}$) need more limited supporting material.

Due to the fact that the modeling results presented in Table 4 fall below the aforementioned ''weight of evidence'' thresholds established by EPA, a limited supplemental analysis was deemed necessary to support the 2009 attainment demonstration. PADEP's supporting evidence includes a brief summary of the modeling demonstration, recent trends in the Philadelphia area's monitoring data and a brief analysis of some of the largest SO_2 sources within the nonattainment area.

4. Reasonably Available Control Measures/Reasonably Available Control Technology

a. Requirements for RACM/RACT

CAA section 172(c)(1) requires that each attainment plan ''provide for the implementation of all RACM as expeditiously as practicable, including such reductions in emissions from the existing sources in the area as may be obtained through the adoption, at a minimum, of RACT, and shall provide for attainment of the national primary ambient air quality standards.'' EPA interprets RACM including RACT under section 172 as measures that a state finds are both reasonably available and contribute to attainment as expeditiously as practicable in the nonattainment area. Thus, what constitutes RACM or RACT in a $PM_{2.5}$ nonattainment area is closely tied to the expeditious attainment demonstration of the plan. *See,* 40 CFR 51.1010; 72 FR 20586 at 20612.

States are required to evaluate RACM/RACT for direct $PM_{2.5}$ emissions and all of the area's attainment plan precursors. *See,* 40 CFR 51.1002(c); 72 FR 20586 at 20589–97. Consistent with the guidance provided for the $PM_{2.5}$ Implementation Rule, a state initially must evaluate RACM/RACT for sources that emit direct $PM_{2.5}$, SO_2, and NO_X. A state may establish with an appropriate demonstration that it should not regulate NO_X in the specific nonattainment area, so it could thereby forgo evaluation of RACM/RACT for NO_X. Because EPA concluded that VOC and NH_3 are presumptively not regulatory precursors for $PM_{2.5}$, unless the state or EPA determines that it is necessary to regulate them in a specific nonattainment area, the state is not required to evaluate RACM/RACT for sources of VOC or NH_3 unless there is a determination supported by an appropriate demonstration that such emissions need to be regulated for expeditious attainment of the NAAQS in the specific area.

For $PM_{2.5}$ attainment plans, the $PM_{2.5}$ Implementation Rule requires a combined approach to RACM and RACT under subpart 1 of Part D of the CAA. Subpart 1, unlike subparts 2 and 4, does not identify specific source categories for which EPA must issue control technique documents or guidelines, or identify specific source categories for state and EPA evaluation during attainment plan development. *See* 72 FR 20586 at 20610. Rather, under subpart 1, EPA considers RACT to be part of an area's overall RACM obligation consistent with the section 172 definition. Because of the variable nature of the $PM_{2.5}$ problem in different nonattainment areas which may require states to develop attainment plans that address widely disparate circumstances, EPA determined not only that states should have flexibility with respect to RACM/RACT controls, but also that in areas needing significant emission reductions, RACM/RACT controls on smaller sources may be necessary to reach attainment as expeditiously as practicable. *See,* 72 FR 20586 at 20612, 20615. Thus, under the $PM_{2.5}$ Implementation Rule, RACM and RACT are those reasonably available measures that contribute to attainment as expeditiously as practicable in the specific nonattainment area. *See,* 40 CFR 51.1010; 72 FR 20586 at 20612.

Specifically, the $PM_{2.5}$ Implementation Rule requires that attainment plans include the list of measures that a state considered and information sufficient to show that the state met all requirements for the determination of what constitutes RACM/RACT in a specific nonattainment area. *See,* 40 CFR 51.1010(a). In addition, the $PM_{2.5}$ Implementation Rule requires that the state, in determining whether a particular emissions reduction measure or set of measures must be adopted as RACM/RACT, consider the cumulative impact of implementing the available measures and to adopt as RACM/RACT any potential measures that are reasonably available considering technological and economic feasibility if, considered collectively, they would advance the attainment date by one year or more. If a measure or measures is not necessary for expeditious attainment of the NAAQS in the area, then by definition that measure is not RACM/RACT for purposes of the 1997 $PM_{2.5}$ NAAQS in that area. Any measures that are necessary to meet these requirements which are not already either Federally promulgated, part of the state's SIP, or otherwise creditable in SIPs must be submitted in enforceable form as part of a state's attainment plan for the area. *See,* 72 FR 20586 at 20614.

Guidance provided in the $PM_{2.5}$ Implementation Rule for evaluating RACM/RACT level controls for an area also indicated that there could be flexibility with respect to those areas that were predicted to attain the 1997 $PM_{2.5}$ NAAQS within five years of designation as a result of existing national or local measures. *See,* 72 FR 20586 at 20612. In such circumstances, EPA indicated that the state may conduct a more limited RACM/RACT analysis that does not involve additional air quality modeling. Moreover, the RACM/RACT analysis for such area would focus on a review of reasonably available measures, the estimation of potential emissions reductions, and the evaluation of the time needed to implement the measures. Thus, the $PM_{2.5}$ Implementation Rule guidance recommended that not all areas would need to conduct as rigorous an analysis, and suggested that a less rigorous analysis would be needed for those areas expected to attain within the initial five years from designation as a nonattainment area for the 1997 $PM_{2.5}$ NAAQS. A more comprehensive discussion of the RACM/RACT requirement for $PM_{2.5}$ attainment plans and EPA's guidance for it can be found in the $PM_{2.5}$ Implementation Rule preamble. *See,* 72 FR 20586 at 20609–20633.

b. Pennsylvania's Analysis of Pollutants and Sources Pennsylvania Portion of the Philadelphia Area

Based upon the emissions inventory for the area, Pennsylvania determined that it would be appropriate to evaluate sources of $PM_{2.5}$, SO_2, and NO_X located in the nonattainment area for potential control as RACM/RACT. Pennsylvania did not determine that controls of sources of VOC or NH_3 would be necessary for expeditious attainment of the NAAQS in this area, nor does EPA believe that there is a need to do so.

After evaluating which pollutants should be addressed in the attainment plan, Pennsylvania identified all source categories of those emissions located within the nonattainment area to

determine available controls that could bring the area into attainment as expeditiously as possible. *See,* section IV.B of the attainment plan submittal. Based on the emissions inventory and other information, Pennsylvania identified the following source categories as sources that should be evaluated for controls: Consumer products; portable fuel containers; adhesives and sealants application; diesel engine chip reflash; cutback and emulsified asphalt paving; cement kilns; glass furnaces; industrial, commercial, and institutional (ICI) boilers; regional fuels; and electric generating units (EGUs).

The attainment plan submittal contains the Ozone Transport Commission (OTC) report entitled, ''Identification and Evaluation of Candidate Control Measures, Final Technical Support Document (MACTEC, February 2007).'' This final report contains detailed information about the process and includes tables summarizing the emission reduction potential of each control measure by source category and projection year. Pennsylvania also participated in an assessment of control measures for pollutants and sources affecting visibility though the MANE–VU regional haze process. MANE–VU developed a list of control measures for consideration and analysis: coal and oil-fired EGUs; point and area source industrial, commercial, and institutional boilers; cement kilns; lime kilns; the use of heating oil; and residential wood combustion and open burning.

The attainment plan submittal, contains the final report entitled, ''Assessment of Reasonable Progress for Regional Haze in MANE–VU Class I Areas (MACTEC, July 2000),'' from the MANE–VU control measure assessment project. This report presents the results of an analysis of the economic and environmental impacts of the potential scenarios that could be implemented by MANE–VU states to reduce emissions from selected source categories in order to make reasonable progress toward meeting visibility improvement goals.

In accordance with 40 CFR 51.1010, a SIP revision for a $PM_{2.5}$ nonattainment area is required to demonstrate that all RACM, including RACT stationary sources necessary to demonstrate attainment as expeditiously as practicable have been adopted. The cumulative impact of implementing available measures must be considered in determining whether a particular emission reduction measure or set of measures is required to be adopted as RACM. Potential measures that are reasonably available considering technical and economic feasibility must be adopted as RACM if, considered collectively, they would advance the attainment date by one year or more. Since the Pennsylvania portion of the Philadelphia area attained at the end of 2009, any RACM measures need to be in effect in 2008. PADEP determined that there are no additional control measures that could be adopted by January 1, 2008. In addition, existing measures and measures planned for implementation by 2009, enabled the Philadelphia area to attain the 1997 $PM_{2.5}$ NAAQS. Therefore, no further actions on RACM or RACT are warranted.

c. Pennsylvania's Evaluation of RACM/RACT Control Measures for the Pennsylvania Portion of the Philadelphia Area

In accordance with section 172 of the CAA, the Pennsylvania portion of the Philadelphia area has adopted all RACM, including RACT, needed to attain the standards ''as expeditiously as practicable.'' Pennsylvania's demonstration for attaining the 1997 $PM_{2.5}$ NAAQS in the Pennsylvania portion of the Philadelphia area is based on the following enforceable measures: Small sources of NO_X, cement kilns and large stationary internal combustion engines; new source review programs; Federal standards for hazardous air pollutants; source surveillance; Federal Motor Vehicle Control Programs and Pennsylvania Clean Vehicle Program for passenger vehicles and light-duty trucks and cleaner gasoline; reformulated gasoline; heavy-duty diesel control programs; vehicle emission inspection/maintenance program; low sulfur gasoline; diesel vehicle idling restrictions; and nonroad sources regulations.

Although VOC is not a regulated $PM_{2.5}$ precursor for the Philadelphia area, VOC control measures approved by EPA were included in the modeling associated with this attainment plan: Portable fuel containers (December 8, 2004, 69 FR 70893); consumer products (December 8, 2004, 69 FR 70895); and architectural and industrial maintenance (AIM) coatings (November 23, 2004, 69 FR 69080).

d. Proposed Action on RACM/RACT Demonstration and Control Strategy

EPA is proposing to approve Pennsylvania's evaluation of RACM/RACT control measures for the Pennsylvania portion of the Philadelphia area. As noted above, the most current monitoring data for this area indicates that it is attaining the 1997 $PM_{2.5}$ NAAQS. EPA's guidance for the $PM_{2.5}$ Implementation Rule recommended that if an area was predicted through the attainment plan to attain the standard within five years after designation, then the state could submit a more limited RACM/RACT analysis and the state could elect not to do additional modeling.

In light of the fact that the Pennsylvania portion of the Philadelphia area is now attaining the standards, EPA proposes to conclude that the attainment plan meets the RACM/RACT requirements of the $PM_{2.5}$ Implementation Rule, and that the level of control in the State's attainment plan constitutes RACM/RACT for purposes of the 1997 $PM_{2.5}$ NAAQS. Because the $PM_{2.5}$ Implementation Rule defines RACM/RACT as that level of control that is necessary to bring the area into attainment, the current level of Federally enforceable controls on sources located within the area is by definition RACM/RACT for this area for this purpose.

5. Reasonable Further Progress

Section 172(c)(2) of the CAA requires that attainment plans include RFP to achieve steady progress toward meeting air quality standards by showing generally linear progress toward attainment. The $PM_{2.5}$ Implementation Rule set forth that an area that demonstrates attainment by 2010 will be considered to have satisfied the RFP requirement and need not submit any additional material to satisfy the RFP requirement. The EPA views the attainment demonstration as also demonstrating that the area is making reasonable further progress toward attainment. A state is required to submit a separate RFP plan for any area for which the state seeks an extension of the attainment date beyond 2010. The RFP plan is required to provide emission reductions such that emissions in 2009 represent generally linear progress from the 2002 baseline year to the attainment year. The Pennsylvania portion of the Philadelphia area attained by 2010, and has therefore met the RFP requirements.

6. Contingency Measures

In accordance with section 172(c)(9) of the CAA, the $PM_{2.5}$ Implementation Rule requires that $PM_{2.5}$ attainment demonstrations include contingency measures. These measures must be fully adopted and should contain trigger mechanisms and an implementation schedule. In addition, they should be measures not already included in the SIP control strategy and should provide for emission reductions equivalent to one year of RFP. Contingency measures are implemented if RFP targets are not

achieved, or if attainment is not realized by the attainment date. Where an area has already achieved attainment by the attainment date, it has no need to rely on contingency measures to come into attainment or to make further progress towards attainment. However, in accordance with section 110(k)(2) of the CAA, EPA must take action on the contingency measures that were submitted by Pennsylvania. The attainment plan for the Pennsylvania portion of the Philadelphia area includes contingency measures to be implemented if the area fails to attain by its attainment date. The following describes the specific control measures that are anticipated to be in place in order to bring the area back into attainment should a violation occur.

The Diesel-Powered Commercial Motor Vehicle Idling Act (Act 124) went into effect on February 6, 2009. PADEP estimates 50 percent of all long duration idling for Class 8 trucks will be eliminated in 2010 when the temperature exemption for sleeper truck rest expires. Statewide emission reductions are estimated to be 1610 tons, 45 tons and 30 tons per year for NO_X, VOC and $PM_{2.5}$, respectively. PADEP will also utilize enhanced enforcement to obtain additional emission reductions.

Significant additional reductions in NO_X, direct $PM_{2.5}$ and SO_2 emissions will occur in emissions from highway and nonmobile sources after 2009. In addition, NO_X controls for cement kilns and glass furnaces were approved by EPA on July 19, 2011 (76 FR 42258) and August 22, 2011 (76 FR 52283), respectively. Furthermore, $PM_{2.5}$ control from the operation of outdoor wood-fired boilers was approved by EPA on September 20, 2011 (76 FR 58114). Sulfur limits for fuel oil (home heating oil and residential oil) are anticipated to be adopted later. Regulations to reduce VOC emissions are also in development, including controls on the manufacture and use of adhesives, primers and sealants and regulations incorporating the Control Technique Guidelines issued by EPA in 2006, 2007 and 2008.

As required, these measures were fully adopted rules or control measures that were ready to be implemented quickly upon failure of the area to attain, were in addition to those measures otherwise relied upon for attainment, had trigger mechanisms and a schedule for implementation, and were at the level of reductions equal to at least one year's worth of reductions needed for attainment in the area. EPA finds that the measures submitted by Pennsylvania have satisfied the requirements for contingency purposes.

EPA's General Preamble interprets the control measure requirements of sections 172(c)(9) and 182(c)(9) to allow states to implement measures before they are triggered (57 FR 13498, 13511). EPA has previously approved a number of SIPs under this interpretation (66 FR 15844, April 3, 1997; 62 FR 66279, December 18, 1997; 66 FR 30811, June 8, 2001; and 66 FR 586, and 66 FR 634, January 3, 2001) and the Fifth Circuit has upheld EPA's interpretation. *Louisiana Environmental Action Network* v. *EPA,* 382 F.3d 575 (Fifth Cir. 2004). It does not matter whether or not a specific contingency measure is already required by law, as long as the emissions reductions that will result from the contingency measure have not been relied upon in the attainment demonstration.

The contingency measures in Pennsylvania's attainment demonstration (described above) that are already implemented and provide reductions in excess of those required by the attainment demonstration to attain the standards. The level of reductions provided is equal to at least one year's worth of reductions needed for attainment in the Pennsylvania portion of the Philadelphia area. Contingency measures are implemented in the event that the Philadelphia area fails to attain the standards by its attainment date. Although the Philadelphia area, as indicated above, met their attainment date of April 5, 2010, and thus is not required to implement contingency measures, by relying on those measures that were already in place, Pennsylvania effectively implemented their control measures in advance.

7. Attainment Date

Pennsylvania provided a demonstration of attainment of the 1997 $PM_{2.5}$ NAAQS in the Pennsylvania portion of the Philadelphia area by 2010. Areas, such as this, that demonstrate attainment of the standard by 2010 are considered to have satisfied the requirement to show RFP toward attainment and need not submit a separate RFP plan. For similar reasons, such areas are not subject to a requirement for a mid-course review.

B. Motor Vehicle Emissions Budgets

Section 176(c) of the CAA requires Federal actions in nonattainment and maintenance areas to ''conform to'' the goals of SIPs. This means that such actions will not cause or contribute to violations of a NAAQS, worsen the severity of an existing violation, or delay timely attainment of any NAAQS. Actions involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval are subject to the transportation conformity rule (40 CFR part 93, subpart A). Under this rule, metropolitan planning organizations (MPOs) in nonattainment and maintenance areas coordinate with State Air Quality and Transportation Agencies, EPA, and the FHWA and FTA to demonstrate that their long range transportation plans and transportation improvement programs (TIP) conform to applicable SIPs. This is typically determined by showing that estimated emissions from existing and planned highway and transit projects are less than or equal to the MVEBs contained in the SIP.

The MVEBs for the 2009 attainment year are based on the projected 2009 on-road motor vehicle source emissions, accounting for the emission reductions from on-road vehicle source control measures, including transportation control measures and vehicle technology, fuel or maintenance-based measures. MVEBs for 2009 attainment year for the Pennsylvania portion of the Philadelphia area are 699 tons per year for $PM_{2.5}$ direct and 36,318 tons per year for NO_X. More detailed information can be found in the TSD entitled, ''Adequacy Findings for Motor Vehicle Emissions Budgets in the Attainment Demonstration for the Pennsylvania Portion of the Philadelphia-Wilmington-New Jersey City 1997 $PM_{2.5}$ NAAQS Nonattainment Area, dated October 6, 2011, available online at *www.regulations.gov,* Docket number EPA–R03–OAR–2011–0391.

For MVEBs to be approvable, they must meet, at a minimum, EPA's adequacy criteria (40 CFR 93.118(e)(4)). The MVEBs for the Pennsylvania portion of the Philadelphia area $PM_{2.5}$ attainment plan are being posted to EPA's conformity Web site concurrently with this proposed action. The public comment period will end at the same time as the public comment period for this proposed action. In this case, EPA is concurrently processing the action on the attainment plan and the adequacy process for the MVEBs contained therein. In this action, EPA is proposing to find the MVEBs adequate, and also proposing to approve the MVEBs as part of the attainment plan. The MVEBs cannot be used for transportation conformity until the attainment plan and associated MVEBs are approved in a final **Federal Register** notice, or EPA otherwise finds the budgets adequate in a separate action following the comment period. Our action on the Pennsylvania portion of the Philadelphia area MVEBs will also be announced on EPA's

conformity Web site: *http://www.epa.gov/otaq/stateresources/transconf/index.htm,* (once there, click on ''Adequacy Review of SIP Submissions).

The budgets that Pennsylvania submitted were calculated using the MOBILE6.2 motor vehicle emissions model. EPA is proposing to approve the inventory and the conformity budgets calculated using this model because this model was the most current model available at the time Pennsylvania was performing its analysis. Separate from today's proposal, EPA has issued an updated motor vehicle emissions model known as the Motor Vehicle Emission Simulator or MOVES. In its announcement of this model, EPA established a grace period for continued use of MOBILE6.2 in transportation conformity determinations for transportation plans and TIPs, after which states and MPOs (other than California) must use MOVES for transportation plan and TIP conformity determinations. This grace period will expire in March 2012 (or March 2013 once the extension becomes official).

Additional information on the use of MOVES in SIPs and conformity determinations can be found in the December 2009, ''Policy Guidance on the Use of MOVES2010 for State Implementation Plan Development, Transportation Conformity, and Other Purposes.'' This guidance document is available at: *http://www.epa.gov/otaq/models/moves/420b09046.pdf.* During the conformity grace period, the state and MPO(s) should use the interagency consultation process to examine how MOVES2010a will impact their future transportation plan and TIP conformity determinations, including regional emissions analyses. For example, an increase in emission estimates due to the use of MOVES2010a may affect an area's ability to demonstrate conformity for its transportation plan and/or TIP. Therefore, state and local planners should carefully consider whether the SIP and motor vehicle emissions budget(s) should be revised with MOVES2010a or if transportation plans and TIPs should be revised before the end of the conformity grace period, since doing so may be necessary to ensure conformity determinations in the future.

We would expect that states and MPOs would work closely with EPA and the local FHWA and FTA offices to determine an appropriate course of action to address this type of situation if it is expected to occur. If Pennsylvania chooses to revise its $PM_{2.5}$ attainment plan, it should consult Question 7 of the December 2009, ''Policy Guidance on the Use of MOVES2010 for State Implementation Plan Development, Transportation Conformity, and Other Purposes,'' for information on requirements related to such revisions.

V. Proposed Action

EPA is proposing to approve the 1997 annual $PM_{2.5}$ NAAQS attainment plan for the Pennsylvania portion of the Philadelphia area that was submitted on April 12, 2010. The attainment plan includes Pennsylvania's attainment demonstration, the MVEBs used for transportation conformity purposes, an analysis of RACM/RACT, a base year emissions inventory, and contingency measures. EPA has determined that the SIP revision meets the applicable requirements of the CAA, as described in the $PM_{2.5}$ Implementation Rule. Specifically, EPA has determined that the Pennsylvania SIP revision includes an attainment demonstration and adopted state regulations and programs needed to support a determination that the Pennsylvania portion of the Philadelphia area would have attain the 1997 annual $PM_{2.5}$ NAAQS by the April 2010 deadline. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VI. Statutory and Executive Order Reviews

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

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

In addition, this proposed rule, pertaining to the 1997 $PM_{2.5}$ attainment plan for the Pennsylvania portion of the Philadelphia area, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: October 26, 2011.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2011–28438 Filed 11–1–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 21

[Docket Number FWS–R9–MB–2009–0045; 91200–1231–9BPP]

RIN 1018–AW75

Migratory Bird Permits; Abatement Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Advance notice of proposed rulemaking; reopening of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the reopening of the public comment period on our July 6, 2011, advance notice of proposed rulemaking in which we solicited comments and suggestions on migratory bird permit regulations for a permit to use raptors (birds of prey) in abatement activities. Abatement means the use of trained raptors to flush, scare (haze), or take birds or other wildlife to mitigate damage or other problems, including risks to human health and safety. We have permitted this activity under special purpose permits since 2007 pursuant to a migratory bird permit policy memorandum. We now intend to prepare a specific permit regulation to authorize this activity. We seek information and suggestions from the public to help us formulate any proposed regulation.

We are reopening the comment period to allow all interested parties another opportunity to comment on the proposed rule. Comments previously submitted need not be resubmitted and will be fully considered in preparation of a proposed rule.

DATES: Electronic comments on this proposal via regulations.gov must be submitted by midnight Eastern time on December 2, 2011. Comments submitted by mail must be postmarked no later than December 2, 2011.

ADDRESSES: You may only submit comments or suggestions by the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. We will not post duplicate comments from any entity, nor will the duplicates be put into our administrative record for this issue.
- U.S. mail or hand-delivery: Public Comments Processing, Attention FWS–R9–MB–2009–0045; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203–1610.

We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: George Allen at (703) 358–1825.

SUPPLEMENTARY INFORMATION:

Public Comments

We request comments and suggestions on this topic from other concerned governmental agencies, the scientific community, industry, or any other interested parties. You may submit your comments and materials concerning this issue by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by email or fax or to an address not listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we use in preparing a proposed rule, will be available for public inspection at *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service (contact the person listed under **FOR FURTHER INFORMATION CONTACT**).

Background

On July 6, 2011, we published in the **Federal Register** an advance notice of proposed rulemaking to gather information and suggestions from the public to help us formulate a proposed regulation for a specific permit authorizing the use of raptors in abatement activities (76 FR 39368). The comment period for the advance notice of proposed rulemaking was open for 90 days, ending on October 4, 2011. At a commenter's request, we are reopening the comment period on the advance notice of proposed rulemaking for an additional 60 days (see **DATES** section). We specifically seek comments concerning any aspect of the use of trained MBTA-protected raptors for abatement activities and potential regulations to govern Federal permitting. We particularly solicit comments on the topics listed below. Explaining the reasons and rationale for your comments where appropriate will help as we consider them in the preparation of a proposed rule.

(1) Qualifications and experience necessary to qualify for a Federal abatement permit.

(2) Limits on the species that should be authorized for use in abatement activities.

(3) Limits on the numbers of raptors that should be authorized for use in abatement activities.

(4) Qualifications and experience of subpermittees (both those authorized to fly the permit holder's raptors and those allowed to care for birds).

(5) Caging requirements for birds, while traveling, being transported and held in ''temporary'' caging for extended periods of time, i.e., multiple birds held in a trailer while conducting seasonal abatement activities at multiple locations.

(6) The use of falconry birds held by subpermittees for abatement.

(7) Any other considerations relating to subpermittees conducting abatement activities under a permit holder's permit, including their business relationship to the permit holder. For example, should falconers located elsewhere in the United States be allowed to conduct abatement activities in their own locale as subpermittees under a permit holder's abatement permit? Why or why not?

(8) Comments on what has worked well under existing permits and what has not worked well.

(9) Report information that should be required from a permit holder, if any.

(10) Other conditions that should apply to these permits.

(11) Examples of situations where raptors are used for abatement and information or documentation of success or lack of success in accomplishing abatement objectives.

If you previously submitted comments in response to the July 6, 2011, advance notice of proposed rulemaking, do not resubmit them. They will be fully considered as we prepare a proposed rule. For more information concerning the advance notice of proposed rulemaking, please refer to that document at 76 FR 39368 (July 6, 2011).

Authority: The authorities for this notice are the Migratory Bird Treaty Act, 40 Stat. 755 (16 U.S.C. 703–712); Public Law 95–616, 92 Stat. 3112 (16 U.S.C. 712(2)); Public Law 106–108, 113 Stat. 1491, and Note Following 16 U.S.C. 703.

Dated: October 21, 2011.

Rachel Jacobson,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2011–28376 Filed 11–1–11; 8:45 a.m.]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 111024651–1650–01]

RIN 0648–XA739

Listing Endangered and Threatened Wildlife and Plants; 90-Day Finding on a Petition To List Alewife and Blueback Herring as Threatened Under the Endangered Species Act

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

ACTION: 90-day petition finding; request for comments.

SUMMARY: We, NMFS, announce a 90-day finding for a petition to list alewife (*Alosa pseudoharengus*) and blueback herring (*Alosa aestivalis*) as threatened under the Endangered Species Act and to designate critical habitat concurrent with a listing. We find that the petition presents substantial scientific information indicating the petitioned action may be warranted. Accordingly, we will conduct a review of the status of alewife and blueback herring, collectively referred to as river herring, to determine if the petitioned action is warranted. To ensure that the review is comprehensive, we solicit information pertaining to this species from any interested party.

DATES: Information related to this petition finding must be received by January 3, 2012.

ADDRESSES: You may submit comments, identified by the RIN 0648–XA739, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail or hand-delivery:* Assistant Regional Administrator, NMFS, Northeast Regional Office, 55 Great Republic Drive, Gloucester, MA 01930.

All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

The petition and other pertinent information are also available electronically at the NMFS Web site at *http://www.nero.noaa.gov/prot_res/CandidateSpeciesProgram/RiverHerringSOC.htm.*

FOR FURTHER INFORMATION CONTACT: Kim Damon-Randall, NMFS, Northeast Regional Office (978) 282–8485 or Marta Nammack, NMFS, Office of Protected Resources (301) 713–1401.

SUPPLEMENTARY INFORMATION:

Background

On August 5, 2011, we, the National Marine Fisheries Service (NMFS), received a petition from the Natural Resources Defense Council (NRDC), requesting that we list alewife (*Alosa pseudoharengus*) and blueback herring (*Alosa aestivalis*) each as threatened throughout all or a significant portion of their range under the Endangered Species Act (ESA). In the alternative, they requested that NMFS designate distinct population segments (DPS) of alewife and blueback herring as specified in the petition (Central New England (CNE), Long Island Sound (LIS), Chesapeake Bay (CB) and Carolina for alewives, and CNE, LIS, and CB for blueback herring). The petition contains information on the two species, including the taxonomy; historical and current distribution; physical and biological characteristics of the species' habitat and ecosystem relationships; population status and trends; and factors contributing to the species' decline. NRDC also included information regarding the possible DPSs of alewife and blueback herring as described above. The petition addresses the five factors identified in section 4(a)(1) of the ESA: (1) Present or threatened destruction, modification, or curtailment of habitat or range; (2) over-utilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; and (5) other natural or man-made factors affecting the species' continued existence.

ESA Statutory Provisions and Policy Considerations

Section 4(b)(3)(A) of the ESA (16 U.S.C. 1533(b)(3)(A)) requires that we make a finding as to whether a petition to list, delist, or reclassify a species presents substantial scientific or commercial information indicating the petitioned action may be warranted. ESA implementing regulations define substantial information as the amount of information that would lead a reasonable person to believe the measure proposed in the petition may be warranted (50 CFR 424.14(b)(1)). In determining whether substantial information exists for a petition to list a species, we take into account several factors, including information submitted with, and referenced in, the petition and all other information readily available in our files. To the maximum extent practicable, this finding is to be made within 90 days of the receipt of the petition (16 U.S.C. 1533(b)(3)(A)), and the finding is to be published promptly in the **Federal Register**. If we find that a petition presents substantial information indicating that the requested action may be warranted, section 4(b)(3)(A) of the ESA requires the Secretary of Commerce (Secretary) to conduct a review of the status of the species. Section 4(b)(3)(B) requires the Secretary to make a finding as to whether the petitioned action is warranted within 12 months of the receipt of the petition. The Secretary has delegated the authority for these actions to the NOAA Assistant Administrator for Fisheries.

The ESA defines an endangered species as ''any species which is in danger of extinction throughout all or a significant portion of its range (ESA section 3(6)).'' A threatened species is defined as a species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range (ESA section 3(19)).'' As stated previously, under section 4(a)(1) of the ESA, a species may be determined to be threatened or endangered as a result of any one of the following factors: (1) Present or threatened destruction, modification, or curtailment of habitat or range; (2) over-utilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms; or (5) other natural or manmade factors affecting its continued existence. Listing determinations are made solely on the basis of the best scientific and commercial data available, after conducting a review of the status of the species and taking into account efforts made by any state or foreign nation to protect such species.

Under the ESA, a listing determination can address a species, subspecies, or a DPS of a vertebrate species (16 U.S.C. 1532 (16)). NRDC presents information in the petition proposing that DPSs of alewife and blueback herring are present in the United States and indicating that it may be appropriate to divide the population

into DPSs of alewife and blueback herring as specified in the petition. If we find that listing at the species level is not warranted, we will determine whether any populations of these species meet the DPS policy criteria, and if so, whether any DPSs are endangered or threatened under the ESA.

Life History of Alewife and Blueback Herring

Alewife and blueback herring are collectively referred to as ''river herring.'' Due to difficulties in distinguishing between the species, they are often harvested together in commercial and recreational fisheries, and managed together by the Atlantic States Marine Fisheries Commission (ASMFC). Throughout this finding, where there are similarities, they will be collectively referred to as river herring, and where there are distinctions they will be identified by species.

River herring can be found along the Atlantic coast of North America, from the maritime provinces of Canada to the southeastern United States (Mullen *et al.,* 1986; Shultz *et al.,* 2009). The coastal ranges of the two species overlap, with blueback herring found in a greater and more southerly distribution ranging from Nova Scotia down to the St. John's River, Florida; and alewife found in a more northerly distribution, from Labrador and Newfoundland to as far south as South Carolina, though the extreme southern range is a less common occurrence (Collette and Klein-MacPhee, 2002; ASMFC, 2009a; Kocik *et al.,* 2009). Adults are most often found at depths less than 100 m (328 ft) in waters along the continental shelf (Neves, 1981; ASMFC, 2009a; Shultz *et al.,* 2009).

River herring have a deep and laterally compressed body, with a small, pointed head with relatively large eyes, and a lower jaw that protrudes further than the upper jaw (Collette and Klein-MacPhee, 2002). The dorsal fin is small and slightly concave, pelvic fins are small, pectorals are moderate and low on the body, and the caudal fin is forked (Collette and Klein-MacPhee, 2002).

The coloring varies, ranging from dark blue and bluish green to grayish green and bluish gray dorsally; and silvery with iridescence in shades of green and violet on the sides and abdomen. In adults, there is often a dusky spot that is located at eye level on both sides behind the margin of the gill cover. The colors of alewife are thought to change in shade according to substrate as the fish migrates upstream, and sea run fish are thought to have a golden cast to their coloring (Collette and Klein-MacPhee, 2002).

Blueback herring and alewife are similar in appearance; however, there are some distinguishable characteristics: Eye diameter and the color of the peritoneum. The eye diameter with alewives is relatively larger than that of blueback herring. In blueback herring, the snout length is generally the same as the eye diameter; however with alewives, the snout length is smaller than the diameter of the eye (Collette and Klein-MacPhee, 2002). In alewives, the peritoneum is generally pale/light gray or pinkish white, whereas the peritoneum in blueback herring is generally dark colored and either brown or black, and sometimes spotted (Collette and Klein-MacPhee, 2002; ASMFC, 2009a).

River herring are anadromous, meaning that they migrate up coastal rivers in the spring from the marine environment, to estuarine and freshwater rivers, ponds, and lake habitats to spawn (Collette and Klein-MacPhee, 2002; ASMFC, 2009a; Kocik *et al.,* 2009). They are highly migratory, pelagic, schooling species, with seasonal spawning migrations that are cued by water temperature (Collette and Klein-MacPhee, 2002; Schultz, 2009). Depending upon temperature, blueback herring typically spawn from late March through mid-May. However, they have been documented spawning in the southern parts of their range as early as December or January, and as late as August in the northern range (ASMFC, 2009a). Alewives generally migrate earlier than other alosine fishes, but have been documented spawning as early as February to June in the southern portion of their range, and as late as August in the northern portion of the range (ASMFC, 2009a). It is thought that river herring return to their natal rivers for spawning, and do exhibit natal homing. However, colonization of streams where river herring have been extirpated has been documented; therefore, some effective straying does occur (ASMFC, 2009a).

Throughout their life cycle, river herring use many different habitats ranging from the ocean, up through estuaries and rivers, to freshwater lakes and ponds. The substrate preferred for spawning varies greatly and can include substrates consisting of gravel, detritus, and submerged aquatic vegetation. Blueback herring prefer swifter moving waters than alewife (ASMFC, 2009a). Nursery areas can include freshwater and semi-brackish waters; however, little is known about their habitat preference in the marine environment (Meadows, 2008; ASMFC, 2009a).

Analysis of Petition and Information Readily Available in NMFS Files

In the following sections, we use the information presented in the petition and in our files to: (1) Describe the distribution of alewife and blueback herring; and (2) evaluate whether alewife and blueback herring are at abundance levels that would lead a reasonable person to conclude that listing under the ESA may be warranted due to any of the five factors listed under section 4(a)(1) of the ESA.

Abundance

The NRDC asserts that alewife and blueback herring populations have suffered dramatic declines over the past 4 decades (ASMFC, 2008). The NRDC cites the ASMFC as stating that alewife and blueback herring harvest averaged almost 43 million pounds (19,504 metric tons (mt)) per year from 1930 to 1970. NRDC also cites ASMFC (2008) in stating that peak harvest occurred in the late 1940s and early 1950s and was highest in Virginia and North Carolina. The NRDC notes that commercial landings of river herring began declining sharply coastwide in the 1970s. However, ASMFC (2009a) reports that 140 million pounds (63,503 mt) of river herring were commercially landed in 1969, marking the peak in river herring catch; this is a discrepancy from what is stated in the petition. From the peak landings in 1969, landings declined to a point where domestic landings recently (2000–2007) exceeded only 2 million pounds (907 mt) yearly (ASMFC, 2009a). Declines in catch per unit effort (CPUE) have also been observed in two rivers for blueback herring and for alewife, and declining trends in CPUE for the combined species were also observed in two out of three rivers examined (ASMFC, 2009a).

ASMFC (2009a) also reports declines in abundance through run size estimates for river herring combined, as well as for individual species of alewife and blueback herring. Abundance declined in seven out of fourteen rivers in New England from the late 1960s to 2007, with no obvious signs of recovery; however, since 2004, there have been some signs of recovery in five out of fourteen rivers (ASMFC, 2009a). Coastwide declines have been observed, particularly in southern New England (Davis and Schultz *et al.,* 2009). In the Connecticut River the number of blueback herring passing Holyoke Dam declined from 630,000 in 1985 to a low of 21 in 2006 (Schultz *et al.,* 2009).

ESA Section 4(a)(1) Factors

Present or Threatened Destruction, Modification or Curtailment of Habitat or Range

In the petition, the NRDC states that habitat alterations, loss of habitat, and impaired water quality have contributed to the decline of river herring since colonial times. NRDC further states that climate change now poses an increasing threat as well. NRDC states that dams and turbines block access to spawning and foraging habitat, may directly injure or kill passing fish, and change water quality through alterations in flow and temperature, which NRDC asserts is significantly impacting river herring. NRDC cites ASMFC (2009b) which indicates that flow variations caused by dams, particularly hydropower dams, can displace eggs as well as disrupt migration patterns, which will adversely affect the survival and productivity of all life stages of river herring as well as other anadromous fish. ASMFC (2009b) indicates that increased flows at dams with fishways can also adversely affect the upstream migration of adults, impeding their ability to make it up through the fishway, as well as the downstream migration of juveniles, causing an early downstream migration and higher flows through sluiceways resulting in mortality. According to NRDC, dams have caused river herring to lose access to significant portions of their spawning and foraging habitat. In addition to altering flow and changing environmental parameters such as temperature and turbidity, NRDC indicates that dams, particularly hydropower dams, cause direct mortality to various life stages of river herring through entrainment and impingement in turbines, and changing water pressures. In addition, NRDC states that turbines used in tidal hydroelectric power plants may impact river herring with each tidal cycle as the fish migrate through the area.

Dredging and blasting were also identified by NRDC as significant threats to river herring. The petition cites ASMFC (2009b), asserting that increased suspended sediment, changes in water velocities, and alteration of substrates through dredging can directly impact river herring habitat. In addition, NRDC asserts that these operations may affect migration patterns and spawning success, and they can directly impact gill tissues, producing near fatal effects (NMFS, 1998; ASMFC, 2009b).

The NRDC also asserts that water quality poses a significant threat to river herring through changes in water temperature and flow, introduction of toxic pollutants, discharge, erosion, and nutrient and chemical run-off (ASMFC, 2009b). NRDC states that ''poor water quality alone can significantly impact an entire population of alewife or blueback herring.'' ASMFC (2008) notes that significant declines in dissolved oxygen (DO) levels in the Delaware River during the 1940s and 1950s from heavy organic loading made portions of the river during the warmer months of the year uninhabitable to river herring. ASMFC (2008, 2009a) indicates that river herring abundance is significantly affected by low DO and hypoxic conditions in rivers and that these conditions may also prevent spawning migrations.

River herring susceptibility to toxic chemicals and metals was also identified by NRDC as a threat to the species. The NRDC asserts that river herring are subjected to contaminants through their habitat, which may be contaminated with dioxins, polychlorinated aromatic hydrocarbons, organophosphate and organochlorine pesticides, polychlorinated biphenyls, and other hydrocarbon compounds, as well as toxic metals. Citing ASMFC (1999), the NRDC states that because of industrial, residential, and agricultural development, heavy metal and various types of organic chemical pollution has increased in nearly all estuarine waters along the Atlantic coast, including river herring spawning and nursery habitat. NRDC asserts that these contaminants can directly impact fish through reproductive impairment, reduced survivorship of various life stages, and physiological and behavioral changes (ASSRT, 2007; 75FR 61872).

The NRDC also identified climate change as a threat to river herring habitat. According to NRDC, the spatial distribution, migration, and reproduction of alewife may be affected through rising water temperatures caused by climate change. Citing the International Panel on Climate Change (IPCC) (2001), NRDC states that fish larvae and juveniles may have a high sensitivity to water temperature and suggests that headwaters and rivers may be more vulnerable; thus, the effects of climate change may be more significant to anadromous species, which utilize a multitude of habitats. According to ASMFC (2009b), as water temperatures rise, the upstream spawning migration of alewife declines, and will mostly cease once temperatures have risen above 21 degrees Celsius. In addition to increasing water temperatures, climate change may affect river herring through increased precipitation that may affect rivers and estuaries along the coast. Citing Kerr *et al.* (2009), the NRDC reports that a 10 percent increase in annual precipitation is expected in the Northeast United States from 1990 to 2095 and that precipitation has already increased 8 percent over the past 100 years (Markham and Wake, 2005). As increased water flows may affect anadromous fish migration, increased precipitation and the potential for flooding in rivers due to climate change may pose a significant threat to river herring (Limburg and Waldman, 2009).

Overutilization for Commercial, Recreational, Scientific or Education Purposes

The NRDC identified direct harvest, bycatch, and incidental catch as significant threats to river herring. River herring were historically fished through inshore fisheries, and constitute one of the oldest fisheries in North America (Haas-Castro, 2006). Commercial landings of river herring reached nearly 34,000 metric tons (mt) in the 1950s, but in the 1970s, landings fell below 4,000 mt. According to ASMFC (2008), foreign commercial exploitation of river herring in the 1960s led to drastic declines in abundance of river herring. Annual commercial landings over the past decade have varied from 137 mt to 931 mt, and 90 percent of this catch was typically harvested by Maine, North Carolina, and Virginia fisheries (Haas-Castro, 2006). Historically, river herring were targeted for food, bait and fertilizer purposes; however, they are currently most often used for bait in commercial fisheries (Collette and Klein-MacPhee, 2002). The NRDC contends that declines in river herring abundance are greatly affected by commercial overharvest, noting that direct harvest of river herring currently takes place in Maine, New Hampshire, New York, New Jersey, some rivers in Delaware, Maryland, Virginia, and South Carolina.

Bycatch and incidental catch were also identified by NRDC as resulting in significant mortality of river herring, stating that this catch occurs in both state and Federal waters. NRDC asserts that the anadromous life history of river herring presents the potential for increased bycatch due to the species schooling behavior at congregation sites throughout different portions of migration. Citing Lessard and Bryan (2011), NRDC indicates that ''hot spots'' of bycatch and incidental catch have been found in the winter between Cape Cod and Cape Hatteras, in the spring with blueback herring in the southern region, and in the fall in the Gulf of Maine and Georges Bank. The NRDC states that a variety of sources including landings records, log books, portside sampling efforts, and the NMFS observer program provide information

on bycatch and incidental catch, asserting that most of these sources are likely to underestimate the amount of bycatch that occurs.

The NRDC cites Lessard and Bryan (2011) in stating that the majority of bycatch of river herring is taken with mid-water otter paired trawls, and that catch with this gear type appears to be increasing from 2000–2008, with an estimation of around 500,000 to 2.5 million pounds (227 to 1,134 mt) of river herring caught annually as bycatch. In addition, the NRDC asserts that the Atlantic herring and Atlantic mackerel fisheries are increasing their use of single and pair mid-water trawls, and are using larger, more efficient nets, increasing the effort and efficiency in this fishery. The petition further outlines specific overharvesting issues within the Damariscotta, Hudson, Delaware, Potomac, Chowan, Santee-Cooper, and the St. John's Rivers, as well as Chesapeake Bay and Albermarle Sound.

Predation and Disease

The NRDC identifies predation and disease as another threat facing river herring. Citing the Maine Department of Marine Resources (ME DMR) (2003), NRDC states that river herring may be preyed upon by striped bass, bluefish, tuna, cod, haddock, halibut, American eel, brook trout, rainbow trout, brown trout, lake trout, landlocked salmon, smallmouth bass, largemouth bass, pickerel, pike, white and yellow perch, seabirds, bald eagle, osprey, great blue heron, gulls, terns, cormorants, seals, whales, otter, mink, fox, raccoon, skunk, weasel, fisher, and turtles. It asserts that the decline of some populations of river herring is due to increased predation, citing ASMFC (2008) as noting a concern with increasing striped bass abundance, and identifying predation by striped bass as contributing significantly to the decline of river herring in some rivers. Additionally, many species of cormorants along the coast are increasing in abundance, and predation on alosines by cormorants has been increasing, although Dalton *et al.* (2009) suggested that the double-crested cormorant is not believed to pose an immediate threat to the recovery of alewife in Connecticut.

According to the NRDC, significant cumulative mortality can occur with viral hemorrhagic septicemia, which is a viral infection known to infect certain anadromous fish, including river herring. Additionally, NRDC asserts that when levels of suspended solids are present during spawning, alewife eggs are significantly more likely to contract a naturally occurring fungus infection.

Inadequacy of Existing Regulatory Mechanisms

The NRDC states that state and Federal regulatory mechanisms are insufficient and contributing to drastic declines in river herring populations that continue throughout all or a significant portion of the species' ranges. Due to difficulties in distinguishing between the species, alewife and blueback herring are managed together by the ASMFC as river herring. NRDC states that ASMFC has the authority to develop and issue interstate fishery management plans (FMP) for fisheries administered by the state agencies and will coordinate management with Federal waters.

According to NRDC, ASMFC adopted an amendment to the coast-wide FMP for American shad and river herring in 2009, to specifically address the declining river herring populations coastwide. The petition asserts that this amendment is not likely to protect river herring sufficiently, as it ''does not require, and is not likely to result in, adequate measures to reduce significant incidental catch and bycatch/bycatch mortality of these species, particularly in federal waters.'' NRDC also asserts that this amendment does not address non-fishing stressors on river herring sufficiently. The petition further states that four states have already had prohibitions on the harvest of river herring in place, and even with this prohibition on all harvest, these states have continued to see declines.

The petition notes that river herring are not subject to the requirements and protections of the Magnuson-Stevens Fishery Conservation and Management Act (MSA) because they are not currently managed under an FMP as a stock, and therefore, are not federally managed in regard to overfishing and depleted stocks under the MSA. Even though river herring are caught and sold as bycatch, and FMPs are meant to minimize bycatch, the NRDC asserts that any provisions in FMPs meant to address bycatch of river herring have proven to be ineffective and inadequate. NRDC further asserts that bycatch reporting is inadequate and limited and that there are currently no FMPs under the MSA that specifically address bycatch and bycatch mortality of river herring.

The NRDC notes that currently the Mid-Atlantic Fisheries Management Council (MAFMC) is developing two amendments to two separate FMPs that include proposals for improving the monitoring of bycatch of river herring in these fisheries; however, it asserts that it was unknown whether the bycatch monitoring measures for river herring would be included in the final amendment.

NRDC also indicates that under the MSA or the Atlantic Coast Fisheries Act, NMFS has the potential to initiate emergency rulemaking or other actions to reduce bycatch of river herring in small mesh fisheries, but has declined to do so thus far. NRDC further notes that NMFS has declined to take emergency rulemaking actions for bycatch of river herring in small-mesh fisheries in New England and the Mid-Atlantic.

Federally managed stocks are required to have essential fish habitat (EFH) designated under the MSA; however, since river herring are not considered a federally managed stock under the MSA, EFH has not been designated for this species. A provision under the 1996 amendments to the MSA provides for comments from regional councils on activities that may affect anadromous fish habitat; however, the NRDC asserts that this provision has not provided any significant modifications to activities affecting anadromous fish habitat.

In addition to fisheries, the petition indicates that Federal laws and regulations have also failed to protect river herring and their habitat from threats such as poor water quality, dredging, and altered water flows. The petition briefly describes the Clean Water Act (CWA), the Federal Power Act (FPA), and the Anadromous Fish Conservation Act, and identifies where these regulations present inadequacies that are failing to protect river herring. NRDC notes that the CWA should limit discharge of pollutants into navigable waters and that some progress has been made in terms of industrial sources. NRDC also concludes that the CWA has not ''adequately regulated nutrients and toxic pollutants originating from non-point sources.'' In addition, some permits for dredging and excavation require permitting from the Army Corps of Engineers, and NRDC notes that these may benefit river herring through placing restrictions on the timing and location of activities in river herring habitats. The FPA allows for protection of fish and wildlife that may be affected by hydroelectric facilities. As mentioned previously, NRDC asserts that fish passage at hydroelectric facilities can be inefficient, and the dams themselves affect water flow which can pose a significant threat to river herring. Thus, according to NRDC, FPA protections for river herring are inadequate. The NRDC further states that the Anadromous Fish Conservation Act does not require any measures for river herring that would improve

habitat, reduce bycatch, or mitigate other threats to river herring, and therefore provides inadequate protection for the species. The NRDC notes that there are Federal protections that may benefit river herring which are intended for other anadromous species such as Atlantic salmon and shortnose sturgeon; however, it asserts that any benefits from these protections are minor and insufficient to fully protect river herring.

Other Natural or Manmade Factors Affecting Its Existence

The petition describes other natural or manmade factors that may be affecting river herring, including invasive species, impingement, entrainment, and water temperature alterations. The petition states that invasive species may threaten food sources for alewives and blueback herring. ASMFC (2008) describes the negative effect zebra mussel introduction to the Hudson River had on phytoplankton and zooplankton, and subsequently water quality. According to ASMFC (2008), a decrease in both micro and macro zooplankton as well as phytoplankton improved water clarity and increased shallow water zoobenthos by 10 percent. Early life stages of river herring feed on zooplankton as well as phytoplankton (ASMFC, 2008). Strayer *et al.* (2004) hypothesized that the introduction of this invasive species created competition for availability of the preferred food source of early life stages of river herring, and found that larval river herring abundance decreased with increased zebra mussel presence. Thus, according to the petition, invasive species introduction and subsequent water quality changes which may affect plankton abundance can decrease the abundance of early life stages of river herring.

As described previously, the petition asserts that various life stages of river herring may be impinged or entrained through water intake structures from commercial, agricultural, or municipal operations. These intake structures alter flow, and may cause direct mortality to various life stages of river herring if they are impinged or entrained by the intake. In addition, aside from direct mortality, the petition asserts that intakes alter flow, which can affect water quality, temperature, substrate, velocity, and stream width and depth. NRDC suggests that these alterations can affect spawning migrations as well as spawning and nursery habitat, which could pose a significant threat to river herring.

Petition Finding

Based on the above information, which indicates ongoing multiple threats to both species as well as potential declines in both species throughout their ranges, and the criteria specified in 50 CFR 424.14(b)(2), we find that the petition presents substantial scientific and commercial information indicating that the petitioned action concerning alewife and blueback herring may be warranted. Under section 4(b)(3)(A) of the ESA, this positive 90-day finding requires NMFS to commence a status review of the species. During our status review, we will review the best available scientific and commercial information, including the effects of threats and ongoing conservation efforts on both species throughout their ranges. Alewife and blueback herring are now considered to be candidate species (69 FR 19976; April 15, 2004). Within 12 months of the receipt of the petition (August 5, 2011), we will make a finding as to whether listing alewife and/or blueback herring as endangered or threatened is warranted, as required by section 4(b)(3)(B) of the ESA. If listing these species is not warranted, we will determine whether any populations of these species meet the DPS policy criteria (61 FR 4722; February 7, 1996), and if so, whether any DPSs are endangered or threatened under the ESA. If listing either species (or any DPS) is warranted, we will publish a proposed listing determination and solicit public comments before deciding whether to publish a final determination to list them as endangered or threatened under the ESA.

References Cited

A complete list of the references used in this finding is available upon request (see **ADDRESSES**).

Information Solicited

To ensure the status review is based on the best available scientific and commercial data, we solicit information pertaining to alewife and blueback herring. Specifically, we solicit information in the following areas: (1) Historical and current distribution and abundance of these species throughout their ranges; (2) population status and trends; (3) any current or planned activities that may adversely impact these species, especially as related to the five factors specified in section 4(a)(1) of the ESA and listed above; (4) ongoing efforts to protect and restore these species and their habitat; and (5) any biological information (life history, morphometrics, genetics, etc.) on these species. We request that all information be accompanied by: (1) Supporting documentation such as maps and bibliographic references; and (2) the submitter's name, address, and any association, institution, or business that the person represents.

Peer Review

On July 1, 1994, NMFS, jointly with the U.S. Fish and Wildlife Service, published a series of policies regarding listings under the ESA, including a policy for peer review of scientific data (59 FR 34270). OMB issued its Final Information Quality Bulletin for Peer Review on December 16, 2004. The Bulletin became effective on June 16, 2005, and generally requires that all ''influential scientific information'' and ''highly influential scientific information'' disseminated on or after that date be peer reviewed. The intent of the peer review policy is to ensure that decisions are based on the best scientific and commercial data available. Independent peer reviewers will be selected to review the status review report from the academic and scientific community, tribal and other Native American groups, Federal and state agencies, the private sector, and public interest groups.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: October 27, 2011.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2011–28430 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 100217095–1652–02]

RIN 0648–AY56

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Amendment 32

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Amendment 32 to the Fishery Management Plan for the Reef Fish

Resources of the Gulf of Mexico (FMP) prepared by the Gulf of Mexico Fishery Management Council (Council). If implemented, this rule would adjust the commercial gag quota and recreational annual catch target (ACT) for 2012 through 2015 and subsequent fishing years, consistent with the gag rebuilding plan established in Amendment 32; adjust the shallow-water grouper (SWG) quota; adjust the commercial and recreational sector's annual catch limits (ACLs) for gag and red grouper; adjust the commercial ACL for SWG; establish a formula-based method for setting gag and red grouper multi-use allocation for the grouper/tilefish individual fishing quota (IFQ) program in the Gulf of Mexico (Gulf); set the recreational gag fishing season from July 1 through October 31; reduce the gag commercial size limit to 22 inches (59 cm) total length (TL); and modify the gag and red grouper accountability measures (AMs). In addition, Amendment 32 would establish gag commercial ACTs and a 10-year gag rebuilding plan consistent with the requirements of the Magnuson-Stevens Act. This proposed rule is intended to end overfishing of gag, allow the gag stock to rebuild, and co-manage gag and red grouper by implementing concurrent management measures.

DATES: Written comments must be received on or before December 2, 2011.

ADDRESSES: You may submit comments on the proposed rule identified by ''NOAA–NMFS–2011–0135'' by any of the following methods:

- *Electronic submissions:* Submit electronic comments via the Federal e-Rulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Peter Hood, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

To submit comments through the Federal e-Rulemaking Portal: *http://www.regulations.gov,* click on ''submit a comment,'' then enter ''NOAA–NMFS–2011–0135'' in the keyword search and click on ''search.'' To view posted comments during the comment period, enter ''NOAA–NMFS–2011–0135'' in the keyword search and click on ''search.'' NMFS will accept anonymous comments (enter N/A in the required field if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Comments through means not specified in this rule will not be accepted.

Electronic copies of Amendment 32, which includes a draft environmental impact statement (DEIS), an initial regulatory flexibility analysis (IRFA), and a regulatory impact review, may be obtained from the Southeast Regional Office Web Site at *http://sero.nmfs.noaa.gov/sf/GrouperSnapperandReefFish.htm.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, Southeast Regional Office, NMFS, *telephone:* (727) 824–5305; *email: Peter.Hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery of the Gulf of Mexico is managed under the FMP. The FMP was prepared by the Council and is implemented through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Act.

Background

The Magnuson-Stevens Act requires NMFS and regional fishery management councils to prevent overfishing and achieve, on a continuing basis, the optimum yield (OY) from federally managed fish stocks. These mandates are intended to ensure fishery resources are managed for the greatest overall benefit to the nation, particularly with respect to providing food production and recreational opportunities, and protecting marine ecosystems. To further this goal, the Magnuson-Stevens Act requires fishery managers to specify their strategy to rebuild overfished stocks to a sustainable level within a certain time frame, and to minimize bycatch and bycatch mortality to the extent practicable. The reauthorized Magnuson-Stevens Act, as amended through January 12, 2007, requires the councils to establish ACLs for each stock/stock complex and AMs to ensure these ACLs are not exceeded. This proposed rule addresses these requirements for gag, red grouper, and the SWG complex.

Status of Stocks

Southeast Data, Assessment, and Review (SEDAR) update stock assessments were conducted for gag and red grouper in 2009. For gag, the assessment indicated the stock size had declined since 2005 and that a large part of the decline was attributed to a 2005 episodic mortality event (most likely associated with red tide). The update assessment indicated the gag stock was both overfished and undergoing overfishing. The Council was informed of this status determination in August 2009.

A rerun of the update assessment for gag was completed by the SEDAR update assessment review panel in December 2010. This rerun assessment identified issues with gag discards and was reviewed by the Council's Scientific and Statistical Committee (SSC) in January 2011. The rerun indicated the gag stock had improved from the 2009 update assessment; however, the improvement was not substantial enough to change the status of the gag stock. Based on the rerun, the Council requested a series of temporary rules to manage the gag stock until Amendment 32 could be implemented. The most recent temporary rule set the gag commercial quota to 430,000 lb (195,045 kg) and established a gag recreational season from September 16 through November 15 (76 FR 31874, June 2, 2011) and became effective June 1, 2011.

For red grouper, a 2009 SEDAR update assessment indicated that although the stock continues to be neither overfished nor undergoing overfishing, the stock has declined since 2005. In late 2010, after reviewing the rerun of the assessment update, the SSC recommended that the overfishing limit for red grouper be set at 8.10 million lb (3.67 million kg) (the equilibrium yield at F_{MSY} (the fishing mortality associated with harvesting the maximum sustainable yield) and the ABC be set at 7.93 million lb (3.60 million kg) (the F associated with equilibrium optimum yield ($F_{REBUILD}$)).

At the request of the Council, NMFS ran a new projection in 2011 that incorporated revised 2010 landings. Actual landings from 2010 were lower than projected, likely due to new longline restrictions implemented through Amendment 31 to the FMP (75 FR 21512, April 26, 2010) and disruptions in the fishery associated with the Deepwater Horizon oil spill that occurred in April 2010. The yield streams from this rerun showed that TAC could be increased in 2011. The Council has submitted a regulatory amendment for red grouper that, if approved, will increase the 2011 TAC and will set TAC through 2015 and subsequent fishing years, following F_{OY} (fishing mortality associated with harvesting at the optimum yield stream as the stock rebuilds). The regulatory amendment also includes a provision to increase the red grouper bag limit.

Gag Rebuilding Plan

The Council selected a 10-year rebuilding plan in Amendment 32 for gag. This is the maximum time frame allowed under the requirements of the Magnuson-Stevens Act. However, because the Council intends to manage the stock using the F_{OY} yield stream, which results in more restrictive TACs than $F_{REBUILD}$, the stock is projected to be rebuilt in 7 years. Given management uncertainties and uncertainties regarding stock assessment projections more than a few years in the future, a 10-year rebuilding plan would allow for fluctuations in catches and provide leeway to account for the needs of fishing communities when setting catch levels and management measures.

Management Measures Contained in This Proposed Rule

ACLs and ACTs

Based on protocols developed in Amendment 30B, sector-specific gag ACLs are derived from allocating the ABC between sectors.

The allocation of gag between the commercial and recreational sectors is 39 percent and 61 percent, respectively. This rule would implement ACLs for the gag commercial and recreational sectors based on this allocation. The ACLs would be set at the $F_{REBUILD}$ (the fishing mortality associated with the harvest needed to rebuild the stock). The ACTs (for the recreational sector only) would be set at the F_{OY} (the fishing mortality associated with harvesting the optimum yield).

This rule would set the commercial gag ACLs at 0.788 million lb (0.357 million kg) for 2012, 0.956 million lb (0.434 million kg) for 2013, 1.100 million lb (0.499 million kg) for 2014, and 1.217 million lb (0.552 million kg) for 2015 and subsequent fishing years. For the recreational sector, this rule would set the ACLs at 1.232 million lb (0.599 million kg) for 2012, 1.495 million lb (0.678 million kg) for 2013, 1.720 million lb (0.780 million kg) for 2014, and 1.903 million lb (0.863 million kg) for 2015 and subsequent fishing years.

This rule would set the recreational ACTs for gag at 1.031 million lb (0.468 million kg) for 2012, 1.287 million lb (0.584 million kg) for 2013, 1.519 million lb (0.689 million kg) for 2014, and 1.708 million lb (0.775 million kg) for 2015 and subsequent fishing years. Recreational landings would be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.

Reductions to the gag quota under the rebuilding plan assume a proportional reduction in dead discards of gag. However, due to the limited amount of gag IFQ allocation available in the initial years of the gag rebuilding plan, gag bycatch and discards from fishermen targeting red grouper or other fish may be higher than assumed in the assessment projections. Therefore, the Council determined the quota should be reduced from the ACT by 14 percent to account for additional dead discards not accounted for in the assessment analyses. Therefore, this rule would set the commercial gag quota at 0.567 million lb (0.257 million kg) for 2012, 0.708 million lb (0.321 million kg) for 2013, 0.835 million lb (0.378 million kg) for 2014, and 0.939 million lb (0.426 million kg) for 2015 and subsequent fishing years.

Reductions in the gag quota correspond to reductions in the SWG quota. Therefore, this rule would set the commercial SWG quota at 6.347 million lb (2.879 million kg) for 2012, 6.648 million lb (3.015 million kg) for 2013, 6.875 million lb (3.118 million kg) for 2014, 7.069 million lb (3.206 million kg) for 2015 and subsequent fishing years.

For red grouper, the protocols for setting sector-specific ACLs are similar to those for gag. The ABC recommended by the SSC is the equilibrium OY. This value was estimated at 7.93 million lb (3.60 million kg). Using the 76 percent commercial and 24 percent recreational allocation as established through Amendment 30B to the FMP (April 16, 2009, 74 FR 17603), this rule would set the commercial ACL at 6.03 million lb (2.735 million kg) and the recreational ACL at 1.90 million lb (0.862 million kg). The rule would set the recreational ACT at 1.730 million lb (0.785 million kg). Recreational landings would be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP. Red grouper commercial quotas and ACTs are being established through a separate regulatory amendment that is expected to become effective in late 2011.

Because the commercial SWG ACL is the sum of the commercial gag and red grouper ACLs, in addition to the 0.41 million lb (0.19 kg) of SWG allowance, the rule proposes to set the commercial SWG ACL at 8.04 million lb (3.65 million kg).

AMs

This proposed rule would modify the AMs for gag, red grouper, and SWG. AMs are intended to prevent ACLs from being exceeded or mitigate overages after ACLs have been exceeded. For the commercial sector, the current AMs were implemented through Amendment 30B to the FMP (74 FR 17603, April 16, 2009), before red grouper, gag and SWG were managed under an IFQ program. Therefore, AMs were triggered if the sector exceeded the respective species' quota. However, the IFQ program acts as an AM because the overall quota is divided among shareholders and the program includes controls that do not allow shareholders to exceed their individual allocation of the quota. To reduce redundancy in the commercial AMs, this rule proposes to eliminate the quota-based AM in favor of the existing IFQ program.

For the recreational sector, the current AMs pertain to red grouper and gag. The AMs restrict subsequent increases in future ACTs and ACLs if the current year's ACL is exceeded. The AMs also allow the Assistant Administrator for Fisheries (AA) to reduce the length of the following recreational SWG fishing season by the amount necessary to ensure recreational landings do not exceed the gag or red grouper ACT the following fishing year.

Current recreational AMs for gag and red grouper have no provisions for handling overages or in-season adjustments as authorized under the National Standard 1 guidelines (74 FR 3178, January 16, 2009). Overage adjustments are needed particularly for gag to follow guidance for stocks and stock complexes in rebuilding plans to include overage adjustments that reduce the ACLs in the next fishing year.

This rule would add an overage adjustment and in-season recreational AMs for gag and red grouper. Should gag or red grouper be in a rebuilding plan and the ACL exceeded, the overage adjustment would be equal to the full amount of the overage, unless the best scientific information available shows that a greater, lesser, or no overage adjustment is needed to mitigate the effects of the overage. In addition, the rule proposes that if gag or red grouper landings have met or are projected to exceed the ACL, as estimated by the Southeast Fisheries Science Center (SEFSC), without regard to overfished status, the AA would file a notification with the Office of the Federal Register closing the recreational harvest for the species projected to reach its ACL for the rest of the fishing year on the date the ACL is projected to be harvested.

In addition to these AMs, this rule proposes an AM for recreational red grouper that incorporates an adaptive management approach should the recreational sector exceed its ACL. A red grouper regulatory amendment, currently being reviewed by NMFS, includes a red grouper bag limit increase from two to four fish, within the four-fish aggregate grouper bag limit.

The adaptive management AM would reduce the bag limit from four fish to three fish if, at the end of any season, it is determined that the recreational sector has exceeded the recreational red grouper ACL. The bag limit would be reduced from three fish to two fish if, at the end of any subsequent season, it is determined that the recreational sector has exceeded its ACL again. The minimum bag limit for red grouper would remain at two fish, regardless of whether the recreational sector exceeded the ACL in subsequent fishing years. Based on past annual landings, a two-fish bag limit is likely to be sufficient to avoid exceeding the recreational ACL.

Other Commercial Management Measures

The commercial grouper and tilefish fisheries are currently managed under an IFQ program implemented on January 1, 2010, through Amendment 29 to the FMP (74 FR 44732, August 31, 2009). To allow for flexibility and account for varying gag to red grouper ratios across the Gulf, at the beginning of each fishing year, a percentage of the gag and red grouper allocation is designated as multi-use allocation, valid for harvesting either gag or red grouper. Currently, 4 percent of the red grouper allocation and 8 percent of the gag allocation are designated as multi-use allocation. However, under the red grouper and gag ACLs proposed in this rule, the current multi-use allocations could result in commercial harvest of red grouper or gag exceeding its sector ACL. To prevent this from occurring, this rule proposes that if a stock is not under a rebuilding plan, the respective multi-use allocation would be based on the difference between the ACL and the ACT. If a stock is under a rebuilding plan, as with gag, then no multi-use allocation would be set aside. Therefore, red grouper multi-use allocation would be set to zero if gag is under a rebuilding plan. The equations used to determine multi-use allocation for gag and red grouper are as follows:

Gag Multi-use (in percent) = 100× [Red Grouper ACL − Red Grouper Allocation]/Gag Allocation.

Red Grouper Multi-use (in percent) = 100× [Gag ACL − Gag Allocation]/Red Grouper Allocation.

National Standard 9 dictates bycatch and the mortality of unavoidable bycatch should be minimized to the extent practicable. Because the commercial sector fishes in deeper waters on average than the recreational sector, it has a higher discard mortality rate. One possible way to reduce gag regulatory dead discards is to reduce the commercial minimum size limit so that gag that would have been discarded can be retained. To reduce gag discards, this rule would reduce the minimum size limit of gag from 24 inches (61 cm) to 22 inches (56 cm) TL. Until an IFQ shareholder's gag allocation is reached, this alternative is expected to reduce total gag discards (live plus dead) by 31 percent for the vertical line component of the Gulf reef fish fishery and by 27.8 percent for the longline component of the Gulf reef fish fishery. After an IFQ shareholder's gag allocation has been fished, all gag would be discarded. However, a commercial fisherman without IFQ allocation available to harvest gag would not specifically target gag and so the species would be encountered less frequently as fishermen target other stocks for harvest. An additional advantage of this measure is that it would simplify enforcement by having a single size limit for both sectors.

Other Recreational Management Measures

In determining the percentage reductions needed in total recreational gag removals (landed fish plus dead discards), the Council evaluated two baseline time periods: 2006–2008 when effort was high, and 2009 when effort was low. The needed reductions are between 36 percent and 61 percent depending on the baseline time period and F value used. In addition, different management strategies used to achieve reductions in the landed catch of gag change the number of discards and dead discards. Thus, the number of dead discards was taken into account in calculating the expected reductions from different management strategies.

In selecting a recreational management strategy, the Council favored achieving the longest fishing season for gag, while maintaining the current size and bag limits. Therefore, this rule proposes to set the gag fishing season from June 1 through October 31. The current two-gag bag limit within the four-fish grouper aggregate bag limit and 22-inch (56-cm) TL minimum size limit will remain unchanged.

Other Changes to Codified Text

This proposed rule also includes minor revisions to codified text to align existing language with new codified terminology. In § 622.49(a)(1) and (2), ''commercial fishery'' and ''recreational fishery'' would be revised to read ''commercial sector'' and ''recreational sector'', and in § 622.49(a)(2)(ii), the last two sentences would be revised to a more generic statement to read, ''Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.'' These revisions are consistent with the terminology used in Amendment 32.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the AA has determined that this proposed rule is consistent with Amendment 32, 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.

NMFS prepared an IRFA, as required by section 603 of the Regulatory Flexibility Act, for this proposed rule. The IRFA describes the economic impact that this rule, if adopted, would have on small entities. A description of the action, why it is being considered, and the objectives of, and legal basis for this action are contained at the beginning of this section in the preamble and in the **SUMMARY** section of the preamble. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. The preamble of this proposed rule provides a statement of the need for and objectives of this proposed rule, and it is not repeated here.

This rule is expected to directly affect commercial harvesting and for-hire operations. The Small Business Administration (SBA) has established size criteria for all major industry sectors in the U.S., including fish harvesters. A business involved in fish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $4.0 million (NAICS code 114111, finfish fishing) for all its affiliated operations worldwide. For for-hire vessels, the other qualifiers apply and the receipts threshold is $7.0 million (NAICS code 713990, recreational industries).

This rule is expected to directly affect commercial fishing vessels whose owners possess gag or red grouper fishing quota shares and for-hire fishing vessels that harvest gag. As of October 1, 2009, 970 entities owned a valid commercial Gulf reef fish permit and thus were eligible for initial shares and allocation in the grouper and tilefish

IFQ program. Of these 970 entities, 908 entities initially received shares and allocation of grouper or tilefish, and 875 entities specifically received gag shares and an initial allocation of the commercial sector's gag quota in 2010. These 875 entities are expected to be directly affected by the actions to reduce the gag commercial quota to 86 percent of the ACT to account for dead discards, modify the percentages of red grouper and gag allocation that can be converted into multi-use allocation, and reduce the commercial size limit for gag. Of these 875 entities, 815 also received red grouper shares and an initial allocation of the commercial sector's red grouper quota in 2010.

Of the 875 entities that initially received gag shares, 215 were not commercially fishing in 2008 or 2009 and thus had no commercial fishing revenue during these years. On average, these 215 entities received an initial allocation of 874 lb (397 kg) of gag in 2010. Eight of these 215 entities also received a bottom longline endorsement in 2010. These 8 entities received a much higher initial allocation of gag in 2010, with an average of 3,139 lb (1,427 kg).

The other 660 entities that initially received gag shares and allocations in 2010 were active in commercial fisheries in 2008 or 2009. The maximum annual commercial fishing gross revenue in 2008 or 2009 by an individual vessel with commercial gag fishing quota shares was approximately $606,000 (2008 dollars).

The average charterboat is estimated to earn approximately $88,000 (2008 dollars) in annual gross revenue, while the average headboat is estimated to earn approximately $461,000 (2008 dollars). Based on these values, all commercial and for-hire fishing vessels expected to be directly affected by this rule are determined for the purpose of this analysis to be small business entities.

Of the 660 commercial fishing vessels with commercial landings in 2008 or 2009, 139 vessels did not have any gag landings in 2008 or 2009. Their average annual gross revenue in these 2 years was approximately $50,800 (2008 dollars). The vast majority of these vessels' commercial fishing revenue is from a combination of snapper, mackerel, dolphin, and wahoo landings. On average, in 2010, these vessels received an initial allocation of 540 lb (245 kg) of gag quota.

The remaining 521 commercially active fishing vessels did have landings of gag in 2008 or 2009. Their average annual gross revenue from commercial fishing was approximately $71,000 (2008 dollars) between the 2 years. On average, these vessels had 2,375 lb (1,080 kg) and 1,300 lb (591 kg) of gag landings in 2008 and 2009 respectively, or 1,835 lb (834 kg) between the 2 years. Gag landings accounted for approximately 8 percent of these vessels' annual average gross revenue, and thus they are somewhat, though not significantly, dependent on revenue from gag landings. These vessels' average initial gag allocation in 2010 was 2,121 lb (964 kg). Therefore, on average, their 2008 gag landings were very near their 2010 gag allocation, but their 2009 gag landings were considerably less than their 2010 allocation.

Of these 521 vessels, 52 vessels also received a bottom longline endorsement in 2010. These particular vessels' average annual revenue was approximately $156,000 (2008 dollars) in 2008 and 2009. Revenue from gag landings decreased from approximately $15,900 to $8,400 in 2009 and thus they became relatively less dependent on gag landings. These vessels are highly dependent on revenue from red grouper landings, which accounted for 54 percent and 47 percent of their gross revenue in 2008 and 2009, respectively. Revenue from deep-water grouper (DWG) landings decreased only slightly, from approximately $36,000 in 2008 to $31,000 in 2009, and thus these vessels became relatively more dependent on revenue from DWG landings. Their average initial 2010 allocation of gag was approximately 5,507 lb (2,503 kg) while their average gag landings were 3,933 lb (1,788 kg) and 2,204 lb (1,002 kg) in 2008 and 2009, respectively. Thus, vessels that now have a bottom longline endorsement have been harvesting well below that allocation in recent years, particularly in 2009.

The for-hire fleet is comprised of charter vessels, which charge a fee on a vessel basis, and headboats, which charge a fee on an individual angler (head) basis. The harvest of gag in the exclusive economic zone (EEZ) by for-hire vessels requires a charter vessel/headboat permit for Gulf reef fish. On March 23, 2010, there were 1,376 valid or renewable for-hire Gulf reef fish permits. A valid permit is a non-expired permit. Expired reef fish for-hire permits may not be actively fished, but are renewable for up to 1 year after expiration. Because of the extended permit renewal period, numerous permits may be expired but still renewable at any given time of the year during the renewal period after the permit's expiration. The majority (823, or approximately 60 percent) of the 1,376 valid or renewable permits were registered with Florida addresses. The registration address for the Federal permit does not restrict operation to Federal waters off that state; however, vessels would be subject to any applicable state permitting requirements. Although the permit does not distinguish between headboats and charter vessels, it is estimated that 79 headboats operate in the Gulf. The majority of these vessels (43, or approximately 54 percent) operate from Florida ports. Given that nearly 99 percent of target effort for gag and 97 percent of the economic impacts from the recreational sector for gag in the Gulf reef fish fishery are in west Florida, it is assumed that the 823 for-hire vessels (780 charter vessels and 43 headboats) in Florida are expected to be directly affected by the proposed action to establish a recreational gag fishing season of July 1 through October 31.

Establishing a rebuilding plan for gag not expected to generate direct, adverse economic effects on commercial or for-hire entities. Thus, the proposed action to establish a rebuilding plan for gag that would rebuild the gag stock to a level consistent with producing maximum sustainable yield in 10 years or less is not expected to reduce profits for commercial or for-hire entities.

Net operating revenues (NOR) are assumed to be representative of profit for for-hire vessels. It is assumed that 823 for-hire vessels, 780 charter vessels, and 43 headboats, participate in the recreational gag component of the Gulf reef fish fishery. Estimates of NOR from recreational fisheries other than gag, and thus across all fisheries in which these charter vessels and headboats participate, are not currently available. However, on average, NOR for charter vessels from trips targeting gag are estimated to be approximately $1.56 million per year while NOR for headboats from trips targeting gag are estimated to be $91,300 per year. NOR for all trips targeting gag are estimated to be approximately $1.65 million per year. The average annual NOR from trips targeting gag are estimated to be $2,000 per charter vessel and $2,124 per headboat.

When the length of the recreational gag season is reduced and the daily bag limit for gag is set at zero, some trips that formerly targeted gag will instead target other species while other trips that formerly targeted gag will be cancelled. Assuming the NOR per trip is constant regardless of the species targeted, for-hire operators will only lose NOR from trips cancelled as a result of the shortened season length. Information regarding the number of trips cancelled as a result of the

shortened season is not currently available. Thus, this analysis assumes all of the current for-hire trips targeting gag will be cancelled when the recreational sector is closed. Because some of these trips would probably not be cancelled, this assumption is expected to overestimate the actual reduction in NOR associated with a shorter season. Thus, the following estimates of losses in NOR and profit for charter vessels and headboats should be considered maximum values.

Under the proposed action to establish a recreational gag fishing season of July 1 through October 31, the losses in NOR from trips targeting gag for charter vessels and headboats are estimated to be approximately $1,304,000 and $76,000, respectively, and thus NOR for all trips targeting gag is estimated to be approximately $1,380,000. The average annual losses in NOR from trips targeting gag are estimated to be $1,672 and $767 per charter vessel and headboat, respectively. These NOR losses represent a loss in profit from trips targeting gag of approximately 84 percent and 36 percent per charter vessel and headboat, respectively.

The proposed action to establish a recreational gag fishing season of July 1 through October 31 is not expected to affect profit from trips not targeting gag for charter vessels and headboats. For-hire vessel dependence on fishing for individual species cannot be determined with available data. Although some for-hire vessels are likely more dependent on trips that target gag than other for-hire vessels, overall, about 3 percent of for-hire anglers are estimated to target gag. As a result, while the action would be expected to substantially affect the NOR derived from gag trips, overall, gag trips do not comprise a substantial portion of total for-hire trips nor would they, by extension, be expected to account for a substantial portion of total for-hire NOR.

Under the proposed action to increase the recreational bag limit for red grouper from two fish to four fish, the number of trips in all recreational fishing modes is assumed to remain the same regardless of any change in the red grouper bag limit. As such, no changes to producer surplus in the for-hire sector are expected. Thus, the proposed action is not expected to reduce profits for for-hire entities.

The 215 entities with gag shares that did not participate in commercial fishing in 2008 or 2009 have no commercial fishing revenue and did not earn profit from commercial fishing in those 2 years. Under the proposed action to reduce the commercial gag quota to 86 percent of the ACT to account for dead discards, their average allocation of gag in 2012 would be reduced from 421 lb (191 kg) to 362 lb (165 kg), or by approximately 59 lb (27 kg). Using the average 2008 price of $3.52 per lb, this loss in allocation could potentially represent a loss of nearly $208 (2008 dollars) in gross revenue per entity. Using the 2010 average price of $1.00 per lb of gag allocation, this loss in allocation could potentially represent a loss of $59 (2008 dollars) in net revenue per entity. For 8 of these 215 entities that also possess longline endorsements, their average allocation of gag in 2012 would be reduced from 1,512 lb (687 kg) to 1,300 lb (591 kg), or by 212 lb (96 kg). Thus, their potential losses in gross revenue and net revenue, estimated to be $746 and $212 (2008 dollars) respectively, are expected to be somewhat higher.

However, in general, these potential losses in gross revenue and net revenue would only be realized if these 215 entities not only become active in commercial fishing but also specifically intend to harvest gag in 2012 and at a level above their reduced allocation. That is, a reduction in allocation can only lead to a reduction in landings, and thus gross revenue, if these entities intend to harvest at levels above their reduced allocation. Alternatively, these losses in gross and net revenue could be due to these entities' inability to sell the allocations they are losing under the proposed action, though this possibility presumes that a demand for these allocations exists. Regardless, the significance of these potential losses in gross and net revenue to these 215 entities cannot be evaluated given the lack of information on potential gross revenue, net revenue, and profits from commercial fishing in general and specifically for gag.

Similarly, for the 139 entities with gag shares that participated in commercial fisheries other than gag, they earned approximately $50,800 in annual gross revenue on average in 2008 and 2009. Profit estimates for these vessels are not currently available. However, because they did not have any gag landings, none of their gross revenue and thus none of their potential profits were the result of gag harvests. Under the proposed action to reduce the commercial gag quota to 86 percent of the ACT to account for dead discards, their average allocation of gag in 2012 would be reduced from 260 lb (118 kg) to 224 lb ((102 kg), or by 36 lb (16 kg). Using the average 2008 price of $3.52 per lb, this loss in allocation could potentially represent a loss of $127 (2008 dollars) in gross revenue per entity. Using the 2010 average price of $1.00 per lb of gag allocation, this loss in allocation could potentially represent a loss of approximately $36 (2008 dollars) in net revenue per entity.

However, these potential losses in gross and net revenue could only lead to a loss in profits if these 139 entities intend to commercially harvest gag in 2012 and at a level above their reduced allocation. That is, a reduction in allocation can only lead to a reduction in landings if these entities intend to harvest at levels above their reduced allocation. Thus, for example, if these vessels intended to harvest gag in 2012 at a level equivalent to their 2012 allocation, and this harvest was in addition to, rather than in place of, their recent commercial fishing activities, the reduction in allocation could lead to a maximum loss of approximately .3 percent in gross revenue, which could in turn reduce net revenue and profits. Alternatively, losses in gross and net revenue could be due to these entities' inability to sell the allocations being lost under the proposed action, though this possibility presumes that a demand for these allocations exists.

The 521 entities with gag shares that commercially harvested gag in 2008 or 2009 earned approximately $71,000 (2008 dollars) in annual gross revenue on average in 2008 and 2009. Profit estimates for these vessels are not currently available. However, gag landings accounted for approximately 8 percent of these vessels' annual average gross revenue, and thus they are somewhat but not significantly dependent on revenue from gag landings. Under the proposed action to reduce the commercial gag quota to account for dead discards, these vessels' 2012 gag allocations would be reduced from 1,022 lb (465 kg) to 879 lb (400 kg), or 143 lb (65 lb) on average. As these vessels have been harvesting at levels near their 2010 allocation in recent years on average, this reduction in gag allocation is likely to lead to an equivalent reduction in gag landings and therefore gross revenue. Using the average 2008 price of $3.52 per lb, it is estimated that these vessels could lose nearly $503 (2008 dollars), or approximately .7 percent, in annual gross revenue on average. Using the 2010 average price of $1.00 per lb of gag allocation, this loss in allocation would represent a loss of $503 (2008 dollars) in net revenue per entity. Since net revenue is assumed to be representative of profits for commercial vessels, these vessels are expected to experience a reduction in profits.

However, 52 of these 521 vessels also received a bottom longline endorsement

in 2010. These particular vessels' average annual gross revenue was approximately $156,000 (2008 dollars) in 2008 and 2009, with gag landings accounting for approximately 8 percent of that gross revenue. These vessels are highly dependent on revenue from red grouper rather than gag landings. Under the proposed action to reduce the commercial gag quota, their allocation of gag in 2012 would decrease from 2,749 lb (1,250 kg) to 2,364 lb (1075 kg), or by 385 lb (175 kg). As these vessels have harvested at levels near their 2010 allocation in recent years on average, this reduction in gag allocation is likely to lead to an equivalent reduction in gag landings and therefore gross revenue. Using the average 2008 price of $3.52 per lb, it is estimated that these vessels could lose $1,355 (2008 dollars), or approximately .9 percent, in annual gross revenue on average. Using the 2010 average price of $1.00 per lb of gag allocation, this loss in allocation would represent a loss of approximately $1,355 (2008 dollars) in net revenue per entity. Since net revenue is assumed to be representative of profits for commercial vessels, these vessels are expected to experience a reduction in profits.

No additional economic effects would be expected to result from the revised SWG quota because the updated SWG quota simply reflects the reduction in the commercial gag quota, the effects of which have already been discussed.

Given the proposed action to establish a rebuilding plan for gag, the conversion of red grouper allocation into multi-use allocation valid toward the harvest of red grouper or gag would be suspended under the proposed action to modify the percentages of red grouper and gag allocation that can be converted into multi-use allocation. Because red grouper is not under a rebuilding plan at this time, gag shareholders would be allowed to convert 8 percent of their gag allocation into multi-use allocation and thus no adverse economic effects are expected. However, minimal adverse economic effects are expected as a result of commercial fishing entities not being allowed to convert 4 percent of their red grouper allocation into multi-use allocation. Multi-use allocation that has been converted from red grouper allocation can only be used to possess, land, or sell gag after an entity's gag and gag multi-use allocation has been landed, sold, or transferred. Given the proposed reduction in the commercial gag quota due to dead discards, it is possible these entities will exhaust their gag and gag multi-use allocations. Gross revenue from gag landings is greater than gross revenue from an equivalent amount of red grouper landings because gag commands a relatively higher market price. Thus, gross revenue from commercial fishing and therefore profits per vessel could be slightly lower than if the conversion were allowed to continue.

Under the proposed action to reduce the commercial size limit for gag from 24 inches (61 cm) to 22 inches (56 cm) total length, commercial fishing entities would be allowed to retain more and discard less of the gag they catch and thus are expected to be economically better off relative to the status quo. However, if commercial fishermen prefer to harvest larger gag due to a higher market demand for larger fish, then additional high-grading may be possible because the commercial sector is managed under the IFQ program. As such, few additional gag may be retained and thus the potential increases in gross revenue, net revenue, and profits per vessel are likely minimal.

Establishing AMs is not expected to generate direct, adverse economic effects on commercial or for-hire entities. Direct, adverse economic effects would only occur if and when the AMs are actually triggered. This action would replace current AMs established under Amendment 30B to the FMP with the current IFQ program because an IFQ functions as an AM. This action would also add an overage adjustment and an in-season closure to the current AMs for the recreational sector when the gag or red grouper stocks are overfished and under a rebuilding plan. Because red grouper is not overfished or under a rebuilding plan, this action does not currently apply to the red grouper component of the reef fish fishery. The action to establish a recreational fishing season of July 1 through October 31 for gag is expected to restrain landings in the gag recreational sector well below its 2012 ACL, and in fact is intended and expected to constrain landings below the 2012 recreational annual catch target. In turn, the probability an overage adjustment or in-season closure will be required in 2013 is also minimal. Thus, the proposed action to establish new AMs for the commercial and recreational sectors of the gag, red grouper, and SWG component of the reef fish fishery is not expected to reduce profits for commercial or for-hire entities.

Three alternatives, including the status quo, were considered for the action to establish a rebuilding plan for gag that would rebuild the gag stock to a level consistent with producing maximum sustainable yield in 10 years or less. In the absence of all fishing mortality, including bycatch mortality, the shortest possible time in which the gag stock can rebuild is 5 years. Under the National Standard 1 guidelines, the maximum time allowed for rebuilding the gag stock is 10 years. In the Generic ACL/AM Amendment, currently under development, the proposed ACLs are based on yields that are projected to rebuild the stock in 10 years, while the proposed ACTs are based on yields that are projected to rebuild the stock in 7 years.

The first alternative, the status quo, would not have established a rebuilding plan for gag. The fishing mortality rate for gag has shown an increasing trend over time and fishing mortality rates in recent years are not consistent with rebuilding or maintaining the gag stock at its maximum sustainable yield level. Moreover, because the gag stock has been determined to be overfished and undergoing overfishing, this alternative does not comply with Magnuson-Stevens Act requirements regarding rebuilding plans.

The second alternative would have established a rebuilding plan that would rebuild the gag stock to a level consistent with producing maximum sustainable yield in 7 years or less. Seven years is the estimated time to rebuild if the stock is managed at F_{OY} rather than the rate corresponding to a 10-year rebuilding plan ($F_{rebuilding}$). Although the yields under a 7-year rebuilding plan would eventually catch up to those for a 10-year plan, the initial catch targets in the early years would be smaller under a 7-year rebuilding plan relative to a 10-year rebuilding plan. Thus, this alternative would potentially imply more restrictive regulations and thus more adverse indirect economic effects in the short-term relative to the proposed action.

The third alternative would have established a rebuilding plan that would rebuild the gag stock to a level consistent with producing maximum sustainable yield in 5 years. If this alternative were adopted, strong measures to reduce bycatch of gag in other fisheries would also need to be considered. Because a total elimination of discard mortality is unlikely to be achieved, this alternative would likely result in the stock being slightly under the rebuilding target at the end of 5 years. Most importantly, this alternative would require a complete closure of the gag component of the reef fish fishery for at least 5 years. Therefore, this alternative would eliminate all net revenue from the commercial sector and all consumer and producer surplus from the recreational sector for at least 5 years and, as such, would lead to the most restrictive regulations and, thus,

considerably greater adverse indirect economic effects in the short-term relative to the proposed action.

Four alternatives, including the status quo, were considered for the action to establish a recreational gag fishing season of July 1 through October 31. The first alternative, the status quo, would maintain a year-round gag recreational fishing season, with the exception of the current February 1 through March 31 closed season for SWG. This alternative would be expected to result in a 14 percent reduction in gag removals relative to the 2006–2008 baseline and a 1 percent increase in gag removals relative to the 2009 baseline. As such, this alternative does not achieve the necessary reduction in removals to rebuild the gag stock, contrary to the Council's goals and objectives and Magnuson-Stevens Act requirements.

The second alternative, which would establish a gag recreational season of September 16 through November 15, would reduce gag removals by 60 percent relative to the 2009 baseline, which exceeds the annual catch target reduction of 47 percent. Relative to the 2006–2008 baseline, this alternative also reduces removals by 60 percent. Therefore, this alternative does not fully meet the annual catch target of 61 percent relative to the 2006–08 baseline, but does exceed the ACL and rebuilding yield reduction level of 53 percent. This alternative is more conservative biologically than the proposed action, but only allows a 61-day fishing season as opposed to the 123-day fishing season allowed under the proposed action.

The third alternative, which would establish a gag recreational season of January and April, would reduce removals by 52 percent, which exceeds the annual catch target reduction of 47 percent. Relative to the 2006–2008 baseline, this alternative reduces removals by 56 percent. This alternative does not fully meet the annual catch target of 61 percent relative to the 2006–2008 baseline, but it does exceed the ACL and rebuilding yield reduction level of 53 percent. This alternative is similar to the second alterative in that it allows 61 days of fishing, and thus is shorter than the 123-day fishing season allowed under the proposed action, but it splits the season into two segments to provide more fishing opportunities. Biologically, this alternative is as conservative as the proposed action.

The fourth alternative would establish the same gag recreational season of July 1 through October 31 as the proposed action. However, rather than maintain the current 22 inch (56 cm) recreational minimum size limit, it would implement a 22–30 inch (56–76 cm) slot limit. Although this alternative would achieve a larger reduction in removals relative to the proposed action, a larger percentage of those removals would consist of dead discards. Furthermore, a portion of those additional dead discards would consist of larger fish above the slot limit. These larger fish produce more eggs in spawning season. Thus, this alternative could negatively impact the spawning potential ratio and in turn the rate of rebuilding.

Two alternatives, including the status quo, were considered for the action to increase the recreational bag limit for red grouper from two fish to four fish. The first alternative, the status quo, would retain the current recreational bag limit for red grouper of two fish. The recreational ACL for red grouper has not been met in recent years. Recreational red grouper landings averaged less than 1 million lb (454,545 kg) between 2006 and 2009. With the planned increase in the red grouper TAC through a regulatory amendment currently under development, the recreational ACL would be increased from 1.51 million lb (686,364 kg) to 1.72 million lb (781,818 kg), which would create a larger difference between the ACL and the expected catch in 2012, and additional increases in the red grouper recreational ACL are planned through 2016. This alternative would not allow for-hire entities to increase their landings per trip even though the recreational sector's harvest has been and is expected to be well below its allocation. As such, opportunities to increase the economic value of red grouper harvests in the recreational sector would be unnecessarily foregone.

The second alternative would increase the recreational bag limit for red grouper from two fish to three fish. This alternative would allow for-hire entities to increase their landings per trip, but would not enhance their opportunities to increase the economic value of red grouper harvests to the same extent as the proposed action. Such opportunities should be enhanced as much as possible given the large difference between the recreational sector's ACL and the expected catch under the current bag limit. Like the proposed action, this alternative includes an adaptive feedback mechanism that would adjust the bag limit if the recreational sector exceeds its ACL, though it would not be a two-stage process as under the proposed action.

Two alternatives, including the status quo, were considered for the action to reduce the gag commercial quota to 86 percent of the ACT to account for dead discards. The first alternative, the status quo, would not adjust the gag commercial quota to account for dead discards. This alternative would set the gag commercial quota at the current ACT. The ACT assumes dead discards in the commercial sector will be reduced by the same proportion as landings. If this assumption is not valid, then total removals of gag will exceed the harvest levels projected in the assessment. The ACT provides a buffer against reaching the ACL, but this buffer may not be sufficient to offset increased removals due to dead discards.

The second alternative would reduce the gag commercial quota to 47 percent of the ACT to account for dead discards. This alternative represents the worst case scenario, under which dead discards are assumed to remain at their 2006–2008 level. Analyses associated with the 2011 gag interim rule indicated that, if dead discards remain at their 2006–2008 levels, the gag commercial quota would need to be reduced to 47 percent of the ACT in order to compensate for the increased removals. Although this alternative would provide the greatest allowance for dead discards and, thus, the highest likelihood of rebuilding the gag stock successfully, it is based on the unlikely assumption that dead discards will remain at their 2006–2008 levels. Longline vessels have historically landed about 34 percent of the commercial gag harvest. As a result of the longline endorsement requirements implemented in 2010, the number of reef fish longline vessels has decreased substantially. Of the 908 initial grouper/tilefish shareholders in 2010, 293 vessels used bottom longline or trap gear for commercial reef fish harvesting purposes between 1999 and 2007. However, only 62 of these vessels qualified for the bottom longline endorsement. Given the substantial reduction in the number of longline vessels, dead discards are expected to be considerably less now and in the future compared to their 2006–2008 levels. As such, reducing the gag commercial quota to 47 percent of the ACT would unnecessarily impose more significant economic and social impacts on commercial harvesters and associated communities relative to the proposed action.

Two alternatives, including the status quo, were considered for the action to modify the percentage of red grouper allocation that can be converted into multi-use allocation if a rebuilding plan for gag is in effect. The first alternative, the status quo, would allow 4 percent of the red grouper allocation to be converted into multi-use allocation at the beginning of each year. Under this

alternative, the amount of red grouper multi-use allocation could exceed the available gag commercial quota, thereby leading to harvests that exceed the ACL. Such a result is contrary to the purposes of the action to establish a rebuilding plan for gag that would rebuild the gag stock to a level consistent with producing maximum sustainable yield in 10 years or less and is therefore inconsistent with Magnuson-Stevens Act requirements and National Standard 1 guidance.

The second alternative would base the amount of red grouper multi-use allocation on the buffer between the gag ACL and ACT. Subsequent ACLs and ACTs may be set by the ACL/ACT control rule adopted in the Generic ACL/AM Amendment. Although a control rule has not been adopted yet, the alternatives currently under consideration would have little or no buffer for IFQ fisheries, which would render this alternative unusable. Furthermore, the gag ACL is set at the level where there is only a 50-percent probability of meeting the target to rebuild the gag stock in 10 years or less. Thus, this alternative will reduce the probability of the rebuilding plan being successful.

One alternative, the status quo, was considered for the action to modify the percentage of gag allocation that can be converted into multi-use allocation if a rebuilding plan for red grouper is in effect. Under this alternative, 8 percent of the gag allocation would be converted into multi-use allocation. If a rebuilding plan for red grouper was necessary in the future, this alternative could result in red grouper harvests that would exceed the commercial ACL in the future, which would in turn trigger AMs and reduce the ability of the red grouper stock to rebuild.

Three alternatives, including the status quo, were considered for the action to reduce the commercial gag minimum size limit from 24 inches (61 cm) to 22 inches (56 cm) in TL. The first alternative, the status quo, would maintain the commercial gag minimum size limit at 24 inches (61 cm) TL. The size at 50 percent female maturity is approximately 24 inches (61 cm) TL. Under this alternative, regulatory discards due to the minimum size limit would continue at the current rate, which is contrary to the Council's goal of reducing gag discards.

The second alternative would reduce the commercial gag minimum size limit from 24 inches (61 cm) to 20 inches (51 cm) TL. Until a commercial fisherman's IFQ allocation is reached, this alternative is expected to reduce total gag discards by 62 percent for the vertical line component of the commercial sector and by 47.2 percent for the longline component. At the same time, the number of gag needed to fill an IFQ allocation is expected to increase by 29.7 percent for the vertical line component and by 0.9 percent for the longline component. This alternative has a greater likelihood of creating a price differential by size, which would in turn likely result in additional high-grading as fishermen attempt to maximize the economic return on their IFQ shares. Additional high-grading would lead to higher rather than lower levels of gag discards, which is contrary to the Council's goals.

The third alternative would eliminate the minimum size limit and thus would effectively require all commercially caught gag be retained regardless of size. As a result, this alternative also effectively requires that each commercial fisherman possess sufficient gag allocation to cover all harvest of gag. Grouper sizes in the commercial sector have been recorded as small as 11 inches (28 cm) prior to the implementation of size limits, but the numbers landed are few below 18 inches (46 cm). At a minimum size limit of 18 inches (46 cm), the expected reduction in total gag discards is 79.9 percent for the vertical line component and 66.7 percent for the longline component. At the same time, the increase in number of gag needed to fill an individual's allocation of gag is expected to be 38.2 percent for the vertical line component and 1.3 percent for the longline component. At minimum size limits less than 18 inches (46 cm), these values will change little because both gears become less selective for gag at smaller sizes. To the extent a market demand for larger fish exists, this alternative is likely to create a price differential for larger size fish. Given the limited amount of gag allocation expected to be distributed under the proposed gag commercial quota, this alternative could encourage high-grading by commercial fishermen, which would lead to higher rather than lower levels of gag discards, contrary to the Council's goals.

Four alternatives, including the status quo, were considered for the action to expand the current time and area closures off the west coast of Florida. The first alternative would expand the current closed areas of Madison-Swanson and the Edges by approximately 70 square miles (181 square km). Four options were considered under this alternative. The first option would prohibit all fishing from November 1 through April 30, but allow surface trolling from May 1 through October 31. The second option would prohibit all fishing from November 1 through April 30, but allow all fishing from May 1 through October 31. The third option would prohibit all fishing from January 1 through April 30, but allow all fishing from May 1 through December 31. The fourth option would prohibit all fishing year-round. The percentage of gag and red grouper commercial landings coming from this area ranges from 0.55 percent for gag and 0.06 percent of red grouper under the third option to 1.25 percent and 0.39 percent for gag and red grouper respectively under fourth option. These numbers indicate it is unlikely that gag and particularly red grouper are being targeted in this area. Thus, the expected reduction in gag bycatch is relatively small and, thus, so are the biological benefits.

The second alternative would expand the current closed areas of Madison-Swanson and the Edges by approximately 244 square miles (632 square km). Four options were considered under this alternative. The first option would prohibit all fishing from November 1 through April 30, but allow surface trolling from May 1 through October 31. The second option would prohibit all fishing from November 1 through April 30, but allow all fishing from May 1 through October 31. The third option would prohibit all fishing from January 1 through April 30, but allow all fishing from May 1 through December 31. The fourth option would prohibit all fishing year-round. Gag bycatch is expected to increase as a result of the proposed action to reduce the gag commercial quota and the resulting reduction in the gag to red grouper quota ratio. The percentage of gag and red grouper commercial landings coming from this area ranges from 3.23 percent for gag and 0.26 percent of red grouper under the third option to 5.92 percent and 0.93 percent for gag and red grouper respectively under fourth option. If this alternative was selected, by limiting where recreational fishermen may fish, the adverse economic and social effects incurred as a result of the proposed recreational fishing season for gag would be amplified, particularly under the fourth option. Furthermore, the Council determined that these additional adverse economic and social effects on the recreational sector outweighed the biological benefits to the gag stock.

The third alternative would modify the seasonal closure dates of The Edges 40 fathom contour area, which is approximately 390 square miles (1,010 square km) in size and currently

prohibits all fishing from January 1 through April 30 and allows all fishing from May 1 through December 31. Four options were also considered under this alternative. The first option would prohibit all fishing from November 1 through April 30, but allow surface trolling from May 1 through October 31. The second option would prohibit all fishing from November 1 through April 30, but allow all fishing from May 1 through October 31. The third option would prohibit all fishing from January 1 through April 30, but allow all fishing from May 1 through December 31. The fourth option would prohibit all fishing year-round. This alternative would close a larger area than the other alternatives that would expand the existing closures. Because The Edges 40 fathom contour area is relatively large, the percentage of gag and red grouper commercial landings coming from it is greater than under the other alternatives that would expand the existing closures, ranging from 4.13 percent for gag and 0.57 percent of red grouper under the third option to 8.92 percent and 2.41 percent for gag and red grouper respectively under fourth option. Thus, the expected reduction in gag bycatch is greater than under the other alternatives that would expand the existing time/area closures. If this alternative was selected, by limiting where recreational fishermen may fish, the adverse economic and social effects incurred as a result of the proposed recreational fishing season for gag would be amplified, particularly under the fourth option. Furthermore, the Council determined that these additional adverse economic and social effects on the recreational sector outweighed the biological benefits to the gag stock.

The fourth alternative would modify the seasonal closure dates for the Madison Swanson and Steamboat Lumps closed areas, which cover approximately 219 square miles (567 square km). At present, these closures prohibit all fishing from November 1 through April 30, but allow surface trolling for species other than reef fish from May 1 through October 31. The first option would prohibit all fishing from November 1 through April 30, but allow surface trolling from May 1 through October 31. The second option would prohibit all fishing from November 1 through April 30, but allow all fishing from May 1 through October 31. The third option would prohibit all fishing from January 1 through April 30, but allow all fishing from May 1 through December 31. The fourth option would prohibit all fishing year-round. Because Madison Swanson and Steamboat Lumps have been closed to reef fish fishing for an extended time period, no data is available to determine how much harvesting activity may occur in these areas. As such, it is not possible to determine the potential effects from closing them for a longer time period and, thus, considerable uncertainty exists regarding those potential effects. However, it is highly likely the biological benefits to the gag stock would be minimal at best.

One alternative, the status quo, was considered for the action to replace the current AMs for the commercial sector of gag, red grouper, and the SWG component of the reef fish fishery with the IFQ program. By retaining the current AMs, this alternative would close the commercial SWG sector if commercial landings of red grouper, gag, or SWG reach or are projected to reach their respective quotas. As such, these measures are inconsistent with the Council's management goals and objectives for the commercial sector of the reef fish fishery, as reflected by the IFQ program. Furthermore, concerns regarding the need for additional AMs appear to be unfounded given that, to this point, commercial landings have been less than the quotas for all individual species and species complexes managed under the IFQ program.

Three alternatives, including the status quo, were considered for the action to establish additional AMs for the recreational harvest of gag and red grouper. The first alternative, the status quo, would retain the existing AMs for the recreational harvest of gag and red grouper. The current AMs do not include in-season management measures or an overage adjustment if either the gag or red grouper stocks are determined to be overfished. The gag stock is currently overfished. Thus, this alternative would allow the recreational ACLs to be exceeded before taking action, which could have short-term negative effects on the red grouper stock and particularly the gag stock. These additional AMs are recommended by the National Standard 1 guidance and are currently being considered by the Council for the management of other reef fish species in the Generic ACL amendment.

The second alternative would add an overage adjustment to the existing AMs if gag or red grouper are determined to be overfished. This alternative would provide some benefit to the gag and red grouper stocks if they are under a rebuilding plan. The Council is proposing an action to establish a rebuilding plan for gag, and, thus, this alternative would be expected to apply immediately to the gag recreational sector. If the recreational ACL is exceeded, the overage adjustment would mitigate any damage done to a stock's recovery by reducing the ACL for the following year by the size of the overage or by some other level depending on what the best available science indicates will place the stock back on its rebuilding path. However, relative to the proposed action, this alternative would not allow in-season closures as a result of projections indicating the recreational sector will exceed its red grouper or gag ACL. Thus, this alternative would allow the recreational ACLs to be exceeded before taking action, which could have short-term negative effects on the red grouper stock and particularly the gag stock.

The third alternative would add in-season AMs to the existing AMs that would allow the gag or red grouper recreational fishing seasons to close early if necessary. This alternative would provide some benefit to the gag and red grouper stocks. However, this alternative does not add an overage adjustment as per National Standard 1 guidance. Moreover, by not requiring an overage adjustment, this alternative would allow overages to occur from one year to the next if the in-season closures are implemented after the ACL has been exceeded. If these overages consistently occur over time, the cumulative effect could be sufficient to preclude rebuilding if a stock is under a rebuilding plan. As such, this alternative is not as beneficial to the red grouper and gag stocks as the proposed action.

This proposed rule does not establish any new reporting, recordkeeping, or other compliance requirements.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: October 28, 2011.

John Oliver,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

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

2. In § 622.20, paragraphs (b)(2)(iv)(A) and (B) are revised to read as follows:

§ 622.20 Individual fishing quota (IFQ) program for Gulf groupers and tilefishes.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(A) *Red grouper multi-use allocation.* (*1*) At the time the commercial quota for red grouper is distributed to IFQ shareholders, a percentage of each shareholder's initial red grouper allocation will be converted to red grouper multi-use allocation. Red grouper multi-use allocation, determined annually, will be based on the following formula:

Red Grouper multi-use allocation (in percent) = 100 * [Gag ACL − Gag commercial quota]/Red grouper commercial quota.

(2) However, if gag is under a rebuilding plan, the percentage of red grouper multi-use allocation is equal to zero. Red grouper multi-use allocation may be used to possess, land, or sell either red grouper or gag under certain conditions. Red grouper multi-use allocation may be used to possess, land, or sell red grouper only after an IFQ account holder's (shareholder or allocation holder's) red grouper allocation has been landed and sold, or transferred; and to possess, land, or sell gag, only after both gag and gag multi-use allocation have been landed and sold, or transferred.

(B) *Gag multi-use allocation.* (*1*) At the time the commercial quota for gag is distributed to IFQ shareholders, a percentage of each shareholder's initial gag allocation will be converted to gag multi-use allocation. Gag multi-use allocation, determined annually, will be based on the following formula:

Gag multi-use allocation (in percent) = 100 * [Red grouper ACL − Red grouper commercial quota]/Gag commercial quota.

(2) However, if red grouper is under a rebuilding plan, the percentage of red grouper multi-use allocation is equal to zero. Gag multi-use allocation may be used to possess, land, or sell either gag or red grouper under certain conditions. Gag multi-use allocation may be used to possess, land, or sell gag only after an IFQ account holder's (shareholder or allocation holder's) gag allocation has been landed and sold, or transferred; and to possess, land, or sell red grouper, only after both red grouper and red grouper multi-use allocation have been landed and sold, or transferred.

* * * * *

3. In § 622.34, paragraph (v) is revised to read as follows:

§ 622.34 Gulf EEZ seasonal and/or area closures.

* * * * *

(v) *Seasonal closure of the recreational sector for gag.* The recreational sector for gag, in or from the Gulf EEZ, is closed from January 1 through June 30 and November 1 through December 31 each year. During the closure, the bag and possession limit for gag in or from the Gulf EEZ is zero.

* * * * *

4. In § 622.37, the heading of paragraph (d)(2)(iii) is revised and paragraph (d)(2)(v) is added to read as follows:

§ 622.37 Size limits.

* * * * *

(d) * * *

(2) * * *

(iii) Black grouper— * * *

* * * * *

(v) Gag—22 inches (55.9 cm), TL.

* * * * *

5. In § 622.39, the first sentence in paragraph (b)(1)(ii) is revised to read as follows:

§ 622.39 Bag and possession limits.

* * * * *

(b) * * *

(1) * * *

(ii) Groupers, combined, excluding goliath grouper and Nassau grouper—4 per person per day, but not to exceed 1 speckled hind or 1 warsaw grouper per vessel per day, or 2 gag per person per day. * * *

* * * * *

6. In § 622.42, paragraphs (a)(1)(iii)(A) and (B) and paragraph (a)(1)(vi) are revised to read as follows:

§ 622.42 Quotas.

(a) * * *

(1) * * *

(iii) * * *

(A) *SWG combined*—(*1*) For fishing year 2012—6.347 million lb (2.879 million kg).

(*2*) For fishing year 2013—6.648 million lb (3.015 million kg).

(*3*) For fishing year 2014—6.875 million lb (3.118 million kg).

(*4*) For fishing year 2015 and subsequent fishing years—7.069 million lb (3.206 million kg).

(B) *Gag.* (*1*) For fishing year 2012—0.567 million lb (0.257 million kg).

(*2*) For fishing year 2013—0.708 million lb (0.321 million kg).

(*3*) For fishing year 2014—0.835 million lb (0.378 million kg).

(*4*) For fishing year 2015 and subsequent fishing years—0.939 million lb (0.426 million kg).

* * * * *

(vi) Gray triggerfish—106,000 lb (48,081 kg), round weight.

* * * * *

7. In § 622.49, the section heading, the headings and first sentences of paragraphs (a)(1)(i) and (ii), the heading and first and last sentences in paragraph (a)(2)(i), paragraph (a)(2)(ii), and paragraphs (a)(3), (a)(4), and (a)(5) are revised to read as follows:

§ 622.49 Annual Catch Limits (ACLs) and Accountability measures (AMs).

(a) * * *

(1) * * *

(i) *Commercial sector.* If commercial landings, as estimated by the SRD, reach or are projected to reach the applicable quota specified in § 622.42(a)(1)(v), the Assistant Administrator for Fisheries, NOAA, (AA) will file a notification with the Office of the Federal Register to close the commercial sector for the remainder of the fishing year. * * *

(ii) *Recreational sector.* If recreational landings, as estimated by the SRD, reach or are projected to reach the applicable quota specified in § 622.42(a)(2)(ii), the AA will file a notification with the Office of the Federal Register to close the recreational sector for the remainder of the fishing year. * * *

(2) * * *

(i) *Commercial sector.* If commercial landings, as estimated by the SRD, reach or are projected to reach the applicable quota specified in § 622.42(a)(1)(vi), the AA will file a notification with the Office of the Federal Register to close the commercial sector for the remainder of the fishing year. * * * The commercial ACL for 2010 and subsequent fishing years is 138,000 lb (62,596 kg).

(ii) *Recreational sector.* If recreational landings, as estimated by the SRD, exceed the ACL, the AA will file a notification with the Office of the Federal Register reducing the length of the following recreational fishing season by the amount necessary to ensure recreational landings do not exceed the recreational target catch for that following fishing year. The recreational ACL for 2010 and subsequent fishing years is 457,000 lb (207,291 kg). The recreational target catch level for 2010 and subsequent fishing years is 405,000 lb (183,705 kg). Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.

(3) *Shallow-water grouper (SWG) combined.* (i) *Commercial sector.* The IFQ program for groupers and tilefishes in the Gulf of Mexico serves as the accountability measure for commercial SWG. The commercial ACL for SWG, in gutted weight, for 2012 and subsequent

fishing years is 8.04 million lb (3.65 million kg).

(ii) [Reserved]

(4) *Gag.* (i) *Commercial sector.* The IFQ program for groupers and tilefishes in the Gulf of Mexico serves as the accountability measure for commercial gag. The applicable commercial ACLs for gag, in gutted weight, are 0.788 million lb (0.357 million kg) for 2012, 0.956 million lb (0.434 million kg) for 2013, 1.100 million lb (0.499 million kg) for 2014, and 1.217 million lb (0.552 million kg) for 2015 and subsequent fishing years.

(ii) *Recreational sector.* (A) Without regard to overfished status, if gag recreational landings, as estimated by the SRD, reach or are projected to reach the applicable ACLs specified in paragraph (a)(4)(ii)(D) of this section, the AA will file a notification with the Office of the Federal Register, to close the recreational sector for the remainder of the fishing year. On and after the effective date of such a notification, the bag and possession limit of gag in or from the Gulf EEZ is zero. This bag and possession limit applies in the Gulf on board a vessel for which a valid Federal charter vessel/headboat permit for Gulf reef fish has been issued, without regard to where such species were harvested, *i.e.* in state or Federal waters. In addition, the notification will reduce the length of the recreational SWG fishing season the following fishing year by the amount necessary to ensure gag recreational landings do not exceed the recreational target catch level in the following fishing year.

(B) Without regard to overfished status, and in addition to the measures specified in paragraph (a)(4)(ii)(A), if gag recreational landings, as estimated by the SRD, exceed the applicable ACLs specified in paragraph (a)(4)(ii)(D), the AA will file a notification with the Office of the Federal Register to maintain the gag target catch level, specified in paragraph (a)(4)(ii)(D) of this section, for that following fishing year at the level of the prior year's target catch, unless the best scientific information available determines that maintaining the prior year's target catch is unnecessary. In addition, the notification will reduce the length of the recreational SWG fishing season the following fishing year by the amount necessary to ensure gag recreational landings do not exceed the recreational target catch level in the following fishing year.

(C) In addition to the measures specified in paragraphs (a)(4)(ii)(A) and (B), if gag recreational landings, as estimated by the SRD, exceed the applicable ACL specified in paragraph (a)(4)(ii)(D) of this section, and gag are overfished, based on the most recent status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year to reduce the ACL for that following year by the amount of the overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

(D) The applicable recreational ACLs for gag, in gutted weight, are 1.232 million lb (0.559 million kg) for 2012, 1.495 million lb (0.678 million kg) for 2013, 1.720 million lb (0.780 million kg) for 2014, and 1.903 million lb (0.863 million kg) for 2015 and subsequent fishing years. The recreational target catch levels for gag, in gutted weight, are 1.031 million lb (0.468 million kg) for 2012, 1.287 million lb (0.584 million kg) for 2013, 1.519 million lb (0.689 million kg) for 2014, and 1.708 million lb (0.775 million kg) for 2015 and subsequent fishing years. Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.

(5) *Red grouper*—(i) *Commercial sector.* The IFQ program for groupers and tilefishes in the Gulf of Mexico serves as the accountability measure for commercial red grouper. The applicable commercial ACL for red grouper, in gutted weight, for 2012 and subsequent fishing years is 6.03 million lb (2.735 million kg).

(ii) *Recreational sector.* (A) Without regard to overfished status, if red grouper recreational landings, as estimated by the SRD, reach or are projected to reach the applicable ACL specified in paragraph (a)(5)(ii)(D) of this section, the AA will file a notification with the Office of the Federal Register, to close the recreational sector for the remainder of the fishing year. On and after the effective date of such a notification, the bag and possession limit of red grouper in or from the Gulf EEZ is zero. This bag and possession limit applies in the Gulf on board a vessel for which a valid Federal charter vessel/headboat permit for Gulf reef fish has been issued, without regard to where such species were harvested, *i.e.* in state or Federal waters.

(B) Without regard to overfished status, and in addition to the measures specified in paragraph (a)(5)(ii)(A), if red grouper recreational landings, as estimated by the SRD, exceed the applicable ACL specified in paragraph (a)(5)(ii)(D), the AA will file a notification with the Office of the Federal Register to maintain the red grouper target catch level, specified in paragraph (a)(5)(ii)(D) of this section, for that following fishing year at the level of the prior year's target catch, unless the best scientific information available determines that maintaining the prior year's target catch is unnecessary. In addition, the notification will reduce the bag limit by one fish and reduce the length of the recreational SWG fishing season the following fishing year by the amount necessary to ensure red grouper recreational landings do not exceed the recreational target catch level in the following fishing year. The minimum red grouper bag limit for 2014 and subsequent fishing years is two fish.

(C) In addition to the measures specified in paragraphs (a)(5)(ii)(A) and (B), if red grouper recreational landings, as estimated by the SRD, exceed the applicable ACL specified in paragraph (a)(5)(ii)(D) of this section, and red grouper are overfished, based on the most recent Status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register, at or near the beginning of the following fishing year to reduce the ACL for that following year by the amount of the overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

(D) The recreational ACL for red grouper, in gutted weight, is 1.90 million lb (0.862 million kg) for 2012 and subsequent fishing years. The recreational target catch level for red grouper, in gutted weight, is 1.730 million lb (0.785 million kg) for 2012 and subsequent fishing years. Recreational landings will be evaluated relative to the ACL based on a moving multi-year average of landings, as described in the FMP.

* * * * *

[FR Doc. 2011–28421 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 76, No. 212

Wednesday, November 2, 2011

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.

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No. CFPB–2011–0034]

Proposed Collection; Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for public comment.

SUMMARY: The Bureau of Consumer Financial Protection (CFPB), 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 CFPB is soliciting comments concerning a proposed generic information collection for development and/or testing of model forms, disclosures, tools, and similar related materials. The CFPB will collect information in connection with the development and testing of new model forms, disclosures, tools, and similar related materials pursuant to the CFPB's authority with respect to Federal consumer financial laws and the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, as well as testing existing model forms and disclosures.

DATES: Written comments are encouraged and must be received on or before January 3, 2012 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number CFPB–2011–0034, by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Mitchell E. Hochberg or Jane Gao, Office of Regulations, Consumer Financial Protection Bureau, 1500 Pennsylvania Avenue NW. (*Attn:* 1801 L Street), Washington, DC 20220.
- *Hand Delivery/Courier:* Mitchell E. Hochberg or Jane Gao, Office of Regulations, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Mitchell E. Hochberg or Jane Gao, Consumer Financial Protection Bureau, (202) 435–7700.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for Development and/or Testing of Model Forms, Disclosures, Tools, and Other Similar Related Materials.

OMB Number: 3170–XXXX.

Summary of Collection: The Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203 (the ''Dodd-Frank Act'') and Federal consumer financial laws authorize or require the Bureau of Consumer Financial Protection (the ''CFPB'' or the ''Bureau'') to develop and prescribe standard model forms, disclosures, tools, and other similar related materials that help to inform consumers about complex financial information related to consumer financial products. Further, such model forms, disclosures, tools, and other similar related materials covered entities may assist covered entities in complying with applicable regulations. The model forms, disclosures, tools, and other similar related materials may also include adjustments, additions, exceptions, or revisions to the disclosures under the Dodd-Frank Act and federal consumer financial laws consistent with the CFPB's statutory authorities.

The CFPB expects to collect qualitative data through a variety of collection methods, including interviews and research, to inform the design, development and implementation of the model form(s). The information collected through qualitative evaluation methods will inform the design and content of the model form(s), using an iterative process to improve the draft forms. For example, information collected from consumers will help the CFPB to design model forms, disclosures, tools, and similar related materials that are responsive to consumer needs and present complex information in an understandable form. Further, information collection from covered entities will help the CFPB to ensure that any such materials can be implemented as easily and cost-effectively as possible.

The development and evaluation process that will be conducted may use think-aloud interviews and usability studies. Data collection tools will include: consent forms; participant questionnaires and protocols for individual interviews. The CFPB may also collect information regarding forms of disclosures and other materials currently used by covered entities with respect to regulations issued by the CFPB. The CFPB further anticipates that it may collect data through the use of internet applications.

The CFPB will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- Personally identifiable information (PII) is collected only to the extent necessary, subject to privacy protections, and is not retained;
- Information gathered and released beyond the CFPB will indicate the qualitative nature of the information; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

The core objective of the data collection is to help identify, evaluate, and refine specific features of the content or design of the model forms, disclosures, tools, and other similar related materials to maximize communication effectiveness while minimizing compliance burden. Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections

that are designed to yield statistically significant results from a representative sample.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Type of Review: New collection.

Affected Public: Individuals and businesses or other for-profit institutions.

Annual Burden Estimates: Below is a preliminary estimate of the aggregate burden hours for this generic clearance with respect to up to approximately twelve (12) design and testing projects.

Process	Number of Respondents	Number of responses per respondent	Average burden per response (minutes)	Total burden (hours)
Informational outreach	300	1	120	600
Screening	5000	1	15	1250
One-on-one interviews	800	1	90	1200
Travel time to sites	800		60	800
Internet Application Feedback	7000	1	15	1750
Total				5600

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 proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Robert Dahl,

PRA Clearance Officer, Department of the Treasury.

[FR Doc. 2011–28337 Filed 11–1–11; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF AGRICULTURE

Forest Service

National Urban and Community Forestry Advisory Council

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The National Urban and Community Forestry Advisory Council will meet in Lake Buena Vista, FL, November 15–16, 2011, at the Coronado Springs Hotel. The purpose of the Council's meeting is to discuss the Council's plan of work, recommendations and accomplishments. Council will also host a listening session and document the public's input on the Vibrant City Initiative.

DATES: The business meeting will be held on Tuesday, November 15, 2011, 2 p.m. to 5 p.m. or until Council business is completed. The listening session will be held Wednesday, November 16, 2011, 5 p.m. to 6 p.m. Both meetings will be held in the hotel's Coronado Room D.

ADDRESSES: The meeting will be held at the Coronado Springs Hotel, 1000 West Buena Vista Drive, Lake Buena Vista, FL 32830, *phone:* (407) 939–1000.

Written comments concerning this meeting should be addressed to Nancy Stremple, Executive Staff to the National Urban and Community Forestry Advisory Council, 201 14th Street, SW., Yates Building (1 Central) MS–1151, Washington, DC 20250–1151. Comments may also be sent via email to *nstremple@fs.fed.us,* or via facsimile to (202) 690–5792.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. To view and inspect these records, visitors are encouraged to call ahead to facilitate entry into the Forest Service building.

FOR FURTHER INFORMATION CONTACT: Nancy Stremple, Executive Staff to the National Urban and Community Forestry Advisory Council, 201 14th Street, SW., Yates Building (1 Central) MS–1151, Washington, DC 20250–1151, phone (202) 205–1054.

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 Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The business meeting is open to the public. Those interested in attending should contact Nancy Stremple to be placed on the meeting attendance list. Council discussion during the business meeting is limited to Forest Service staff and Council members; however, persons who wish to bring urban and community forestry matters to the attention of the Council may file written statements with the Council staff (201 14th Street SW., Yates Building (1 Central) MS–1151, Washington, DC 20250–1151, email: *nstremple@fs.fed.us*) before or after the meeting. The listening session is open to the public. Public comments will be compiled, and recommendations will be included in the Council's annual recopmmendations to the Secretary of Agriculture.

Dated: October 26, 2011

Robin L. Thompson,

Associate Deputy Chief, State and Private Forestry.

[FR Doc. 2011–28336 Filed 11–1–11; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Basin Electric Power Cooperative, Inc.: Notice of Intent To Prepare an Environmental Impact Statement and Hold Public Scoping Meetings

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Utilities Service (RUS), an agency within the U.S. Department of Agriculture (USDA), intends to prepare an environmental impact statement (EIS) for Basin Electric Power Cooperative's (Basin Electric) proposed Antelope Valley Station (AVS) to Neset Transmission Project (Project) in North Dakota. RUS is issuing this Notice of Intent (NOI) to inform the public and interested parties about the proposed Project, conduct a public scoping process, and invite the public to comment on the scope, proposed action, and other issues to be addressed in the EIS.

The EIS will address the construction, operation, and maintenance of Basin Electric's proposed Project. The Project includes construction, operation and maintenance of approximately 190 miles of new 345-kV single pole transmission line and double circuit 345/115-kV transmission lines, 2 new substations, modifications to 4 existing substations, a 345-kV switchyard, maintenance access roads, temporary construction roads, river crossings, temporary construction staging sites, and other facilities to be described in the proposed EIS. Basin Electric's proposed Project would be located in portions of Billings, Dunn, McKenzie, Mercer, Mountrail, and Williams counties in western North Dakota.

Portions of Basin Electric's proposed Project may affect floodplains and wetlands. This NOI also serves as a notice of proposed floodplain or wetland action. RUS will hold public scoping meetings to share information and receive comments and suggestions on the scope of the EIS in areas near and affected by the proposed Project.

DATES: An open-house public scoping meetings will be held on November 15, 2011, from 4 to 7 p.m. central time at the Ernie French Center, North Dakota State University Williston Research Extension Office, 14120 Highway 2, Williston, North Dakota 58801; and on November 16, 2011, from 4 to 7 p.m. mountain time at the American Legion Hall Post 46, 42 Central Avenue, Killdeer, North Dakota 58640. In order to be considered, all fax or email comments or suggestions regarding the appropriate scope of the EIS must be received by the end of the scoping period. Comments regarding the Project may be submitted in writing at the public scoping meeting or mailed to the RUS address provided in this Notice. Mailed comments must be postmarked no later than midnight on December 2, 2011.

ADDRESSES: Written comments on the scope of the EIS should be addressed to Mr. Dennis Rankin, Environmental Protection Specialist, USDA, Rural Utilities Service, 1400 Independence Avenue SW., Stop 1571, Washington, DC 20250–1571, *telephone:* (202) 720–1953, or *email: dennis.rankin@wdc.usda.gov.*

FOR FURTHER INFORMATION CONTACT: For information on the proposed Project, the EIS process, and RUS financing, contact Mr. Dennis Rankin, Engineering and Environmental Staff, Rural Utilities Service, 1400 Independence Avenue SW., Mail Stop 1571, Washington, DC 20250–1571, *telephone:* (202) 720–1953, or *email: dennis.rankin@wdc.usda.gov*. Parties wishing to be placed on the Project mailing list for future information and to receive copies of the Draft and Final EIS when they are available should also contact Mr. Rankin.

SUPPLEMENTARY INFORMATION: RUS is authorized to make loans and loan guarantees that finance the construction of electric distribution, transmission, and generation facilities, including system improvements and replacements required to furnish and improve electric service in rural areas, as well as demand side management, energy conservation programs, and on-grid and off-grid renewable energy systems. Based on an interconnection with the Western Area Power Administration's (Western) transmission system, Western has in accordance with 40 CFR 1501.6 Cooperating agencies, requested to serve as a cooperating agency for the environmental review of the proposed project.

Basin Electric is a regional wholesale electric generation and transmission cooperative owned and controlled by its member cooperatives. Basin Electric serves approximately 2.5 million customers covering 430,000 square miles in portions of nine states, including Colorado, Iowa, Minnesota, Montana, Nebraska, New Mexico, North Dakota, South Dakota, and Wyoming.

Project Description: Basin Electric has identified the need for additional electric transmission capacity in northwestern North Dakota as a result of increased demand and to meet reliability and system stability requirements for the region. Investigations and analyses conducted for the overall power delivery systems found that without improvements, the flow of power along existing lines may result in local line overloads, especially in the vicinity of Williston, North Dakota.

To resolve these issues, Basin Electric is proposing to construct, own and operate a new 345-kV transmission line and associated supporting infrastructure. The entire project will consist of constructing approximately 190 miles of new single circuit 345-kV and double circuit 345/115-kV transmission lines, the construction of 2 new substations, modifications to 4 existing substations, a 345-kV switchyard, maintenance access roads, temporary construction roads, river crossings, temporary construction staging sites, and other facilities. The Project would connect to the Integrated System at several locations, including Western's Williston Substation. The proposed Project would be located in portions of Billings, Dunn, McKenzie, Mercer, Mountrail, and Williams counties in western North Dakota.

Basin Electric has requested financial assistance for the proposed Project from the U.S. Department of Agriculture, Rural Utilities Service (RUS). Completing the EIS is one of RUS's requirements in processing Basin Electric's application, along with other technical and financial considerations.

In accordance with 40 CFR 1501.5(b) of the Council of Environmental Quality's Regulation for Implementing the Procedural Provisions of the National Environmental Policy Act, RUS will serve as the-lead agency in the preparation of the EIS. Other agencies and Native American Tribes with jurisdiction or special expertise will be invited to participate as cooperating agencies per § 1501.6.

The proposed Project is subject to the jurisdiction of the North Dakota Public Service Commission (NDPSC), which has regulatory authority for siting electrical transmission facilities within the State. Basin Electric will submit an application for NDPSC Transmission Corridor and Route Permits. The NDPSC Permits would authorize Basin Electric to construct the proposed Project under North Dakota rules and regulations.

RUS intends to prepare an EIS to analyze the impacts of its respective federal actions and the proposed Project in accordance with NEPA, as amended, CEQ's Regulation for Implementing the Procedural Provisions of the National Environmental Policy Act (40 CFR parts 1500–1508), DOE NEPA Implementing Procedures (10 CFR part 1021), and RS

Environmental Policies and Procedures (7 CFR part 1794).

Because the proposed Project may involve action in floodplains or wetlands, this NOI also serves as a notice of proposed floodplain or wetland action. The EIS will include a floodplain/wetland assessment and, if required, a floodplain/wetland statement of findings will be issued with the Final EIS.

Agency Responsibilities: RUS is serving as the lead Federal agency, as defined at 40 CFR 1501.5, for preparation of the EIS. With this notice, Native American Tribes and agencies with jurisdiction or special expertise are invited to be cooperating agencies. Such tribes or agencies may make a request to RUS to be a cooperating agency by contacting Mr. Rankin. Designated cooperating agencies have certain responsibilities to support the NEPA process, as specified at 40 CFR 1501.6(b).

Environmental Issues: This notice is to inform agencies and the public of RUS' federal action, and the proposed Project, and to solicit comments and suggestions for consideration in preparing the EIS. To help the public frame its comments, this notice contains a list of potential environmental issues that RUS has tentatively identified for analysis. These issues include:

1. Impacts on protected, threatened, endangered, or sensitive species of animals or plants;
2. Impacts on avian and bat species;
3. Impacts on land use, recreation, and transportation;
4. Impacts on cultural resources or historic properties and tribal values;
5. Impacts on human health and safety;
6. Impacts on air, soil, and water resources (including air quality and surface water impacts);
7. Visual impacts; and
8. Socioeconomic impacts and whether there would be any disproportionately high and adverse impacts to minority and low-income populations.

This list is not intended to be all-inclusive or to imply any predetermination of impacts. Environmental issues associated with the action of RUS, and Basin Electric's proposed Project will be addressed separately in the EIS. RUS invites interested parties to suggest specific issues within these general categories, or other issues not included above, to be considered in the EIS.

Public Participation: Public participation and full disclosure are planned for the entire EIS process. The EIS process will include open-house public scoping meetings and a scoping comment period to solicit comments from interested parties; consultation and involvement with appropriate Federal, State, local, and tribal governmental agencies; public review and a hearing on the draft EIS; publication of a final EIS; and publication of a Record of Decision. Expected EIS completion date is December 2013. Additional informal public meetings may be held in the proposed Project areas, if public interest and issues indicate a need; if additional public meeting are determined to be necessary public notices will be published as appropriate.

RUS will hold open-house public scoping meetings in Williston, North Dakota, and Killdeer, North Dakota as noted above. The time and locations of these meetings will be well advertised in local media outlets a minimum of 15 days prior to the time of the meetings. Attendees are welcome to come and go at their convenience and to speak one-on-one with Project representatives and agency staff. The public will have the opportunity to provide written comments at the meeting. In addition, attendees may provide written comments by letter, fax, email.

The public scoping period begins with publication of this notice in the **Federal Register** and closes December 2, 2011. To be considered in defining the scope of the EIS, comments should be received by the end of the scoping period.

Dated: October 27, 2011.

Mark Plank,

Director, Engineering and Environmental Staff, Rural Utilities Service.

[FR Doc. 2011–28309 Filed 11–1–11; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Connecticut, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, and Pennsylvania Advisory Committees

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA), that a webinar briefing meeting of the Connecticut, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, and Pennsylvania State Advisory Committees will convene on Monday, November 14, 2011, at 10:30 a.m. (E.S.T.). The briefing will be at Commission Headquarters, 624 9th Street NW., Room 540, Washington, DC 20425. The purpose of the meeting is to receive a briefing from experts on Human Trafficking.

Those who are unable to attend the briefing at the Commission Headquarters in person may join through an Internet connection. Please contact the Eastern Regional Office for details on the internet connection by calling (202) 376–7533 or by email at *ero@usccr.gov.*

Members of the public are entitled to submit written comments. The comments must be received in the regional office by Monday, December 5, 2011. The address is Eastern Regional Office, 624 9th Street NW., Suite 740, Washington, DC 20425. Persons wishing to email their comments, or who desire additional information should contact the Eastern Regional Office at (202) 376–7533 or by email to: *ero@usccr.gov.*

People seeking disability accommodations should contact the Eastern Regional Office at least five (5) working days before the scheduled meeting date.

Records generated from this briefing may be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the webinar. Persons interested in the work of these advisory committees are advised to go to the Commission's Web site, *http://www.usccr.gov,* or to contact the Eastern Regional Office at the above email or street address.

The briefing will be conducted pursuant to the rules and regulations of the Commission and FACA.

Dated in Washington, DC, on October 27, 2011.

Peter Minarik,

Acting Chief, Regional Programs Coordination Unit.

[FR Doc. 2011–28383 Filed 11–1–11; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 1795]

Grant of Authority for Subzone Status; VF Jeanswear, (Apparel Distribution), Mocksville, NC

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones Act provides for "* * * the establishment

* * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved, and when the activity results in a significant public benefit and is in the public interest;

Whereas, the Piedmont Triad Partnership, grantee of Foreign-Trade Zone 230, has made application to the Board for authority to establish a special-purpose subzone at the warehouse and distribution facility of VF Jeanswear, located in Mocksville, North Carolina, (FTZ Docket 15–2011, filed 03/01/2011);

Whereas, notice inviting public comment has been given in the **Federal Register** (76 FR 12022, 3/4/2011) 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 Board's regulations are satisfied, and that the proposal is in the public interest;

Now, therefore, the Board hereby grants authority for subzone status for activity related to apparel warehousing and distribution at the facility of VF Jeanswear, located in Mocksville, North Carolina (Subzone 230E), as described in the application and **Federal Register** notice, subject to the FTZ Act and the Board's regulations, including Section 400.28.

Signed at Washington, DC, this 24th day of October 2011.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration, Alternate Chairman, Foreign-Trade Zones Board.

ATTEST:

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–28410 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 69–2011]

Proposed Foreign-Trade Zone; Genesee County, NY, Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board (the Board) by the Genesee Gateway Local Development Corporation to establish a general-purpose foreign-trade zone at sites in Genesee County, New York, adjacent to the Rochester Customs and Border Protection (CBP) port of entry, under the alternative site framework (ASF) adopted by the Board (74 FR 1170–1173, 1/12/09 (correction 74 FR 3987, 1/22/09); 75 FR 71069–71070, 11/22/10). The ASF is an option for grantees for the establishment or reorganization of general-purpose zones and can permit significantly greater flexibility in the designation of new ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the Board's standard 2,000-acre activation limit for a general-purpose zone project. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on October 27, 2011. The applicant is authorized to make the proposal under the New York State County Law, Section 224 (21).

The proposed zone would be the second general-purpose zone for the Rochester CBP port of entry. The existing zone is as follows: FTZ 141, County of Monroe, New York (Grantee: County of Monroe, New York, Board Order 355, 04/15/87).

The applicant's proposed service area under the ASF would be Genesee County, New York. If approved, the applicant would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The proposed service area is adjacent to the Rochester Customs and Border Protection port of entry.

The proposed zone would include two ''magnet'' sites in Genesee County: Proposed Site 1 (186 acres)—Apple Tree Acres, southeast corner of the intersection of State Route 33 & State Route 19, Bergen; and, Proposed Site 2 (200 acres)—Genesee Valley Agri-Business Park, between State Route 63 and State Route 5, Batavia. Both sites are owned by Genesee Gateway Local Development Corporation. The ASF allows for the possible exemption of one magnet site from the ''sunset'' time limits that generally apply to sites under the ASF, and the applicant proposes that Site 2 be so exempted.

The application indicates a need for zone services in Genesee County, New York. Several firms have indicated an interest in using zone procedures for warehousing/distribution activities for a variety of products. Specific manufacturing approvals are not being sought at this time. Such requests would be made to the Board on a case-by-case basis.

In accordance with the Board's regulations, Kathleen Boyce of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 3, 2012. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 17, 2012.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Kathleen Boyce at *Kathleen.Boyce@trade.gov* or (202) 482–1346.

Dated: October 27, 2011.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2011–28427 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–808]

Certain Stainless Steel Wire Rods From India: Final Results of the Expedited Sunset Review of the Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 1, 2011, the Department of Commerce (the Department) initiated the third sunset review of the antidumping duty order on certain stainless steel wire rods from India, pursuant to section 751(c) of the

Tariff Act of 1930, as amended (the Act). See *Initiation of Five-Year ("Sunset") Review,* 76 FR 38613 (July 1, 2011) (*Notice of Initiation*). The Department has conducted an expedited (120-day) sunset review of this order. As a result of this sunset review, the Department finds that revocation of the antidumping duty order would be likely to lead to continuation or recurrence of dumping as indicated in the "Final Results of Review" section of this notice.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Dustin Ross or Minoo Hatten, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0747 or (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2011, the Department published the notice of initiation of the sunset review of the antidumping duty order on certain stainless steel wire rods from India (wire rods) [1] pursuant to section 751(c) of the Act. See *Notice of Initiation.*

The Department received a notice of intent to participate on behalf of Carpenter Technology Corporation (the petitioner) within the deadline specified in 19 CFR 351.218(d)(1)(i). The petitioner claimed interested-party status under section 771(9)(C) of the Act as a manufacturer of a domestic like product for the proceeding.

The Department received a complete substantive response to the *Notice of Initiation* from the petitioner within the 30-day period specified in 19 CFR 351.218(d)(3)(i). The Department received no substantive responses from any respondent interested parties. In accordance with section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department is conducting an expedited (120-day) sunset review of the antidumping duty order on certain stainless steel wire rods from India.

Scope of the Order

The merchandise covered by the antidumping duty order is wire rods, which are hot-rolled or hot-rolled annealed and/or pickled rounds, squares, octagons, hexagons or other shapes, in coils. Wire rods are made of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements. These products are only manufactured by hot-rolling and are normally sold in coiled form, and are of solid cross section. The majority of wire rods sold in the United States are round in cross-section shape, annealed, and pickled. The most common size is 5.5 millimeters in diameter.

The wire rods subject to this order are currently classifiable under subheadings 7221.00.0005, 7221.00.0015, 7221.00.0030, 7221.00.0045, and 7221.00.0075 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.

Analysis of Comments Received

All issues raised in this sunset review are addressed in the "Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Certain Stainless Steel Wire Rods from India" from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, dated concurrently with this notice (Issues and Decision Memo), which is hereby adopted by this notice. The issues discussed in the Issues and Decision Memo include the likelihood of continuation or recurrence of dumping and the magnitude of the margin of dumping likely to prevail if the order were revoked. Parties can find a complete discussion of the issues raised in this sunset review and the corresponding recommendations in this public memorandum, which is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). Access to IA ACCESS is available in the Central Records Unit (CRU), room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memo can be accessed directly on the internet at *http://www.trade.gov/ia/.* The signed Issues and Decision Memo and the electronic versions of the Issues and Decision Memo are identical in content.

Final Results of Review

The Department determines that revocation of the antidumping duty order on certain stainless steel wire rods from India would be likely to lead to continuation or recurrence of dumping at the following weighted-average percentage margins:

Company	Weighted-average margin (percent)
Mukand Ltd	48.80
Sunstar Metals Ltd	48.80
Grand Foundry Ltd	48.80
All Others	48.80

Notification Regarding APO

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

The Department is issuing and publishing the final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: October 24, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–28411 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–DS–P

[1] *Antidumping Duty Order: Certain Stainless Steel Wire Rods from India,* 58 FR 63335 (December 1, 1993).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–810, A–583–815]

Welded ASTM A–312 Stainless Steel Pipe From South Korea and Taiwan: Final Results of Expedited Sunset Reviews of the Antidumping Duty Orders

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On July 1, 2011, the Department of Commerce (the Department) initiated sunset reviews of the antidumping duty orders on welded ASTM A–312 stainless steel pipe from South Korea and Taiwan, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). The Department has conducted expedited (120-day) sunset reviews for both orders pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2). As a result of these sunset reviews, the Department finds that revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith or Dana Mermelstein, AD/CVD Operations, Office 6, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230; *telephone:* (202) 482–5255 and (202) 482–1391, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2011, the Department published the notice of initiation of the third sunset reviews of the antidumping duty orders on welded ASTM A–312 stainless steel pipe from South Korea and Taiwan pursuant to section 751(c) of the Act. *See Initiation of Five-Year (''Sunset'') Review,* 76 FR 38613 (July 1, 2011).

The Department received a letter of intent to participate on behalf of Bristol Metals LLC and Felker Bros. Corp. (collectively ''domestic interested parties''), within the deadline specified in 19 CFR 351.218(d)(1)(i) for each sunset review. The companies claimed interested party status under section 771(9)(C) of the Act as producers of the subject merchandise in the United States.

The Department received an adequate substantive response to the notice of initiation from the domestic interested parties within the deadline specified in 19 CFR 351.218(d)(3)(i). We received no substantive responses from respondent interested parties with respect to either of the orders covered by these sunset reviews. As a result, pursuant to 19 CFR 351.218(e)(1)(ii)(C)(2), the Department has conducted expedited (120-day) sunset reviews of the antidumping duty orders on welded ASTM A–312 stainless steel pipe from South Korea and Taiwan .

Scope of the Orders

The merchandise subject to the antidumping duty order is welded austenitic stainless steel pipe that meets the standards and specifications set forth by the American Society for Testing and Materials (ASTM) for the welded form of chromium-nickel pipe designated ASTM A–312. The merchandise covered by the scope of the order also includes austenitic welded stainless steel pipes made according to the standards of other nations which are comparable to ASTM A–312.

Welded ASTM A–312 stainless steel pipe (WSSP) is produced by forming stainless steel flat-rolled products into a tubular configuration and welding along the seam. WSSP is a commodity product generally used as a conduit to transmit liquids or gases. Major applications for steel pipe include, but are not limited to, digester lines, blow lines, pharmaceutical lines, petrochemical stock lines, brewery process and transport lines, general food processing lines, automotive paint lines, and paper process machines. Imports of WSSP are currently classifiable under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7306.40.5005, 7306.40.5015, 7306.40.5040, 7306.40.5062, 7306.40.5064, and 7306.40.5085.[1] Although these subheadings include both pipes and tubes, the scope of the antidumping duty order is limited to welded austenitic stainless steel pipes. The HTSUS subheadings are provided for convenience and customs purposes. However, the written description of the scope of the order is dispositive.

Analysis of Comments Received

All issues raised in these reviews are addressed in the ''Issues and Decision Memorandum: Final Results of Expedited Sunset Reviews of the Antidumping Duty Orders on Welded ASTM A–312 Stainless Steel Pipe from South Korea and Taiwan'' from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, dated concurrently with this notice (Issues and Decision Memorandum), which is hereby adopted by this notice. The issues discussed in the ''Issues and Decision Memorandum'' consist of the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the orders were revoked. Parties can find a complete discussion of all issues raised in these reviews and corresponding recommendations in this public memorandum, which is on file in the Central Records Unit, room 7046 of the main Commerce Department building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://ia.ita.doc.gov/frn*. The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Reviews

We determine that revocation of the antidumping duty orders on Welded ASTM A–312 Stainless Steel Pipe from South Korea and Taiwan would be likely to lead to continuation or recurrence of dumping. We determine that the following weighted-average percentage margins are likely to prevail:

ANTIDUMPING DUTY ORDER ON WELDED ASTM–A312 STAINLESS STEEL PIPE FROM SOUTH KOREA

Manufacturer/Exporter	Weighted average margin (percent)
Sammi Metal Products Co., Ltd.	7.92
SeAH Steel Corp (successor to Pusan Steel Pipe Co., Ltd.)[2]	2.67
All Others	7.00

ANTIDUMPING DUTY ORDER ON WELDED ASTM–A312 STAINLESS STEEL PIPE FROM TAIWAN

Manufacturer/Exporter	Weighted average margin (percent)
Jaung Yuann Enterprise Co., Ltd.	31.90

[1] HTS 7306.40.5065 previously listed in the scope of the order for this product is no longer a valid reporting number, having been replaced by 7306.40.6052 and 7306.40.6054 as of January 1, 1996.

[2] *See Certain Welded Stainless Steel Pipe from Korea; Final Results of Antidumping Duty Changed Circumstances Review,* 63 FR 16979 (April 7, 1998).

ANTIDUMPING DUTY ORDER ON WELDED ASTM–A312 STAINLESS STEEL PIPE FROM TAIWAN—Continued

Manufacturer/Exporter	Weighted average margin (percent)
Yeun Chyang Industrial Co., Ltd.	31.90
All Others	22.92

This notice also serves as the only reminder to parties subject to administrative protective orders (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing the results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act.

Dated: October 26, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–28425 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–865]

Notice of Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Negative Critical Circumstances Determination: Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: We preliminarily determine that bottom mount combination refrigerator-freezers (bottom mount refrigerators) from the Republic of Korea (Korea) are being sold, or are likely to be sold, in the United States at less than fair value (LTFV), as provided in section 733(b) of the Tariff Act of 1930, as amended (the Act). In addition, we preliminarily determine that there is no reasonable basis to believe or suspect that critical circumstances exist with respect to the subject merchandise exported from Korea.

Interested parties are invited to comment on this preliminary determination. Because we are postponing the final determination, we will make our final determination not later than 135 days after the date of publication of this preliminary determination in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Henry Almond or Elizabeth Eastwood, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0049 or (202) 482–3874, respectively.

Preliminary Determination

We preliminarily determine that bottom mount refrigerators from Korea are being sold, or are likely to be sold, in the United States at LTFV, as provided in section 733(b) of the Act. The estimated margins of sales at LTFV are shown in the ''Suspension of Liquidation'' section of this notice. In addition, we preliminarily determine that there is no reasonable basis to believe or suspect that critical circumstances exist with respect to the subject merchandise exported from Korea. The critical circumstances analysis for the preliminary determination is discussed below under the section ''Critical Circumstances.''

Background

Since the initiation of this investigation on April 19, 2011 (*see Initiation of Antidumping Duty Investigations: Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea and Mexico,* 76 FR 23281 (April 26, 2011) (*Initiation Notice*)), the following events have occurred.

On May 2, 2011, Daewoo Electronics Corporation (Daewoo) identified itself as an exporter and producer of the subject merchandise in Korea and requested that it be designated as a mandatory respondent. On May 10, 2011, we included Daewoo as a mandatory respondent in this investigation. *See* Memorandum to James Maeder, Director, Office 2, from David Goldberger, Senior International Trade Analyst, entitled, ''Inclusion of Daewoo as a Mandatory Respondent,'' dated May 10, 2011.

On May 13, 2011, the United States International Trade Commission (ITC) preliminarily determined that there is a reasonable indication that imports of bottom mount refrigerators from Mexico are materially injuring the United States industry. *See* ITC Investigation Nos. 701–TA–477 and 731–TA–1180–1181 (Publication No. 4232).

On May 20, 2011, we issued section A of the questionnaire (*i.e.,* the section covering general information) to Daewoo, LG Electronics, Inc. (LG), and Samsung Electronics Co., Ltd. (Samsung). We issued sections B through E of the questionnaire (*i.e.,* the sections covering comparison market sales, U.S. sales, cost of production (COP) information, and further manufacturing information, respectively) to these respondents on May 25, 2011.

Also, in May 2011, various interested parties, including Whirlpool Corporation (hereafter, the petitioner), submitted comments on the scope of this and the concurrent antidumping and countervailing duty investigations of bottom mount refrigerators from Mexico and Korea. *See* ''Scope Comments'' section of this notice.

We received responses to section A of the questionnaire from Daewoo, LG, and Samsung in June 2011, and to sections B, C, and D of the questionnaire in July 2011. No responses to section E of the questionnaire were necessary.

We issued supplemental questionnaires from July through September 2011, and we received responses to these supplemental questionnaires from July through October 2011.

On July 29, 2011, the petitioner alleged that critical circumstances existed with respect to bottom mount refrigerators produced and exported from Korea. On August 10, 2011, we requested monthly shipment data from the respondents for the period January 2008 through July 2011 for purposes of this analysis.

On August 11, 2011, the petitioner submitted allegations related to affiliated party transactions and the major input rule with respect to subject merchandise produced and exported from Korea by LG and Samsung.

Also on August 11, 2011, the petitioner requested that the date for the issuance of the preliminary determination in this investigation be

fully extended pursuant to section 733(c)(1) of the Act and 19 CFR 351.205(e). On August 16, 2011, pursuant to sections 733(c)(1)(A) and (c)(2) of the Act and 19 CFR 351.205(f), the Department postponed the preliminary determination until no later than October 26, 2011. *See Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea and Mexico: Postponement of Preliminary Determinations of Antidumping Duty Investigations,* 76 FR 52313 (August 22, 2011).

Also on August 16, 2011, LG objected to the Department's request for monthly shipment data, arguing that the petitioner's critical circumstances allegation did not meet the necessary statutory criteria. We responded to LG's objection on August 18, 2011. Daewoo, LG, and Samsung submitted the requisite shipment data on August 24, 2011. In their submissions, LG and Samsung provided comments on how the Department should analyze whether critical circumstances exist with respect to their imports of bottom mount refrigerators from Korea.

On September 9, 2011, the petitioner alleged that targeted dumping was occurring with respect to bottom mount refrigerators produced and exported from Korea by LG and Samsung.

On October 5, 2011, we issued an additional supplemental questionnaire regarding Samsung's section D response. Although the October 14, 2011, response to this questionnaire was timely, it was received too late for consideration in the preliminary determination. Moreover, subsequent to this date, we also received various submissions from interested parties to this investigation. As with Samsung's supplemental questionnaire response, these submissions were also received too late for consideration in the preliminary determination. We will consider each of these submissions in our final determination.

On October 6, 2011, we requested updated shipment data from Daewoo, LG, and Samsung for consideration in our critical circumstances analysis for the final determination.

On October 18, 19, and 21, 2011, respectively, Daewoo, Samsung, and LG requested a postponement of the final determination.

Also on October 21, 2011, we received an amendment to the petitioner's targeted dumping allegation for LG. Because the petitioner's original allegation was based on data which were superseded by LG's supplemental response, we have accepted this amendment for purposes of the preliminary determination.

Postponement of Final Determination

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. The Department's regulations, at 19 CFR 351.210(e)(2), require that requests by respondents for postponement of a final determination be accompanied by a request for extension of provisional measures from a four-month period to not more than six months.

Pursuant to section 735(a)(2) of the Act, on October 18, 19, and 21, 2011, respectively, Daewoo, Samsung, and LG requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until not later than 135 days after the date of the publication of the preliminary determination in the **Federal Register,** and extend the provisional measures to not more than six months. In accordance with 19 CFR 351.210(b), because (1) our preliminary determination is affirmative for LG and Samsung, (2) LG and Samsung account for a significant proportion of exports of the subject merchandise, and (3) no compelling reasons for denial exist, we are granting LG's and Samsung's requests and are postponing the final determination until no later than 135 days after the publication of this notice in the **Federal Register.** Suspension of liquidation will be extended accordingly.

Period of Investigation

The period of investigation (POI) is January 1, 2010, through December 31, 2010. This period corresponds to the four most recent fiscal quarters prior to the month of the filing of the petition (*i.e.,* March 2011).

Scope of Investigation

The products covered by the investigation are all bottom mount combination refrigerator-freezers and certain assemblies thereof from Korea. For purposes of the investigation, the term ''bottom mount combination refrigerator-freezers'' denotes freestanding or built-in cabinets that have an integral source of refrigeration using compression technology, with all of the following characteristics:

- The cabinet contains at least two interior storage compartments accessible through one or more separate external doors or drawers or a combination thereof;
- An upper-most interior storage compartment(s) that is accessible through an external door or drawer is either a refrigerator compartment or convertible compartment, but is not a freezer compartment; [1] and
- There is at least one freezer or convertible compartment that is mounted below an upper-most interior storage compartment(s).

For purposes of the investigation, a refrigerator compartment is capable of storing food at temperatures above 32 degrees F (0 degrees C), a freezer compartment is capable of storing food at temperatures at or below 32 degrees F (0 degrees C), and a convertible compartment is capable of operating as either a refrigerator compartment or a freezer compartment, as defined above.

Also covered are certain assemblies used in bottom mount combination refrigerator-freezers, namely: (1) Any assembled cabinets designed for use in bottom mount combination refrigerator-freezers that incorporate, at a minimum: (a) an external metal shell, (b) a back panel, (c) a deck, (d) an interior plastic liner, (e) wiring, and (f) insulation; (2) any assembled external doors designed for use in bottom mount combination refrigerator-freezers that incorporate, at a minimum: (a) An external metal shell, (b) an interior plastic liner, and (c) insulation; and (3) any assembled external drawers designed for use in bottom mount combination refrigerator-freezers that incorporate, at a minimum: (a) an external metal shell, (b) an interior plastic liner, and (c) insulation.

The products subject to the investigation are currently classifiable under subheadings 8418.10.0010, 8418.10.0020, 8418.10.0030, and 8418.10.0040 of the Harmonized Tariff System of the United States (HTSUS). Products subject to this investigation may also enter under HTSUS subheadings 8418.21.0010, 8418.21.0020, 8418.21.0030, 8418.21.0090, and 8418.99.4000, 8418.99.8050, and 8418.99.8060. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.

[1] The existence of an interior sub-compartment for ice-making in an upper-most storage compartment does not render an upper-most storage compartment a freezer compartment.

Scope Comments

In accordance with the preamble to the Department's regulations (*see Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997)), in our *Initiation Notice* we set aside a period of time for parties to raise issues regarding product coverage, and encouraged all parties to submit comments within 20 calendar days of publication of the *Initiation Notice.*

On May 9, 2011, we received timely comments on the scope of the investigation from Samsung. Specifically, Samsung requested that the Department clarify the current description of a freezer compartment and exclude a certain type of refrigerator-freezer from the scope. These scope requests are as follows:

1. Samsung requested that the Department use the Association of Home Appliance Manufacturers (AHAM) definition to revise the current description of a freezer compartment; and

2. Samsung requested that the Department determine that a certain type of refrigerator with four compartments known as ''Quatro Cooling Refrigerators'' be excluded from the scope due to its upper-left non-convertible freezer compartment.

On May 18, 2011, Daewoo and LG submitted comments in response to Samsung's May 9 submission. In their comments, Daewoo and LG agreed with Samsung that the Department should amend the scope language to use the AHAM definition. Alternatively, LG requested that at a minimum the Department exclude from the scope any refrigerator, regardless of freezing capability, that is specifically designed to store kimchi.

Also on May 18, 2011, as well as on June 30, 2011, the petitioner submitted comments objecting to the requests filed by Samsung and LG, respectively. As part of these comments, the petitioner proposed a modification to the scope language with respect to the positioning of the freezer in relation to the upper-most compartment. Samsung submitted rebuttal comments on July 25, 2011.

Based on our analysis of these issues, we have preliminarily determined that the scope of this and the concurrent antidumping and countervailing duty investigations on bottom mount refrigerators from Mexico and Korea remains fundamentally unchanged. We have not modified the description of a freezer compartment in the scope of this investigation to be consistent with the AHAM definition, nor have we excluded kimchi refrigerators or Quatro Cooling Refrigerators from the scope of the investigation. However, as suggested by the petitioner, we have clarified the scope to eliminate any ambiguity with respect to the inclusion of Quatro Cooling Refrigerators in the scope of investigation.[2] *See* Memorandum to Gary Taverman, Acting Deputy Assistant Secretary for AD/CVD Operations, from James Maeder, Director, Office 2, entitled, ''Scope Modification Requests,'' dated October 26, 2011, for further discussion.

Facts Available Related to Samsung's Sales of Kimchi Refrigerators

The scope of the investigation includes all bottom mount refrigerators, including ''kimchi refrigerators,'' that meet the scope definition. As noted in the ''Scope Comments'' section of this notice, above, LG argued that the Department should modify the scope to exclude kimchi refrigerators. Therefore, in order to eliminate any confusion with respect to our reporting requirements, in June 2011 we clarified the reporting requirements of the questionnaire to include a product characteristic to specifically identify sales of kimchi refrigerators. While Daewoo and LG complied with our instructions and reported their home market sales of kimchi refrigerators, Samsung did not, arguing that its kimchi refrigerators did not fall within the scope. In July 2011, we instructed Samsung to report its sales of kimchi refrigerators and, again, Samsung refused to do so, repeating its claim that they were out-of-scope merchandise.

On September 1, 2011, we instructed Samsung to provide the technical specifications of its kimchi refrigerator models demonstrating that they fall outside the scope definition. At this time, we once again provided Samsung the alternative of reporting its sales of these models. In its September 29, 2011, response, Samsung continued to maintain that these models were not in scope. Nonetheless, instead of providing the technical specifications to support its claim, Samsung reported sales of kimchi refrigerators totaling many thousands of units, a figure which represents the vast majority of Samsung's home market sales.

On October 5, 2011, the petitioner provided further data which it states demonstrate that Samsung's kimchi refrigerators are in-scope merchandise.

Samsung eventually elected to report its sales of kimchi refrigerators, but because this new information was not received until the end of September, the Department did not have time to issue an associated supplemental questionnaire. Our initial analysis, however, indicates that there are serious problems with the sales data. Specifically, we have identified numerous areas of concern, including the following:

- There are significant inconsistencies in the methodology Samsung used to report its rebates, packing expenses, and indirect selling expenses between the kimchi sales databases and its other home market sales databases;
- Samsung reported many complicated schedules which include discrepancies for which Samsung has provided no explanation;
- There are inconsistencies between Samsung's narrative response and its reported data;
- Samsung reported kimchi refrigerator-specific rebate programs, and given Samsung's reporting issues with respect to its home market rebates (*see* the ''Calculation of Normal Value Based on Comparison Market Prices'' section, below), we cannot presume that these programs are not similarly deficient;
- Samsung departed from our specific instructions regarding the reporting of its control numbers; and
- Samsung did not separately identify packing expenses for its kimchi refrigerator models.

In light of these serious concerns, it became necessary to determine if the application of facts available was warranted.

Section 776(a) of the Act provides that the Department will apply ''facts otherwise available'' if necessary information is not available on the record or an interested party: (1) Withholds information that has been requested by the Department; (2) fails to provide such information within the deadlines established, or in the form or manner requested by the Department, subject to subsections (c)(1) and (e) of section 782 of the Act; (3) significantly impedes a proceeding; or (4) provides such information, but the information cannot be verified.

Pursuant to section 776(a)(2)(B) of the Act, we find that Samsung failed to provide information in the form and manner requested by the Department and that it is appropriate to resort to facts otherwise available to account for the unreported information. In selecting from among the facts otherwise

[2] The scope language has been revised as follows: The two references to ''the upper-most interior storage compartment(s)'' have been replaced with ''an upper-most interior storage compartment;'' and the two references in the footnote to ''the upper-most storage compartment'' have been replaced with ''an upper-most storage compartment.''

available, section 776(b) of the Act authorizes the Department to use an adverse inference if the Department finds that an interested party failed to cooperate by not acting to the best of its ability to comply with a request for information. The legislative history of the Act also provides guidance by explaining that adverse inferences are appropriate ''to ensure that the party does not obtain a more favorable result by failing to cooperate than if it had cooperated fully.'' *See* Statement of Administrative Action, accompanying the Uruguay Round Agreements Act, H.R. Doc. No. 103–465 at 870 (1995). Information used to make an adverse inference may include such sources as the petition, other information placed on the record, or determinations in a prior proceeding regarding the subject merchandise. *Id.* and 19 CFR 351.308(c). Furthermore, ''affirmative evidence of bad faith on the part of a respondent is not required before the Department may make an adverse inference.'' *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27340 (May 19, 1997); *see also Nippon Steel Corp.* v. *United States,* 337 F.3d 1373, 1383 (Fed. Cir. 2003) (*Nippon*).

Based on the information contained in Samsung's questionnaire responses, we find that Samsung's kimchi refrigerator sales data are not useable in their current form. Although, after numerous requests, this information was eventually submitted, it was received too close in time to the preliminary determination to permit the Department to issue a supplemental questionnaire to Samsung to remedy the deficiencies noted above. Moreover, because Samsung could have either reported the information at issue in the form and manner requested by the Department at an earlier date in response to the Department's prior questionnaires or provided the technical specifications to prove its claim that the models in question were not in-scope merchandise, and instead failed to do either, we find that Samsung has failed to cooperate to the best of its ability with our requests for information. Specifically, we find that an adverse inference is appropriate because Samsung: (1) Had the necessary information within its control and did not report this information; and (2) failed to put forth the maximum effort to provide the requested information. *See, e.g., Nippon,* 337 F.3d at 1883; and *Notice of Final Determination of Sales at Less Than Fair Value: Citric Acid and Certain Citric Salts from Canada,* 74 FR 16843, 16844–45 (April 13, 2009). Thus, for this preliminary determination, pursuant to section 776(b) of the Act, we find that it is appropriate to apply adverse facts available (AFA) with respect to Samsung's U.S. sales either: (1) Which had as their closest product comparison a kimchi refrigerator model; or (2) for which normal value (NV) was based on constructed value (CV).[3]

As AFA for the percentage of U.S. sales meeting the above criteria, we have preliminarily used the highest margin calculated for any U.S. transaction for Samsung, in accordance with our practice. *See, e.g., Notice of Final Determination of Sales at Less than Fair Value: Certain Cold-Rolled Carbon Steel Flat Products From Brazil,* 67 FR 62132 (October 3, 2002), and accompanying issues and Decision Memorandum at Comment 1; *Static Random Access Memory Semiconductors From Taiwan; Final Results of Antidumping Duty New Shipper Review,* 65 FR 12214 (March 8, 2000), and accompanying Issues and Decision Memorandum at Comment 1; *Notice of Final Determination of Sales at Less Than Fair Value: Static Random Access Memory Semiconductors From Taiwan,* 63 FR 8909, 8912 (February 23, 1998); *Final Determination of Sales at Less Than Fair Value; Stainless Steel Sheet and Strip in Coils From Germany,* 64 FR 30710, 30732 (June 8, 1999); and *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa,* 62 FR 61731, 61747 (November 19, 1997). In selecting a facts available margin, we sought a margin that is sufficiently adverse so as to effectuate the statutory purposes of the AFA rule, which is to induce respondents to provide the Department with complete and accurate information in a timely manner. We also sought a margin that is rationally related to the transactions to which the AFA is being applied and indicative of Samsung's customary selling practices. To that end, we selected the highest margin on an individual sale in a commercial quantity that fell within the mainstream of Samsung's transactions (*i.e.,* transactions that reflect sales of products that are representative of the broader range of models used to determine normal value).

We intend to issue an additional supplemental questionnaire to Samsung to allow it to remedy the deficiencies in the sales data for kimchi model refrigerators noted above, and we will consider this information for purposes of our final determination. However, if Samsung fails to respond adequately to this subsequent request for information, for purposes of the final determination, we may consider whether total versus partial AFA is appropriate for Samsung given the high percentage of comparisons affected by these deficiencies. *See* the Memorandum to the File from Elizabeth Eastwood, Senior Analyst, entitled, ''Calculations Performed for Samsung Electronics Corporation (Samsung) for the Preliminary Determination in the Antidumping Duty Investigation of Bottom Mount Refrigerators from Korea'' (Samsung Calculation Memo), dated October 26, 2011.

Targeted Dumping Allegations

The statute allows the Department to employ the average-to-transaction margin-calculation methodology under the following circumstances: (1) There is a pattern of export prices that differ significantly among purchasers, regions, or periods of time; and (2) the Department explains why such differences cannot be taken into account using the average-to-average or transaction-to-transaction methodology. *See* section 777A(d)(1)(B) of the Act.

On September 9, 2011, the petitioner submitted allegations of targeted dumping with respect to LG and Samsung and asserted that the Department should apply the average-to-transaction methodology in calculating the margins for these respondents. In its allegations, the petitioner asserted that there are patterns of U.S. sales prices for comparable merchandise that differ significantly among time periods. The petitioner relied on the Department's targeted dumping test in *Certain Steel Nails From the United Arab Emirates: Notice of Final Determination of Sales at Not Less Than Fair Value,* 73 FR 33985 (June 16, 2008), and *Certain Steel Nails From the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 33977 (June 16, 2008) (collectively *Nails*), as applied in more recent investigations such as *Multilayered Wood Flooring from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 76 FR 30656, 30659–60 (May 26, 2011). *See* the Petitioner's Submission of Targeted Dumping Allegations dated September 9, 2011, at pages 8–12.

On October 21, 2011, we received an amendment to the petitioner's targeted dumping allegation for LG. In this amended allegation, the petitioner

[3] We find that it is appropriate to base the margin for those U.S. sales for which NV is based on CV on AFA because home market sales of kimchi refrigerators would be used to determine CV profit and selling expenses.

defined the time period over which targeted dumping occurred as the fourth calendar quarter of 2010. The petitioner's original allegation covered essentially the same period, but it defined the fourth quarter by reference to weeks. As noted above in the ''Background'' section, because the petitioner's original allegation was based on data which was superseded by LG's supplemental response, we have accepted this amendment for purposes of the preliminary determination.

A. Targeted Dumping Test

We conducted time-period targeted dumping analyses for LG and Samsung using the methodology we adopted in *Nails* and most recently articulated in *Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From Indonesia: Final Determination of Sales at Less Than Fair Value,* 75 FR 59223 (September 27, 2010), and accompanying Issues and Decision Memorandum at Comment 1 (*Coated Paper*); and *Multilayered Wood Flooring From the Peoples' Republic of China: Final Determination of Sales at Less Than Fair Value,* 76 FR 64318 (October 18, 2011) (*Wood Flooring*), and accompanying Issues and Decision Memorandum at Comment 4.

The methodology we employed involves a two-stage test; the first stage addresses the pattern requirement and the second stage addresses the significant-difference requirement. *See* section 777A(d)(1)(B)(i) of the Act, *Nails, Coated Paper,* and *Wood Flooring.* In this test we made all price comparisons on the basis of identical merchandise (*i.e.,* by control number or CONNUM). We based all of our targeted dumping calculations on the U.S. net price which we determined for U.S. sales by LG and Samsung in our standard margin calculations. For further discussion of the test and results, see Memorandum to the File from Henry Almond, Senior Analyst, entitled, ''Calculations Performed for LGE for the Preliminary Determination in the Antidumping Duty Investigation of Bottom Mount Combination Refrigerator-Freezers from the Republic of Korea'' (LG Calculation Memo); and the Samsung Calculation Memo. As a result of our analysis, we preliminarily determine that there is a pattern of U.S. prices for comparable merchandise that differs significantly among certain time periods for LG and Samsung in accordance with section 777A(d)(1)(B)(i) of the Act and our current practice as discussed in *Nails, Wood Flooring,* and *Coated Paper.*

B. Price Comparison Method

Section 777A(d)(1)(B)(ii) of the Act states that the Department may compare the weighted average of the NV to export prices (EPs) (or constructed export prices (CEPs)) of individual transactions for comparable merchandise if the Department explains why differences in the patterns of EPs (or CEPs) cannot be taken into account using the average-to-average methodology. As described above, we preliminarily determine that, with respect to sales by Samsung and LG, for certain time periods there was a pattern of prices that differed significantly.

For both LG and Samsung, we find that these differences cannot be taken into account using the average-to-average methodology because the average-to-average methodology conceals differences in the patterns of prices between the targeted and non-targeted groups by averaging low-priced sales to the targeted group with high-priced sales to the non-targeted group. Therefore, for the preliminary determination, we find that the standard average-to-average methodology does not take into account LG's and Samsung's price differences because the alternative average-to-transaction methodology yields a material difference in the margin. Accordingly, for this preliminary determination we applied the average-to-transaction methodology to all U.S. sales made by LG and Samsung. *See* the LG Calculation Memo and the Samsung Calculation Memo for further discussion.

Fair Value Comparisons

To determine whether sales of bottom mount refrigerators from Korea to the United States were made at LTFV, we compared the EP or CEP to the NV, as described in the ''Export Price/Constructed Export Price'' and ''Normal Value'' sections of this notice, below. In accordance with section 777A(d)(1)(A)(i) of the Act, we compared POI weighted-average EPs and CEPs to weighted-average NVs for Daewoo, and in accordance with section 777A(d)(1)(B) of the Act, we compared transaction-specific EPs and CEPs to weighted-average NVs for LG and Samsung.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced and sold by the respondents in Korea during the POI that fit the description in the ''Scope of Investigation'' section of this notice to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We compared U.S. sales to sales made in the home market, where appropriate. Where there were no sales of identical merchandise in the home market made in the ordinary course of trade to compare to U.S. sales, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade. Where there were no sales of identical or similar merchandise, we made product comparisons using CV.

In making product comparisons, we matched foreign like products based on the physical characteristics reported by the respondents in the following order of importance: Completed unit or subassembly, unit type, calculated volume, number of compartments, refrigerator door/drawer configuration, other external door/drawer configurations, icemaker and water dispenser feature, door finish, type of compressor, number of evaporators, type of user interface, existence of a through-the-door feature, existence of an interior temperature-controlled sub-compartment, and existence of thin-wall insulation panels.

Export Price/Constructed Export Price

For certain U.S. sales made by Daewoo, LG, and Samsung, we used the EP methodology, in accordance with section 772(a) of the Act, because the subject merchandise was sold directly to the first unaffiliated purchaser in the United States before the date of importation by the producer or exporter of the subject merchandise outside the United States, and the use of the CEP methodology was not otherwise warranted based on the facts of record.

For the remaining U.S. sales made by Daewoo, LG, and Samsung, we calculated CEP in accordance with section 772(b) of the Act because the subject merchandise was first sold (or agreed to be sold) in the United States after the date of importation by or for the account of the producer or exporter, or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter.

A. Daewoo

With respect to EP sales, we based the starting price on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of duty drawback reported by Daewoo. We made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these expenses included, where appropriate, foreign inland freight, foreign brokerage and handling, freight subcontractor service fees, international

freight, and marine insurance. Regarding foreign inland freight, Daewoo used an affiliated company to arrange delivery of its merchandise to the United States. Because Daewoo's affiliate did not provide the same service to unaffiliated parties, nor did Daewoo use unaffiliated companies to arrange its deliveries, we were unable to test the arm's-length nature of the fees paid by Daewoo. Therefore, we based these expenses on the affiliate's costs. For further discussion, see the Memorandum to the File from David Crespo, Analyst, entitled, ''Calculations Performed for Daewoo Electronics Corporation for the Preliminary Determination in the Antidumping Duty Investigation of Bottom Mount Combination Refrigerator-Freezers from the Republic of Korea'' (Daewoo Calculation Memo) dated October 26, 2011.

We based CEP on the packed delivered prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of duty drawback reported by Daewoo. We made deductions for movement expenses for Daewoo's CEP transactions, as well, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign brokerage and handling, freight subcontractor service fees (adjusted as noted above), international freight, marine insurance, U.S. duties, and U.S. brokerage and handling.

In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses and warranties), and indirect selling expenses. We recalculated Daewoo's U.S. credit expenses to base them on its U.S. affiliate's revised U.S. dollar borrowing rate obtained from page 14 of Daewoo's October 4, 2011, response. For further discussion, see the Daewoo Calculation Memo.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by Daewoo on its sales of the subject merchandise in the United States and the profit associated with those sales.

B. LG

LG reported certain U.S. sales of refurbished merchandise. Because these sales were unusual and represented an insignificant quantity of total U.S. sales, we disregarded them for purposes of our analysis.

With respect to EP sales, we based the starting price on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments and duty drawback reported by LG. We made deductions for discounts and rebates, as appropriate. We also made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these expenses included, where appropriate, foreign inland freight, foreign brokerage and handling, international freight, and marine insurance. Regarding foreign inland freight, LG used an affiliated company to arrange delivery of its merchandise to the port of exportation. Because LG's affiliate did not provide the same service to unaffiliated parties, nor did LG use unaffiliated companies for its deliveries, we were unable to test the arm's-length nature of the expenses paid by LG. Therefore, we based these expenses on the affiliate's costs. For further discussion, see the LG Calculation Memo dated October 26, 2011.

We based CEP on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments and duty drawback reported by LG. We made deductions for discounts and rebates, as appropriate.

We made deductions for movement expenses for LG's CEP transactions, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight (adjusted as noted above), foreign brokerage and handling, international freight, marine insurance, U.S. brokerage and handling, U.S. warehousing, and U.S. inland freight expenses.

In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses, bank charges, advertising expenses, and warranty expenses), and indirect selling expenses (including inventory carrying costs and other indirect selling expenses). We recalculated LG's U.S. inventory carrying costs using the company's reported cost of manufacturing (COM), revised as stated below. For further discussion, see the ''Cost of Production Analysis'' section of the notice.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by LG on its sales of the subject merchandise in the United States and the profit associated with those sales. *See* the LG Calculation Memo for further discussion.

D. Samsung

In accordance with the Department's policy, Samsung reported the earlier of the date of invoice or shipment as its date of sale for both EP and CEP sales made during the POI. However, Samsung did not report its actual date of shipment from the factory, but rather it reported the bill of lading date. Samsung's methodology is not consistent with the Department's practice of using the date of shipment from the factory as the date of shipment. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Narrow Woven Ribbons With Woven Selvedge From Taiwan,* 75 FR 41804 (July 19, 2010), and accompanying Issues and Decision Memorandum at Comment 5. Because Samsung did not provide the number of days between shipment from the factory and shipment from the port, we have accepted the dates reported as facts available for purposes of the preliminary determination, pursuant to section 776(A)(2)(B) of the Act. However, following the issuance of the preliminary results, we intend to request that Samsung report its shipment dates from the factory, as well as any additional sales of merchandise shipped from the factory during the POI but invoiced afterwards. Should Samsung provide the Department with that information in a timely fashion, we intend to use it for purposes of the final determination.

In addition, Samsung reported certain U.S. sales of defective merchandise. Because these sales were unusual and represented an insignificant quantity of total U.S. sales, we disregarded them for purposes of our analysis.

With respect to EP, we based the starting price on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of duty drawback reported by Samsung. We made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign loading expenses, and foreign brokerage and handling expenses. Regarding foreign inland freight and loading expenses, Samsung used an affiliated company to load the merchandise into containers and arrange its delivery to the port of

exportation. Because Samsung's affiliate did not provide the same services to unaffiliated parties, nor did Samsung use unaffiliated companies for these services, we were unable to test the arm's-length nature of the fees paid by Samsung. Therefore, we based these expenses on the affiliate's costs. For further discussion, see the Samsung Calculation Memo.

We based CEP on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments and duty drawback reported by Samsung. We made deductions for discounts and rebates, as appropriate. We reclassified certain early payment ''rebates'' as discounts because these amounts were established in accordance with Samsung's normal payment terms set forth on the invoice.

Regarding Samsung's remaining rebates, in a supplemental questionnaire dated September 1, 2011, we instructed Samsung to report its rebates on as customer-specific, product-specific and time period-specific basis as possible. However, Samsung declined to report its U.S. rebates as instructed. While Samsung reported its U.S. rebates on a customer-specific basis, based on information reported in Samsung's supplemental questionnaire responses, we believe that it is possible for Samsung to report certain rebates (*i.e.,* REBATE3U and REBATE4U) on a product-specific and possibly a time period-specific basis, as well.[4] Therefore, pursuant to section 776(a)(2)(B) of the Act, we find that Samsung failed to provide information in the form and manner requested by the Department and that it is appropriate to resort to facts otherwise available to account for the unreported information. Moreover, we find that, pursuant to section 776(b) of the Act, an adverse inference is appropriate because: (1) Samsung had the necessary information within its control and did not report this information; and (2) it failed to put forth the maximum effort to provide the requested information. Therefore, for this preliminary determination, pursuant to section 776(b) of the Act, we find that it is appropriate to apply AFA with respect to these rebates. Specifically, as AFA, we recalculated both of these rebates by assigning the highest customer-specific rebate percentage reported for each rebate program to all POI sales that were eligible for a rebate under that particular rebate program. We intend to request additional information concerning Samsung's rebate programs, as well as its rebate reporting methodologies, prior to verification for consideration in the final determination.

We made deductions for movement expenses for Samsung's CEP transactions, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign loading expenses, foreign brokerage and handling expenses, ocean freight, marine insurance, U.S. customs duties (including merchandise processing fees and customs broker fees), U.S. warehousing expenses, U.S. inland insurance expenses, and U.S. inland freight expenses. Regarding foreign inland freight, foreign loading expenses, and ocean freight, Samsung used the affiliated company referenced above to provide the associated freight services. Therefore, we adjusted the freight expenses reported for CEP sales in the same manner as was done for EP sales.

In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses, advertising expenses, bank charges, and warranty expenses), and indirect selling expenses (including inventory carrying costs and other indirect selling expenses). Regarding credit expenses, Samsung reported the dates that its customers paid for the merchandise based on the payment terms of each sale; however, documentation on the record shows that payment may occur after this date. Because Samsung did not report actual payment dates for its U.S. sales and its reported methodology was inaccurate based on record evidence, pursuant to section 776(a)(2)(B) of the Act, as facts available, we increased Samsung's credit period by the additional time between the end of the payment terms and the actual payment for the sale for which Samsung provided this information, and we recalculated credit expenses using this revised information. For further discussion, see the Samsung Calculation Memo.

Regarding indirect selling expenses, we revised the calculation ratio for Samsung's U.S. affiliate to remove certain offsets which were not adequately substantiated in Samsung's response. We also recalculated Samsung's U.S. inventory carrying costs using the company's reported COM, revised as stated below. For further discussion, see the ''Cost of Production Analysis'' section of the notice and the Samsung Calculation Memo.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by Samsung and its affiliate on their sales of the subject merchandise in the United States and the profit associated with those sales. *See* the Samsung Calculation Memo for further discussion.

Normal Value

A. Home Market Viability

In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.,* the aggregate volume of home market sales of the foreign like product is equal to or greater than five percent of the aggregate volume of U.S. sales), we compared each respondent's volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with sections 773(a)(1)(A) and (B) of the Act.

In this investigation, we determined that Daewoo's, LG's, and Samsung's aggregate volume of home market sales of the foreign like product was greater than five percent of the aggregate volume of U.S. sales of the subject merchandise. Therefore, we used home market sales as the basis for NV in accordance with section 773(a)(1)(B) of the Act.

B. Affiliated Party Transactions and Arm's-Length Test

During the POI, Daewoo, LG, and Samsung sold foreign like product to affiliated customers. To test whether the sales made by Daewoo and certain sales by Samsung were made at arm's-length prices, we compared, on a product-specific basis, the starting prices of sales to affiliated and unaffiliated customers, net of all applicable billing adjustments, discounts and rebates, movements charges, direct selling expenses and packing expenses. Where the price to the affiliated party was, on average, within a range of 98 to 102 percent of the price of the same or comparable merchandise sold to unaffiliated parties, we determined that sales made to the affiliated party were at arm's-length. *See* 19 CFR 351.403(c); *see also Stainless Steel Sheet and Strip in Coils From Japan: Preliminary Results of Antidumping Duty Administrative Review,* 74 FR 39615 (August 7, 2009), unchanged in *Stainless Steel Sheet and Strip in Coils From Japan: Final Results of Antidumping Duty Administrative Review,* 75 FR 6631 (February 10, 2010).

[4] *See, e.g.,* Exhibit 12 of Samsung's September 29, 2011, supplemental questionnaire response.

Sales to affiliated customers in the home market that were not made at arm's-length prices were excluded from our analysis because we considered them to be outside the ordinary course of trade. *See* section 771(15) of the Act and 19 CFR 351.102(b)(35).

Because sales of foreign like product to certain of Samsung's affiliated resellers failed the arm's length test, Samsung reported its home market sales by these resellers. Therefore, we used Samsung's reported downstream home market sales data for all affiliates failing the arm's length test in our calculations for the preliminary determination. Where sales to one or more affiliates passed the arm's length test, we included these sales in our analysis, rather than the affiliate's downstream sales.

With respect to LG, this respondent reported downstream sales by its affiliated reseller, rather than both sales to the affiliate and the affiliate's downstream sales. Therefore, we used the downstream sales in our analysis for purposes of the preliminary determination.

C. Level of Trade

Section 773(a)(1)(B)(i) of the Act states that, to the extent practicable, the Department will calculate NV based on sales at the same level of trade (LOT) as the EP or CEP. Sales are made at different LOTs if they are made at different marketing stages (or their equivalent). *See* 19 CFR 351.412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stages of marketing. *Id; see also Certain Orange Juice From Brazil: Final Results of Antidumping Duty Administrative Review and Notice of Intent Not To Revoke Antidumping Duty Order in Part,* 75 FR 50999, 51001 (August 18, 2010), and accompanying Issues and Decision Memorandum at Comment 7 (*OJ from Brazil*). In order to determine whether the comparison market sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.,* the chain of distribution), including selling functions, class of customer (customer category), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying LOTs for EP and comparison market sales (*i.e.,* NV based on either home market or third country prices),[5] we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. *See Micron Tech., Inc.* v. *United States,* 243 F.3d 1301, 1314–16 (Fed. Cir. 2001).

When the Department is unable to match U.S. sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the Department may compare the U.S. sale to sales at a different LOT in the comparison market. In comparing EP or CEP sales at a different LOT in the comparison market, where available data make it possible, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if the NV LOT is at a more advanced stage of distribution than the LOT of the CEP and there is no basis for determining whether the difference in LOTs between NV and CEP affects price comparability (*i.e.,* no LOT adjustment was possible), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. *See, e.g., OJ from Brazil,* 75 FR at 51001.

In this investigation, we obtained information from Daewoo, LG, and Samsung regarding the marketing stages involved in making the reported home market and U.S. sales, including a description of the selling activities performed by each respondent for each channel of distribution. Company-specific LOT findings are summarized below.

Daewoo

Daewoo reported that it made EP and CEP sales through a single channel of distribution (*i.e.,* sales to distributors), and performed the following selling functions for sales to U.S. customers: Sales forecasting, order input/processing, freight and delivery services, warranty services, and packing. These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, based on the selling function categories, we find that Daewoo performed sales and marketing, freight and delivery services, and warranty and technical support for U.S. sales. Because all sales in the United States are made through a single distribution channel (*i.e.,* sales to distributors) and the selling activities to Daewoo's customers did not vary within this channel, we preliminarily determine that there is one LOT in the U.S. market.

With respect to the home market, Daewoo reported that it made sales to retailers and end users. Daewoo reported that its home market sales were made through a single channel of distribution and that it performed the following selling functions for sales to all home market customers: Sales forecasting, strategic/economic planning, personnel training/exchange, engineering services, market research, sales promotion, advertising, order input/processing, technical assistance, direct sales personnel, sales/marketing, freight and delivery services, inventory maintenance, warranty services, and packing. Additionally, for sales to retailers, Daewoo also provided cash discounts and distributor/dealer training. These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, we find that Daewoo performed sales and marketing, freight and delivery services, inventory maintenance and warehousing, and warranty and technical support at the same relative level of intensity for all customers in the home market. Because all sales in the home market sales are made through a single distribution channel and the selling activities to Daewoo's customers did not vary significantly within this channel, we preliminarily determine that there is one LOT in the home market for Daewoo.

Finally, we compared the U.S. LOT to the home market LOT and found that the selling functions Daewoo performed for home market customers are more advanced than those performed for its U.S. customers. This difference is sufficient to determine that the U.S. LOT is different from the home market LOT. Therefore, based on the totality of the facts and circumstances, we preliminarily determine that sales to the home market during the POI were made at a different LOT than sales to the United States. Additionally, because the home market LOT is at a more advanced stage of distribution than Daewoo's U.S. LOT and no LOT adjustment is possible, a CEP offset is warranted.

LG

LG reported that it made U.S. sales through three channels of distribution (*i.e.,* direct EP sales to original equipment manufacturer (OEM) customers, CEP sales to OEM customers,

[5] Where NV is based on CV, we determine the NV LOT based on the LOT of the sales from which we derive selling expenses, general and administrative (G&A) expenses, and profit for CV, where possible.

and CEP sales out of inventory of LG branded products). For all three channels of distribution, LG reported that it performed the following selling functions in Korea for sales to U.S. customers: Sales and marketing support, market research, advertising, order processing, direct sales personnel, freight and delivery services, warranty and after sales services, and packing. These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, based on the selling function categories, we find that LG performed sales and marketing, freight and delivery services, and warranty and technical support for U.S. sales. Although LG reported sales through three different channels of distribution, because the selling functions performed by LG in Korea do not differ between channels we preliminarily determine that there is one LOT in the U.S. market.

With respect to the home market, LG reported that it also made sales through three channels of distribution (*i.e.,* sales to construction companies, sales to unaffiliated retailers, and sales to unaffiliated retailers for which LG was responsible for delivery and installation at the end user's residence). Additionally, LG reported a fourth channel of distribution for sales made to unaffiliated end user customers by its affiliated retailer, HiPlaza.

LG reported that it performed the following selling functions for sales to all home market customers: Sales forecasting, product development/market research, advertising, sales promotion, packing, inventory maintenance, order input, direct sales personnel/sales support, warranty services, payment of commissions, and arrangement of freight and delivery. In addition to these activities, LG reported that its affiliated retailer maintained an extensive retail presence in Korea during the POI and performed the following additional selling functions for its sales: Sales forecasting, advertising, sales promotion, order input, direct sales personnel/sales support, and the payment of commissions.

These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, we find that LG performed sales and marketing, freight and delivery services, and inventory maintenance and warehousing at the same relative level of intensity for three of its reported sales channels in the home market. Regarding sales made by HiPlaza, we find that it also performed substantial sales and marketing activities for sales to its unaffiliated customers. These activities are sufficient to determine that the sales made by HiPlaza were at a more advanced level of trade than those made by LG. Accordingly, based on the totality of the facts and circumstances, we preliminarily determine that LG made sales at two levels of trade in the home market.

Finally, we compared the U.S. LOT to the home market LOTs and found that the selling functions LG performed for home market customers (at both home market LOTs) are more advanced than those performed for its U.S. customers. This difference is sufficient to determine that LG's U.S. LOT is different from the home market LOTs. Therefore, based on the totality of the facts and circumstances, we preliminarily determine that sales to the home market during the POI were made at different LOTs than sales to the United States. Additionally, because the home market LOTs are at a more advanced stage of distribution than LG's U.S. LOT and no LOT adjustment is possible, a CEP offset is warranted.

Samsung

Samsung reported that it made EP and CEP sales through two channels of distribution (*i.e.,* direct sales to unaffiliated customers and CEP sales out of inventory). Samsung reported that it packed subject merchandise in Korea for sales to both its EP and CEP customers. In addition, Samsung reported that it performed sales/marketing support and market research for its CEP sales, while it performed order input/processing for its EP sales. Moreover, Samsung sold subject merchandise to its U.S. affiliate during the POI (and thus it processed orders for CEP sales), and the sales listing shows that Samsung delivered subject merchandise to U.S. customers. These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, based on the selling function categories, we find that Samsung performed freight and delivery and sales and marketing activities for U.S. sales. Further, while Samsung reported sales through two different channels of distribution, because the selling functions performed by Samsung in Korea do not differ significantly between channels we preliminarily determine that there is one LOT in the U.S. market.

With respect to the home market, Samsung reported that it made sales through two channels of distribution (*i.e.,* sales to unaffiliated customers and sales to affiliated resellers). Additionally, Samsung reported a third channel of distribution for sales made to unaffiliated end users by its affiliated resellers. For its sales, Samsung reported that it performed the following selling functions for sales to all home market customers: Sales forecasting, strategic/economic planning, personnel training/exchange, provision of engineering services, advertising, distributor/dealer training, packing, inventory maintenance, order input/processing, employment of direct sales personnel, sales/marketing support, market research, technical assistance, provision of rebates and cash discounts, payment of commissions, provision of warranty services, provision of guarantees, provision of after-sales services, and provision of freight and delivery services. In addition to these activities, Samsung reported that its affiliated resellers maintained an extensive retail presence in Korea during the POI and performed the following additional selling functions for sales to the unaffiliated end users: Sales forecasting, strategic/economic planning, personnel training/exchange, advertising, sales promotion, inventory maintenance, order input/processing, employment of direct sales personnel, sales/marketing support, market research, provision of after-sales services, and provision of freight and delivery services.

These selling activities can be generally grouped into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, we find that Samsung performed sales and marketing, freight and delivery services, inventory maintenance and warehousing, and warranty and technical support at the same relative level of intensity for both of its reported sales channels in the home market. Regarding sales made by Samsung's affiliated resellers, we find that the affiliated resellers performed sales and marketing, freight and delivery services, and inventory maintenance and warehousing for sales to its unaffiliated customers. The additional selling functions performed by the affiliated resellers are sufficient

to determine that the affiliated resellers' home market sales were at a more advanced level of trade than those home market sales made by Samsung. Accordingly, based on the totality of the facts and circumstances, we preliminarily determine that Samsung made sales at two LOTs in the home market.

Finally, we compared the U.S. LOT to the home market LOTs and found that the selling functions Samsung performed for home market customers (in both home market LOTs) are more advanced than those performed for its U.S. customers. This difference is sufficient to determine that the U.S. LOT is different from either of the home market LOTs. Therefore, based on the totality of the facts and circumstances, we preliminarily determine that sales to the home market during the POI were made at different LOTs than sales to the United States. Additionally, because Samsung's home market LOTs are at a more advanced stage of distribution than its U.S. LOT and no LOT adjustment is possible, a CEP offset is warranted.

D. Cost of Production Analysis

Based on our analysis of an allegation contained in the petition, we found that there were reasonable grounds to believe or suspect that Daewoo's, LG's, and Samsung's sales of bottom mount refrigerators in the home market were made at prices below their COP. Accordingly, pursuant to section 773(b) of the Act, we initiated a country-wide sales-below-cost investigation to determine whether Daewoo's, LG's, and Samsung's sales were made at prices below their respective COPs.

1. Calculation of COP

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of the cost of materials and fabrication for the foreign like product, plus an amount for G&A, interest expenses, and home market packing costs. *See* ''Test of Home Market Sales Prices'' section below for treatment of home market selling expenses. Based on the review of record evidence, none of the respondents appeared to experience significant changes in the cost of manufacturing during the POI. Therefore, we followed our normal methodology of calculating an annual weighted-average cost.

We relied on the COP data submitted by Daewoo, LG, and Samsung. For LG and Samsung, we made the following adjustments to the companies' COP data: [6]

A. LG

- We analyzed LG's transactions with certain affiliated parties in accordance with section 773(f)(2) of the Act (the transactions disregarded rule) to determine whether the prices paid for the inputs used in the production of the merchandise under consideration reflect arm's-length prices. Based on our analysis, we found that the sum of the extended weighted-average prices paid by LG for inputs purchased from its affiliate LG Chemical was less than the sum of the extended weighted-average market prices. As such, we increased LG's reported COM to reflect market prices for the input supplied by LG Chemical.
- We revised LG's reported R&D expense ratio for the home appliance division to exclude internal transfers from the denominator of the ratio.
- We also revised the denominator of LG's common R&D expense ratio to reflect LG's unconsolidated cost of sales (COS) rather than consolidated COS.
- We revised the denominator of LG's G&A expense ratio to exclude unconsolidated scrap offsets and packing expenses.

See Memorandum to Neal Halper from Heidi Shriefer entitled, ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—LG Electronics Inc. and LG Electronics USA, Inc.,'' dated October 26, 2011.

B. Samsung

- We analyzed Samsung's transactions with certain affiliated parties in accordance with the transactions disregarded rule to determine whether the prices paid for the inputs used in the production of the merchandise under consideration reflect arm's-length prices. Based on our analysis, we found that the sum of the extended weighted-average prices paid by Samsung Gwangju Electronics Co., Ltd. (Samsung Gwangju), the producer of the merchandise under consideration, for inputs purchased from an affiliated party was less than the sum of the extended weighted-average market prices. As such, we increased Samsung Gwangju's reported COM to reflect market prices for inputs supplied by these affiliated parties.
- We reclassified the offset reported for Samsung Gwangju's sales of scrap from Samsung Gwangju's G&A expenses to the COM. We recalculated Samsung's G&A expenses, originally calculated by Samsung based on the income statements of its Digital Appliance Division, based on Samsung's fiscal year 2010 audited unconsolidated financial statements.
- We revised the costs reported in Samsung's October 3, 2011, COP data file to exclude packing expenses. We also revised the calculations of Samsung Gwangju's R&D and G&A expense ratios, used to calculate the per-unit expenses, to exclude packing costs from the denominators of those ratios. Likewise, we revised the denominators of Samsung's R&D and G&A expense ratios to exclude packing expenses.

See Memorandum to Neal Halper from LaVonne Clark entitled, ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—Samsung Electronic Co., Ltd. and Samsung Electronics America, Inc.,'' dated October 26, 2011.

2. Test of Home Market Sales Prices

On a product-specific basis, we compared the adjusted weighted-average COP to the home market sales of the foreign like product, as required under section 773(b) of the Act, in order to determine whether the sale prices were below the COP. The prices were exclusive of any applicable billing adjustments, discounts and rebates, movement charges, and actual direct and indirect selling expenses. In determining whether to disregard home market sales made at prices less than their COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether such sales were made: (1) Within an extended period of time in substantial quantities, and (2) at prices which permitted the recovery of all costs within a reasonable period of time.

3. Results of the COP Test

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of the respondent's sales of a given product during the POI are at prices less than the COP, we do not disregard any below-cost sales of that product, because we determine that in such instances the below-cost sales were not made in substantial quantities. Where 20 percent or more of the respondent's sales of a given product during the POI are at prices less than the COP, we disregard those sales of that product, because we determine that in such instances the

[6] We have preliminarily determined that a portion of LG's and Samsung's home appliance research and development (R&D) costs benefit the operations in Mexico. As a result, these respondents' submitted R&D costs allocated to Korea should be adjusted downward. The information needed to make this adjustment is not currently on the record; however, we intend to request the necessary information for consideration in the final determination.

below-cost sales represent substantial quantities within an extended period of time, in accordance with section 773(b)(1)(A) of the Act. In such cases, we also determine whether such sales were made at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(1)(B) of the Act.

We found that, for certain specific products, more than 20 percent of Daewoo's, LG's, and Samsung's home market sales during the POI were at prices less than the COP and, in addition, the below-cost sales did not provide for the recovery of costs within a reasonable period of time. We therefore excluded these sales and used the remaining sales, if any, as the basis for determining NV, in accordance with section 773(b)(1) of the Act.

D. Calculation of Normal Value Based on Comparison Market Prices

LG

We calculated NV based on delivered prices to unaffiliated customers. We made deductions, where appropriate, from the starting price for discounts and rebates. We also made deductions for movement expenses, including inland freight, handling, and warehousing, under section 773(a)(6)(B)(ii) of the Act. Regarding inland freight, handling, and warehousing, LG paid an affiliated company to arrange unaffiliated subcontractors to perform these services. Because LG's affiliate did not provide the same service to unaffiliated parties, nor did LG use unaffiliated companies for these services, we were unable to test the arm's-length nature of the expenses paid by LG. Therefore, we based these expenses on the affiliate's costs. *See* the LG Calculation Memo for further discussion.

For comparisons to EP sales, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for direct selling expenses (including bank charges, direct advertising and promotional expenses, and warranties), and commissions. Regarding advertising expenses, LG characterized certain home market advertising expenses as being direct in nature; however, we have reclassified these expenses as indirect because they are not product-specific (*i.e.,* they relate to a broader class of merchandise than is covered by this investigation). *See* the LG Calculation Memo for further discussion.

For comparisons to CEP sales, in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, we deducted from NV direct selling expenses (*i.e.,* imputed credit expenses, bank charges, direct advertising and promotional expenses, and warranties).

For all price-to-price comparisons, where commissions were granted in the comparison market but not in the U.S. market, we made an upward adjustment to NV for the lesser of: (1) The amount of commission paid in the comparison market; or (2) the amount of indirect selling expenses (including inventory carrying costs) incurred in the comparison market. *See* 19 CFR 351.410(e).

Furthermore, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also deducted home market packing costs and added U.S. packing costs in accordance with section 773(a)(6)(A) and (B) of the Act.

Finally, for comparisons to CEP sales, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses on the home market sales or the indirect selling expenses deducted from the starting price in calculating CEP. We reclassified certain advertising expenses as indirect, as discussed above. We also reclassified certain expenses incurred by LG's affiliated retailer in maintaining its retail presence in the Korean market as indirect selling expenses because these expenses related to rent, sales staff salaries, and other overhead expenses and did not result from or bear a direct relationship to particular sales. In addition, we recalculated LG's home market inventory carrying costs using the company's reported COM, revised as stated above. *See* the LG Calculation Memo for further discussion.

Samsung

We calculated NV based on delivered prices to unaffiliated customers and/or prices to affiliated customers that we determined to be at arm's-length. We made deductions, where appropriate, from the starting price for rebates and billing adjustments. We disallowed Samsung's reported early payment discounts because Samsung failed to calculate these discounts on a transaction-specific basis as instructed by the Department. We also disallowed certain rebates which were not calculated in accordance with the stated rebate program terms.

Finally, regarding an additional rebate program, in a supplemental questionnaire dated September 20, 2011, we instructed Samsung to report this rebate on a customer-specific, model-specific, and time-period-specific basis and it failed to do so. Based on information reported in Samsung's supplemental questionnaire responses, we believe that it is possible for Samsung to report these rebates on a customer-, model-, and time-period-specific basis. Therefore, as with U.S. rebates, pursuant to section 776(a)(2)(B) of the Act, we find that Samsung failed to provide information in the form and manner requested by the Department and that it is appropriate to resort to facts otherwise available to account for the unreported information. Moreover, we find that an adverse inference, pursuant to section 776(b) of the Act, is appropriate because: (1) Samsung had the necessary information within its control and did not report this information; and (2) it failed to put forth the maximum effort to provide the requested information. Therefore, for this preliminary determination, we are applying AFA with respect to these rebates. As AFA, we based the amounts of this additional rebate program on the lowest percentage calculated for any home market customer. We intend to request additional information concerning Samsung's rebate programs, as well as its rebate reporting methodologies, prior to verification for consideration in the final determination. *See* the Samsung Calculation Memo for further discussion.

We also made deductions for movement expenses, including inland freight and warehousing expenses, under section 773(a)(6)(B)(ii) of the Act. Regarding inland freight and warehousing expenses, these expenses were charged by an affiliated company in the home market. Because Samsung's affiliate did not provide the same service to unaffiliated parties, nor did Samsung use unaffiliated companies for these services, we were unable to test the arm's-length nature of the expenses paid by Samsung. Therefore, we based these expenses on the affiliate's costs. Finally with respect to inland freight, we reclassified certain expenses as indirect selling expenses because they were related to merchandise returns. *See* the Samsung Calculation Memo for further discussion.

For comparisons to EP sales, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for credit expenses, bank charges, and warranties. We recalculated EP credit expenses to base the credit period on the payment terms offered to the customer because Samsung's explanation of its payment date was not consistent with the payment terms.

Regarding warranties, we reclassified a portion of warranty expenses as indirect because they appeared to be unrelated to materials or labor expenses. Further, we based these expenses on the actual cost of Samsung's affiliated warranty provider because Samsung was unable to demonstrate that the expenses paid to the affiliate were at arm's length. For further discussion, see the Samsung Calculation Memo.

For comparisons to CEP sales, in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, we deducted from NV direct selling expenses (*i.e.,* imputed credit expenses and warranties (adjusted as noted above)).

For all price-to-price comparisons, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also deducted home market packing costs and added U.S. packing costs in accordance with section 773(a)(6)(A) and (B) of the Act. We based the packing expenses for downstream sales on the amounts reported for Samsung's direct home market sales because Samsung did not separately report these expenses in its downstream sales database.

Finally, for comparisons to CEP sales, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses on the home market sales or the indirect selling expenses deducted from the starting price in calculating CEP. We reclassified home market advertising expenses as indirect because they were brand-, but not product-, specific. We also recalculated Samsung's home market inventory carrying costs using the company's reported COM, revised as stated above. For further discussion, see the ''Cost of Production Analysis'' section of the notice.

E. Calculation of Normal Value Based on Constructed Value

In accordance with section 773(a)(4) of the Act, for all of Daewoo's sales and for certain refrigerator models sold by LG, we based NV on CV because there were no sales in the home market in the ordinary course of trade that could be reasonably compared to those U.S. sales.

In accordance with section 773(e) of the Act, we calculated CV based on the sum of the respondents' cost of materials and fabrication for the foreign like product, plus amounts for selling, general, and administrative expenses, profit, and U.S. packing costs. We calculated the cost of materials and fabrication, G&A and interest based on the methodology described in the ''Calculation of COP'' section of this notice.

For comparisons to EP, we made a circumstance-of-sale adjustment by deducting home market direct selling expenses and adding U.S. direct selling expenses. For comparisons to CEP, we deducted from CV the weighted-average home market direct selling expenses. We adjusted LG's direct selling expenses using the same methodology noted in the ''Calculation of Normal Value Based on Comparison Market Prices'' section of this notice, above. With respect to Daewoo, we adjusted the reported home market sales data to: (1) Reclassify certain expenses reported as imputed credit expenses to treat them as non-imputed direct selling expenses; and (2) recalculate indirect selling expenses incurred in Korea to include certain bad debt expenses which had been excluded from the calculation. *See* the Daewoo Calculation Memorandum for further information on these adjustments.

Finally, for comparisons to CEP sales, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses on the comparison market sales or the indirect selling expenses deducted from the starting price in calculating CEP.

Currency Conversion

We made currency conversions into U.S. dollars in accordance with section 773A(a) of the Act based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Critical Circumstances

On July 29, 2011, the petitioner filed a timely allegation, pursuant to section 733(e)(1) of the Act and 19 CFR 351.206, that critical circumstances exist with respect to imports of the merchandise under investigation. In accordance with 19 CFR 351.206(c)(2)(i), because the petitioner submitted its critical circumstances allegation more than 20 days before the scheduled date of the preliminary determination, the Department must issue a preliminary critical circumstances determination not later than the date of the preliminary determination.

Section 733(e)(1) of the Act provides that the Department will preliminarily determine that critical circumstances exist if there is a reasonable basis to believe or suspect that: (A)(i) There is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise; or (ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales, and (B) there have been massive imports of the subject merchandise over a relatively short period. Section 351.206(h)(1) of the Department's regulations provides that, in determining whether imports of the subject merchandise under investigation have been ''massive,'' the Department normally will examine: (i) The volume and value of the imports; (ii) seasonal trends; and (iii) the share of domestic consumption accounted for by the imports. In addition, 19 CFR 351.206(h)(2) provides that an increase in imports of 15 percent during the ''relatively short period'' of time may be considered ''massive.'' Section 351.206(i) of the Department's regulations defines ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed) and ending at least three months later. The regulations also provide, however, that if the Department finds that importers, exporters, or producers had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely, the Department may consider a period of not less than three months from that earlier time.

In determining whether the above statutory criteria have been satisfied, we examined the evidence presented in the petitioner's submission of July 29, 2011, the ITC preliminary injury determination, and the respondents' shipment volume submissions.

To determine whether there is a history of injurious dumping of the merchandise under investigation, in accordance with section 733(e)(1)(A)(i) of the Act, the Department normally considers evidence of an existing antidumping duty order on the subject merchandise in the United States or elsewhere to be sufficient. *See Preliminary Determination of Critical Circumstances: Steel Concrete Reinforcing Bars From Ukraine and Moldova,* 65 FR 70696 (November 27, 2000). The petitioner notes that in 2001, after finding both dumping and injury, New Zealand imposed antidumping duties on the subject merchandise produced in Korea. However, this order was terminated in 2006. Moreover, the petitioner did not identify any additional proceedings with respect to Korean-origin products, nor are we

aware of any antidumping duty order in any country on bottom mount refrigerators from Korea. For this reason, the Department does not find a history of injurious dumping of the subject merchandise from Korea pursuant to section 733(e)(1)(A)(i) of the Act.

To determine whether the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales in accordance with section 733(e)(1)(A)(ii) of the Act, the Department normally considers margins of 25 percent or more for EP sales or 15 percent or more for CEP transactions sufficient to impute knowledge of dumping. *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Lined Paper Products From Indonesia,* 71 FR 15162 (March 27, 2006) unchanged in *Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances: Certain Lined Paper Products From Indonesia,* 71 FR 47171 (August 16, 2006).

For Daewoo and LG, we preliminarily determine that there is not a sufficient basis to find that importers should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales pursuant to section 733(e)(1)(A)(ii) of the Act, because the calculated margins were not 25 percent or more for EP sales, or 15 percent or more for CEP sales. Because the knowledge criterion has not been met for these respondents, we have not addressed the second criterion of whether or not imports were massive in the comparison period when compared to the base period.

With respect to Samsung, however, we preliminarily determine that there is a sufficient basis to find that importers should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales pursuant to section 733(e)(1)(A)(ii) of the Act, because Samsung's calculated margin exceeded 25 percent or more for EP sales, or 15 percent or more for CEP sales. In addition, for the companies covered by the ''All Others'' rate, we calculated a preliminary margin of 18.15 percent, which meets the 15-percent threshold necessary to impute knowledge of dumping for CEP sales, which are the vast majority of the sales on which the calculation of the ''All Others'' rate is based. Therefore, because the knowledge criterion has been met for Samsung and the ''All Others'' rate companies, we must address the second criterion of whether imports were massive in the comparison period when compared to the base period.

In determining whether there are ''massive imports'' over a ''relatively short period,'' pursuant to section 733(e)(1)(B) of the Act, the Department normally compares the import volumes of the subject merchandise for at least three months immediately preceding the filing of the petition (*i.e.,* the ''base period'') to a comparable period of at least three months following the filing of the petition (*i.e.,* the ''comparison period''). Imports normally will be considered massive when imports during the comparison period have increased by 15 percent or more compared to imports during the base period.

The Department requested and obtained from each of the respondents monthly shipment data from January 2008 to July 2011. To determine whether imports of subject merchandise have been massive over a relatively short period, we compared, pursuant to 19 CFR 351.206(h)(1)(i), Samsung's export volumes for the four months before the filing of the petition (*i.e.,* December 2010—March 2011) to those during the four months after the filing of the petition (*i.e.,* April through July 2011). These periods were selected based on the Department's practice of using the longest period for which information is available from the month that the petition was filed through the effective date of the preliminary determination. According to the monthly shipment information, we found the volume of shipments of bottom mount refrigerators increased by more than 15 percent for Samsung.

In determining whether imports for the companies subject to the ''All Others'' rate were massive, we relied on the experience of Daewoo, LG, and Samsung. Because the volume of imports for Daewoo, LG, and Samsung increased by more than 15 percent from April to July 2011 when compared to the import volume in the base period of December 2010 to March 2011, we find that imports for the companies subject to the ''All Others'' rate also increased by more than 15 percent.

For purposes of our ''massive imports'' determination, we also considered the impact of seasonality on imports of bottom mount refrigerators. Based on our analysis of the company-specific shipment data reported for 2008, 2009, 2010, and January–July 2011, we find that there is a consistent pattern of seasonality evidenced by a significant increase in shipments during quarters 2 and 3, in comparison to quarters 1 and 4 in each year. As a result, we find that any surge in U.S. imports of bottom mount refrigerators during the period after the filing of the petition in this investigation can be explained by seasonal trends. Therefore, we preliminarily determine that imports of bottom mount refrigerators during the comparison period were not massive in accordance with section 733(e)(1)(B) of the Act. *See* the Memorandum to James P. Maeder, Director, Office 2, from The Team entitled, ''Antidumping Duty Investigation of Bottom Mount Combination Refrigerator-Freezers from Korea—Preliminary Determination of Critical Circumstances,'' (Critical Circumstances Memo) dated October 26, 2011.

In summary, we do not find that there is a reasonable basis to believe or suspect importers had knowledge of dumping and the likelihood of material injury with respect to bottom mount refrigerators from Korea purchased by Daewoo or LG, while we find that there is a reasonable basis to believe or suspect importers had knowledge of dumping and the likelihood of material injury with respect to bottom mount refrigerators from Korea purchased from Samsung and companies covered by the ''All Others'' rate. However, we do not find that there have been massive imports of bottom mount refrigerators over a relatively short period from Samsung or the ''All Others'' rate companies due to seasonality. Given the analysis summarized above, and described in more detail in the Critical Circumstances Memo, we preliminarily determine that critical circumstances do not exist with respect to imports of bottom mount refrigerators produced in, and exported from, Korea.

Verification

As provided in section 782(i) of the Act, we will verify information relied upon in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we are directing CBP to suspend liquidation of all imports of subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register.**

Consistent with our practice, where the product under investigation is also subject to a concurrent countervailing duty investigation, we instruct CBP to require a cash deposit or posting of a bond equal to the amount by which the normal value exceeds the export price

or constructed export price, less the amount of the countervailing duty determined to constitute an export subsidy. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Carbazole Violet Pigment 23 From India,* 69 FR 67306, 67307 (November 17, 2004). In this case, although the product under investigation is also subject to a concurrent countervailing duty investigation, the Department found no countervailing duty determined to constitute an export subsidy. *See Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea: Preliminary Negative Countervailing Duty Determination and Alignment of Final Determination With Final Antidumping Determination,* 76 FR 55044 (September 6, 2011). Therefore, we have not offset the cash deposit rates shown below for purposes of this preliminary determination.

We will instruct CBP to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the NV exceeds EP or CEP, as indicated in the chart below. These suspension-of-liquidation instructions will remain in effect until further notice. The weighted-average dumping margins are as follows:

Exporter/ Manufacturer	Weighted-average margin percentage	Critical circumstances
Daewoo Electronics Corporation.	0.00	No.
LG Electronics, Inc.	4.09	No.
Samsung Electronics Co., Ltd.	32.20	No.
All Others	18.15	No.

The ''All Others'' rate is derived exclusive of all *de minimis* or zero margins and margins based entirely on adverse facts available. Specifically, this rate is based on the simple average of the margins calculated for LG and Samsung. Because we cannot apply our normal methodology of calculating a weighted-average margin due to requests to protect business-proprietary information, we find this rate to be the best proxy of the actual weighted-average margin determined for these respondents. *See, e.g., Certain Frozen Warmwater Shrimp From India: Final Results of Antidumping Duty Administrative Review, Partial Rescission, and Final No Shipment Determination,* 76 FR 41203, 41205 (July 13, 2011). For further discussion of this calculation, see the memorandum from Henry Almond, Senior Analyst, to the file entitled, ''Calculation of the All Others Rate for the Preliminary Results of the Antidumping Duty Investigation of Bottom Mount Combination Refrigerator-Freezers From Korea'', dated October 26, 2011.

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Disclosure

The Department will disclose to parties the calculations performed in connection with this preliminary determination within five days of the date of publication of this notice. *See* 19 CFR 351.224(b).

Public Comment

Case briefs for this investigation must be submitted to the Department no later than seven days after the date of the final verification report issued in this proceeding. Rebuttal briefs must be filed five days from the deadline date for case briefs. *See* 19 CFR 351.309(d). A list of authorities used, a table of contents, and an executive summary of issues should accompany any briefs submitted to the Department. Executive summaries should be limited to five pages total, including footnotes. Case briefs must present all arguments that continue to be relevant to the Department's final determination, in the submitter's view. *See* 19 CFR 351.309(c)(2). Section 774 of the Act provides that the Department will hold a public hearing to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs, provided that such a hearing is requested by an interested party. *See* 19 CFR 351.310(c). If a request for a hearing is made in this investigation, the hearing will tentatively be held two days after the rebuttal brief deadline date at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, within 30 days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs.

We will make our final determination no later than 135 days after the publication of this notice in the **Federal Register**.

This determination is published pursuant to sections 733(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: October 26, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–28415 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–839]

Notice of Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Affirmative Critical Circumstances Determination: Bottom Mount Combination Refrigerator-Freezers From Mexico

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of preliminary determination of sales at less than fair value.

SUMMARY: We preliminarily determine that bottom mount combination refrigerator-freezers (bottom mount refrigerators) from Mexico are being sold, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733(b) of the Tariff Act of 1930, as amended (the Act). In addition, we preliminarily determine that there is a reasonable basis to believe or suspect that critical circumstances exist with respect to the subject merchandise exported from Mexico by Samsung Electronics Mexico, S.A. de C.V. (Samsung). Interested parties are invited to comment on this preliminary determination. Because we are postponing the final determination, we will make our final determination not later than 135 days after the date of publication of this preliminary determination in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Kate Johnson, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and

Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–4929, respectively.

Preliminary Determination

We preliminarily determine that bottom mount refrigerators from Mexico are being sold, or are likely to be sold, in the United States at LTFV, as provided in section 733(b) of the Act. The estimated margins of sales at LTFV are shown in the ''Suspension of Liquidation'' section of this notice. In addition, we preliminarily determine that there is a reasonable basis to believe or suspect that critical circumstances exist with respect to the subject merchandise exported from Mexico by Samsung. The critical circumstances analysis for the preliminary determination is discussed below under the section ''Critical Circumstances.''

Background

Since the initiation of this investigation on April 19, 2011 (*see Initiation of Antidumping Duty Investigations: Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea and Mexico,* 76 FR 23281 (April 26, 2011) (*Initiation Notice*)), the following events have occurred.

On April 21, 2011, we issued quantity and value (Q&V) questionnaires to four Mexican producers/exporters: Electrolux Home Products, Corp. NV/ Electrolux Home Products De Mexico, S.A. de C.V. (Electrolux); LG Electronics Monterrey Mexico, S.A. de C.V. (LGEMM); Controladora Mabe, S.A. de C.V./Mabe, S.A. de C.V. (Mabe); and Samsung to determine which producers/exporters accounted for the largest volume of sales of bottom mount refrigerators from Mexico. On May 13, 2011, Electrolux requested that it be treated as a mandatory respondent in this investigation. On May 18, 2011, we selected the three largest producers/ exporters of bottom mount refrigerators from Mexico as the mandatory respondents in this proceeding. *See* Memorandum entitled ''Selection of Respondents for Individual Review,'' dated May 18, 2011. We issued section A of the questionnaire (*i.e.,* the section covering general information) to LGEMM, Mabe, and Samsung on May 20, 2011. We issued sections B through E of the questionnaire (*i.e.,* the sections covering comparison market sales, U.S. sales, cost of production (COP) information, and further manufacturing information, respectively) to these respondents on May 25, 2011. Subsequently, we re-evaluated our resources in the context of our casework and determined that we were able to examine four respondents. Therefore, on May 27, 2011, we included Electrolux as a mandatory respondent in this investigation and issued a questionnaire to Electrolux. *See* Memorandum entitled ''Inclusion of Electrolux Home Products, Corp. N.V. as a Mandatory Respondent,'' dated May 27, 2011.

On May 13, 2011, the United States International Trade Commission (ITC) preliminarily determined that there is a reasonable indication that imports of bottom mount refrigerators from Mexico are materially injuring the United States industry. *See* ITC Investigation Nos. 701–TA–477 and 731–TA–1180–1181 (Publication No. 4232).

Also, in May 2011, various interested parties, including Whirlpool Corporation (hereafter, the petitioner), submitted comments on the scope of this and the concurrent antidumping and countervailing duty investigations of bottom mount refrigerators from the Republic of Korea. *See* ''Scope Comments'' section of this notice.

We received responses to section A of the questionnaire from the four respondents in June 2011, and to sections B, C, and D of the questionnaire in July 2011. No responses to section E of the questionnaire were necessary.

We issued supplemental questionnaires from July through September 2011, and we received responses to these supplemental questionnaires from July through October 2011.

On July 29, 2011, the petitioner alleged that critical circumstances existed with respect to bottom mount refrigerators produced and exported from Mexico. On August 10, 2011, we requested monthly shipment data from the respondents for the period January 2008 through July 2011 for purposes of this analysis. On August 16, 2011, LGEMM objected to this request, arguing that the petitioner's critical circumstances allegation did not meet the necessary statutory criteria. We responded to LGEMM's objection on August 18, 2011. All four respondents submitted the requisite shipment data between August 24 and 26, 2011. In their submissions, Electrolux, LGEMM, and Samsung provided comments on how the Department should analyze whether critical circumstances exist with respect to their imports or bottom mount refrigerators from Mexico.

On August 1, 2011, the petitioner alleged that Electrolux and LGEMM made third country sales below the COP and, therefore, requested that the Department initiate a sales-below-cost investigation of both respondents. On August 24 and 26, 2011, the Department initiated sales-below-cost investigations of Electrolux and LGEMM, respectively. *See* the ''Cost of Production Analysis'' section, below.

On August 11, 2011, the petitioner submitted allegations related to affiliated party transactions and the major input rule with respect to subject merchandise produced and exported from Mexico by Samsung and LGEMM. On the same date, the petitioner alleged that the ''Special Rule for Certain Multinational Corporations'' (MNC provision) applies in relation to bottom mount refrigerators produced and exported from Mexico by LGEMM. LGEMM objected to this allegation on August 23, 2011.

Also on August 11, 2011, the petitioner requested that the date for the issuance of the preliminary determination in this investigation be fully extended pursuant to section 733(c)(1) of the Act and 19 CFR 351.205(e). On August 16, 2011, pursuant to sections 733(c)(1)(A) and (c)(2) of the Act and 19 CFR 351.205(f), the Department postponed the preliminary determination until no later than October 26, 2011. *See Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea and Mexico: Postponement of Preliminary Determinations of Antidumping Duty Investigations,* 76 FR 52313 (August 22, 2011).

On September 6, 2011, we issued a letter to LGEMM requesting that it submit the responses to sections B and D of the Department's questionnaire that were filed on the administrative record of the investigation of bottom mount refrigerators from Korea, by its Korean affiliate, LG Electronics, Inc. (LGE), along with all of LGE's subsequent supplemental questionnaire responses. This request was made in the context of the petitioner's August 11, 2011, allegation (supplemented on September 26, 2011) that the MNC provision applies in relation to bottom mount refrigerators produced and exported from Mexico by LGEMM. LGE/LGEMM complied with this request on September 11, 2011, and with subsequent submissions in September and October.[1]

On September 9, 2011, the petitioner alleged that targeted dumping was occurring with respect to bottom mount refrigerators produced and exported from Mexico by Electrolux, LGEMM, and Samsung.

[1] We subsequently requested on October 11, 2011, that LGEMM submit LGE's response to section A of the Department's questionnaire (filed on the record of the Korea investigation by LGE), along with all subsequent supplemental section A questionnaire responses. LGEMM complied with this request on October 12, 2011.

On September 26, 2011, the petitioner amended its critical circumstances allegation to include only Electrolux, LGEMM and Samsung.

On October 3, 2011, the petitioner alleged that targeted dumping was occurring with respect to bottom mount refrigerators produced and exported from Mexico by Mabe. On October 7, 2011, we rejected as untimely the petitioner's targeted dumping allegation with respect to Mabe.

On October 6, 2011, we requested updated shipment data from Electrolux, LGEMM, and Samsung for consideration in our critical circumstances analysis for the final determination of this investigation.

We received various submissions from interested parties after October 11, 2011, including database corrections from Electrolux and LGEMM. However, these submissions were received too late to be considered for purposes of the preliminary determination. We will consider each of these submissions in our final determination.

Postponement of Final Determination

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. The Department's regulations, at 19 CFR 351.210(e)(2), require that requests by respondents for postponement of a final determination be accompanied by a request for extension of provisional measures from a four-month period to not more than six months.

Pursuant to section 735(a)(2) of the Act, on October 17, 19, 20, and 21, 2011, Mabe, Samsung, Electrolux, and LGEMM, respectively, requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone its final determination until not later than 135 days after the date of the publication of the preliminary determination in the **Federal Register**, and extend the provisional measures to not more than six months. In accordance with 19 CFR 351.210(b), because (1) Our preliminary determination is affirmative, (2) the respondents account for a significant proportion of exports of the subject merchandise, and (3) no compelling reasons for denial exist, we are granting the respondents' request and are postponing the final determination until no later than 135 days after the publication of this notice in the **Federal Register**. Suspension of liquidation will be extended accordingly.

Period of Investigation

The period of investigation (POI) is January 1, 2010, through December 31, 2010. This period corresponds to the four most recent fiscal quarters prior to the month of the filing of the petition (*i.e.,* March 2011).

Scope of Investigation

The products covered by the investigation are all bottom mount combination refrigerator-freezers and certain assemblies thereof from Mexico. For purposes of the investigation, the term ''bottom mount combination refrigerator-freezers'' denotes freestanding or built-in cabinets that have an integral source of refrigeration using compression technology, with all of the following characteristics:

- The cabinet contains at least two interior storage compartments accessible through one or more separate external doors or drawers or a combination thereof;
- An upper-most interior storage compartment(s) that is accessible through an external door or drawer is either a refrigerator compartment or convertible compartment, but is not a freezer compartment; [2] and
- There is at least one freezer or convertible compartment that is mounted below an upper-most interior storage compartment(s).

For purposes of the investigation, a refrigerator compartment is capable of storing food at temperatures above 32 degrees F (0 degrees C), a freezer compartment is capable of storing food at temperatures at or below 32 degrees F (0 degrees C), and a convertible compartment is capable of operating as either a refrigerator compartment or a freezer compartment, as defined above.

Also covered are certain assemblies used in bottom mount combination refrigerator-freezers, namely: (1) Any assembled cabinets designed for use in bottom mount combination refrigerator-freezers that incorporate, at a minimum: (a) an external metal shell, (b) a back panel, (c) a deck, (d) an interior plastic liner, (e) wiring, and (f) insulation; (2) any assembled external doors designed for use in bottom mount combination refrigerator-freezers that incorporate, at a minimum: (a) An external metal shell, (b) an interior plastic liner, and (c) insulation; and (3) any assembled external drawers designed for use in bottom mount combination refrigerator-freezers that incorporate, at a minimum: (a) an external metal shell, (b) an interior plastic liner, and (c) insulation.

The products subject to the investigation are currently classifiable under subheadings 8418.10.0010, 8418.10.0020, 8418.10.0030, and 8418.10.0040 of the Harmonized Tariff System of the United States (HTSUS). Products subject to this investigation may also enter under HTSUS subheadings 8418.21.0010, 8418.21.0020, 8418.21.0030, 8418.21.0090, and 8418.99.4000, 8418.99.8050, and 8418.99.8060. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.

Scope Comments

In accordance with the preamble to the Department's regulations (*see Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997)), in our *Initiation Notice* we set aside a period of time for parties to raise issues regarding product coverage, and encouraged all parties to submit comments within 20 calendar days of publication of the *Initiation Notice.*

On May 9, 2011, we received timely comments on the scope of the investigation from Samsung. Specifically, Samsung requested that the Department clarify the current description of a freezer compartment and exclude a certain type of refrigerator-freezer from the scope. These scope requests are as follows:

1. Samsung requested that the Department use the Association of Home Appliance Manufacturers (AHAM) definition to revise the current description of a freezer compartment; and
2. Samsung requested that the Department determine that a certain type of refrigerator with four compartments known as ''Quatro Cooling Refrigerators'' be excluded from the scope due to its upper-left non-convertible freezer compartment.

On May 18, 2011, Daewoo and LGEMM submitted comments in response to Samsung's May 9, 2011, submission. In their comments, Daewoo and LGEMM agreed with Samsung that the Department should amend the scope language to use the AHAM definition. Alternatively, LGEMM requested that at a minimum the Department exclude from the scope any refrigerator,

[2] The existence of an interior sub-compartment for ice-making in an upper-most storage compartment does not render an upper-most storage compartment a freezer compartment.

regardless of freezing capability, that is specifically designed to store kimchi.

Also, on May 18, 2011, as well as on June 30, 2011, the petitioner submitted comments objecting to the requests filed by Samsung and LGEMM, respectively. As part of these comments, the petitioner proposed a modification to the scope language with respect to the positioning of the freezer in relation to the upper-most compartment. Samsung submitted rebuttal comments on July 25, 2011.

Based on our analysis of these issues, we have preliminarily determined that the scope of this and the concurrent antidumping and countervailing duty investigations on bottom mount refrigerators from Korea remains fundamentally unchanged. We have not modified the description of a freezer compartment in the scope of this investigation to be consistent with the AHAM definition, nor have we excluded kimchi refrigerators or Quatro Cooling Refrigerators from the scope of the investigation. However, as suggested by the petitioner, we have clarified the scope to eliminate any ambiguity with respect to the inclusion of Quatro Cooling Refrigerators in the scope of investigation.[3] *See* Memorandum entitled ''Scope Modification Requests,'' dated October 26, 2011.

Targeted Dumping Allegations

The statute allows the Department to employ the average-to-transaction margin-calculation methodology under the following circumstances: (1) There is a pattern of export prices that differ significantly among purchasers, regions, or periods of time; and (2) the Department explains why such differences cannot be taken into account using the average-to-average or transaction-to-transaction methodology. *See* section 777A(d)(1)(B) of the Act.

On September 9, 2011, the petitioner submitted allegations of targeted dumping with respect to Samsung, LGEMM, and Electrolux and asserted that the Department should apply the average-to-transaction methodology in calculating the margins for these respondents. In its allegations, the petitioner asserted that there are patterns of U.S. sales prices for comparable merchandise that differ significantly among time periods. The petitioner relied on the Department's targeted dumping test in *Certain Steel Nails from the United Arab Emirates: Notice of Final Determination of Sales at Not Less Than Fair Value,* 73 FR 33985 (June 16, 2008), and *Certain Steel Nails from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances,* 73 FR 33977 (June 16, 2008) (collectively *Nails*), as applied in more recent investigations such as *Multilayered Wood Flooring from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 76 FR 30656, 30659–60 (May 26, 2011). *See* Petitioners' Submission of Targeted Dumping Allegations dated September 9, 2011, at pages 7–11.

A. Targeted Dumping Test

We conducted time-period targeted dumping analyses for Samsung, LGEMM, and Electrolux using the methodology we adopted in *Nails* and most recently articulated in *Certain Coated Paper Suitable for High-Quality Print Graphics Using Sheet-Fed Presses From Indonesia: Final Determination of Sales at Less Than Fair Value,* 75 FR 59223 (September 27, 2010) and accompanying Issues and Decision Memorandum at Comment 1 (*Coated Paper*), and *Multilayered Wood Flooring From the Peoples' Republic of China: Final Determination of Sales at Less Than Fair Value,* 76 FR 64318 (October 18, 2011) (*Wood Flooring*) and accompanying Issues and Decision Memorandum at Comment 4.

The methodology we employed involves a two-stage test; the first stage addresses the pattern requirement and the second stage addresses the significant-difference requirement. *See* section 777A(d)(1)(B)(i) of the Act, *Nails, Coated Paper,* and *Wood Flooring.* In this test we made all price comparisons on the basis of identical merchandise (*i.e.,* by control number or CONNUM). We based all of our targeted dumping calculations on the U.S. net price which we determined for U.S. sales by Samsung, LGEMM, and Electrolux in our standard margin calculations. As a result of our analysis, we preliminarily determine that there is a pattern of U.S. prices for comparable merchandise that differs significantly among certain time periods for Samsung and LGEMM, in accordance with section 777A(d)(1)(B)(i) of the Act and our current practice as discussed in *Nails, Coated Paper,* and *Wood Flooring.* We also preliminarily determine that no such pattern exists for Electrolux. For further discussion of the test and results, see the Department's memoranda entitled ''Preliminary Determination Margin Calculation for Electrolux Home Products, Corp. N.V. and Electrolux Home Products De Mexico, S.A de C.V.'' (Electrolux Calculation Memo); ''Preliminary Determination Margin Calculation for LG Electronics Monterrey Mexico, S.A. de C.V.'' (LGEMM Calculation Memo); and ''Preliminary Determination Margin Calculation for Samsung Electronics Mexico, S.A. de C.V.'' (Samsung Calculation Memo), dated October 26, 2011.

B. Price Comparison Method

Section 777A(d)(1)(B)(ii) of the Act states that the Department may compare the weighted average of the normal value (NV) to export prices (EPs) or constructed export prices (CEPs) of individual transactions for comparable merchandise if the Department explains why differences in the patterns of EPs or CEPs cannot be taken into account using the average-to-average methodology. As described above, we preliminarily determine that, with respect to sales by Samsung and LGEMM for certain time periods there was a pattern of prices that differed significantly.

For Samsung, we find that these differences can be taken into account using the average-to-average methodology because the average-to-average methodology does not conceal differences in the patterns of prices between the targeted and non-targeted groups by averaging low-priced sales to the targeted group with high-priced sales to the non-targeted group. Therefore, for the preliminary determination, we find that the standard average-to-average methodology takes into account the price differences because the alternative average-to-transaction methodology yields no difference in the margin or yields a difference in the margin that is so insignificant relative to the size of the resulting margin as to be immaterial. Accordingly, for this preliminary determination we have applied the standard average-to-average methodology to all U.S. sales made by Samsung. *See* Samsung Calculation Memo.

For LGEMM, we find that these differences cannot be taken into account using the average-to-average methodology because the average-to-average methodology conceals differences in the patterns of prices between the targeted and non-targeted groups by averaging low-priced sales to the targeted group with high-priced sales to the non-targeted group. Therefore, for the preliminary determination, we find that the standard

[3] The scope language has been revised as follows: the two references to ''the upper-most interior storage compartment(s)'' have been replaced with ''an upper-most interior storage compartment;'' and the two references in the footnote to ''the upper-most storage compartment'' have been replaced with ''an upper-most storage compartment.''

average-to-average methodology does not take into account the price differences because the alternative average-to-transaction methodology yields a material difference in the margin. Accordingly, for this preliminary determination we applied the average-to-transaction methodology to all U.S. sales made by LGEMM. *See* LGEMM Calculation Memo.

For Electrolux, because we did not find a pattern of prices that differed significantly for certain time periods pursuant to section 777A(d)(1)(B) of the Act, we applied our standard average-to-average price comparison methodology to all U.S. sales made by Electrolux pursuant to section 777A(d)(1)(A) of the Act. *See* Electrolux Calculation Memo.

Fair Value Comparisons

To determine whether sales of bottom mount refrigerators from Mexico to the United States were made at LTFV, we compared the EP or CEP to the NV, as described in the ''Export Price/ Constructed Export Price'' and ''Normal Value'' sections of this notice, below. In accordance with section 777A(d)(1)(A)(i) of the Act, we compared POI weighted-average EPs and CEPs to weighted-average NVs (for Electrolux, Mabe, and Samsung), and transaction-specific EPs and CEPs to weighted-average NVs (for LGEMM) in accordance with section 777A(d)(1)(B) of the Act.

All four respondents reported sales of damaged and/or refurbished merchandise in their U.S. and/or comparison markets during the POI. Because the quantity of such sales does not constitute a significant percentage of the respondents' total U.S. and/or comparison market sales made during the POI, we have excluded these sales from our margin analysis for purposes of the preliminary determination. *See, e.g., Notice of Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from Ecuador,* 69 FR 76913 (December 23, 2004), and accompanying Issues and Decision Memorandum at General Comment 2.

MNC Provision

On August 11, 2011, the petitioner alleged that all of the criteria for invoking the MNC provision have been satisfied with respect to LGEMM. To determine whether sales of LGEMM's bottom mount refrigerators from Mexico to the United States were made at LTFV, we compared the U.S. price to the appropriate NV as required by the MNC provision.

The MNC provision, contained in section 773(d) of the Act, requires the Department to determine if the following three criteria are satisfied:

(1) Subject merchandise exported to the United States is being produced in facilities which are owned or controlled, directly or indirectly, by a person, firm or corporation which also owns or controls, directly or indirectly, other facilities for the production of the foreign like product which are located in another country or countries;

(2) Sales of the foreign like product by the company concerned in the home market of the exporting country are nonexistent or insufficient as a basis for comparison with the sales of the subject merchandise to the United States; and,

(3) The NV of the foreign like product produced in one or more of the facilities outside the exporting country is higher than the NV of the foreign like product produced in the facilities located in the exporting country. (In this comparison, we must adjust the NVs for any differences between the two countries (including taxes, labor, materials and overhead), pursuant to section 773(d) of the Act.)

If the above criteria are satisfied, then the MNC provision instructs the Department to compare U.S. price to the NV at which the foreign like product is sold in substantial quantities from one or more facilities outside the exporting country.

Regarding the first criterion, LGEMM reported that it is owned by LGE in part; LGE produces and sells bottom mount refrigerators in Korea. Thus, the first criterion is satisfied.

Regarding the second criterion, we compared the reported volume of home market sales of bottom mount refrigerators to the reported volume of U.S. sales of bottom mount refrigerators, in accordance with section 773(d)(2) of the Act and 19 CFR 351.404, in order to determine whether there were sufficient sales of bottom mount refrigerators in the home market to compare to sales of bottom mount refrigerators in the United States. We found that LGEMM's Mexican home market was not viable for comparison to sales to the United States. Based on LGEMM's questionnaire response, we determined, pursuant to 19 CFR 351.404, that Canada is the most appropriate third country market for purposes of the comparison of NVs under the MNC provision because Canada is LGEMM's largest third country market with respect to sales of bottom mount refrigerators.

Regarding the third criterion, we compared the NV of sales made by LGEMM to Canada (Canadian NV) with the NV of the sales made by LGE in Korea (Korean NV). We used in this comparison only those sales to Canada and Korea made in the ordinary course of trade.[4] We also excluded sales of refurbished merchandise, as discussed in the ''Fair Value Comparison'' section of this notice. To compare the NVs, we first calculated the Canadian and Korean NVs using our normal methodology under section 773(a) of the Act.

1. Canadian NV

We calculated the Canadian NV based on ex-warehouse or delivered prices to unaffiliated customers. We made deductions, where appropriate, from the starting price for discounts, rebates, and billing adjustments. We also made deductions for movement expenses, including foreign inland freight, foreign brokerage and handling, international freight, Canadian brokerage and handling, Canadian warehousing, and Canadian inland freight expenses. In addition, we made deductions for commissions, advertising expenses, imputed credit expenses, warranties, and packing costs. *See* LGEMM Calculation Memo for further discussion of the adjustments to the Canadian NV.

2. Korean NV

We calculated the Korean NV based on delivered prices to unaffiliated customers. We made deductions, where appropriate, from the starting price for discounts and rebates. We also made deductions for movement expenses, including inland freight, handling, and warehousing. Regarding inland freight, handling, and warehousing, LGE paid an affiliated company to arrange unaffiliated subcontractors to perform these services. Because LGE's affiliate did not provide the same service to unaffiliated parties, nor did LGE use unaffiliated companies for these services, we were unable to test the arm's-length nature of the expenses paid by LGE. Therefore, we based these expenses on the affiliate's costs.

In addition, we made deductions for direct selling expenses (including bank

[4] We initiated sales-below-cost investigations with respect to LGEMM's third country sales to Canada and LGE's home market sales in Korea. *See* Memorandum entitled ''The Petitioner's Allegation of Sales below the Cost of Production for LG Electronics Monterrey Mexico, S.A. de C.V.'', dated August 26, 2011, and *Initiation Notice.* Accordingly, we used in our analysis only those sales that passed the sales below cost test. With respect to LGEMM's affiliated party transactions in Canada, we used in our analysis only those Canadian sales that passed the arm's-length test, as described in the ''Affiliated Party Transactions and Arm's-Length Test'' section of this notice. With respect to LGE's affiliated party transactions in Korea, LGE reported downstream sales by its affiliated reseller rather than both sales to the affiliate and the affiliate's downstream sales. Therefore, we used only the downstream sales in our analysis.

charges, direct advertising and promotional expenses, imputed credit expenses, and warranties), commissions, and packing costs. *See* LGEMM Calculation Memo for further discussion of the adjustments to the Korean NV.

Once we had calculated the two NVs, we then matched the NVs, to LGEMM's U.S. sales according to the product-comparison criteria discussed below under the ''Product Comparisons'' section of this notice. We matched the U.S. sales with the NV at the most similar level of trade (LOT), where possible. *See* LGEMM Calculation Memo for discussion of our LOT analysis with respect to Canadian sales, and ''Level of Trade'' section of this notice, below, for discussion of our LOT analysis with respect to Korean sales. Next, we calculated a comparison adjustment for each product-specific NV to determine whether any of the observed differences in value between the NV of products produced and sold in Korea and the NV of products produced in Mexico and sold in Canada were attributable to differences in COPs. The comparison adjustment included the costs of materials, labor, fixed and variable overhead, general and administrative (G&A) expense and interest incurred in producing the product. To calculate the comparison adjustment, the Department relied on the submitted cost information except in the following instances where the costs were not appropriately quantified or valued.

1. Mexican-Produced Merchandise

We analyzed LGEMM's transactions with affiliated parties in accordance with section 773(f)(2) of the Act (the transactions disregarded rule) to determine whether the prices paid for the inputs used in the production of the merchandise under consideration reflect arm's-length prices. Based on our analysis, we found that the sum of the extended weighted-average prices paid by LGEMM for inputs purchased from LG Chemical America Inc. were at less than the sum of the extended weighted-average market prices. As such, we increased LGE's reported cost of manufacturing (COM) to reflect market prices.

We adjusted LGEMM's reported costs to include research and development (R&D) expenses incurred by its affiliate, LGE. Because LGEMM appears to have benefited from LGE's R&D activities associated with the production of the merchandise under consideration, we added LGE's R&D expenses to LGEMM's reported costs. We also revised LGEMM's CONNUM-specific G&A expenses. We adjusted the denominator of LGEMM's G&A expense ratio for packing expenses and scrap revenue. We applied the revised G&A expense ratio to the reported CONNUM-specific COM to determine the revised G&A expenses. *See* Memorandum entitled ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—LG Electronics Monterrey Mexico, S.A. de C.V. and LG Electronics USA, Inc.'' (LGEMM Cost Calculation Memo), dated October 26, 2011.

2. Korean-Produced Merchandise

We analyzed LGE's transactions with certain affiliated parties in accordance with section 773(f)(2) of the Act (transactions disregarded rule) to determine whether the prices paid for the inputs used in the production of the merchandise under consideration reflect arm's-length prices. Based on our analysis, we found that the sum of the extended weighted-average prices paid by LGE for inputs purchased from LG Chemical were at less than the sum of the extended weighted-average market prices. As such, we increased LGE's reported COM to reflect market prices. We also revised LGE's reported G&A expense ratio for certain R&D expenses. *See* Memorandum entitled ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—LG Electronics Inc. and LG Electronics USA, Inc.'' (LG Cost Calculation Memo), dated October 26, 2011, included at Attachment 8 to LGEMM Calculation Memo.

Next, we converted the COP and NV data to U.S. dollars, and calculated the comparison adjustment as the difference between the Canadian NV COP and the Korean NV COP. We applied the comparison adjustment to the Korean NV. We then multiplied the NVs by the quantity of U.S. product to which the NVs were compared in order to provide for an equitable comparison. Finally, we summed the total value for each market. From these aggregated values, we determined that the Korean value was higher than the Canadian value. Thus, the third criterion for invoking the MNC provision has been satisfied.

Because all of the above criteria for the MNC provision have been satisfied, we are required to base NV for LGEMM on the prices of sales made by LGE in Korea (*see* LGEMM Calculation Memo for additional discussion of the Department's application of the MNC provision methodology).

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced and sold by the respondents in Mexico, or in Korea in the case of LGEMM under the MNC provision, during the POI that fit the description in the ''Scope of Investigation'' section of this notice to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. We compared U.S. sales to sales made in the comparison market, where appropriate. Where there were no sales of identical merchandise in the comparison market made in the ordinary course of trade to compare to U.S. sales, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade. Where there were no sales of identical or similar merchandise, or there was no viable comparison market, we made product comparisons using constructed value (CV).

In making the product comparisons, we matched foreign like products based on the Physical characteristics reported by the respondents in the following order of importance: completed unit or subassembly, unit type, calculated volume, number of compartments, refrigerator door/drawer configuration, other external door/drawer configurations, icemaker and water dispenser feature, door finish, type of compressor, number of evaporators, type of user interface, existence of a through-the-door feature, existence of an interior temperature-controlled sub-compartment, and existence of thin-wall insulation panels.

Export Price/Constructed Export Price

For certain U.S. sales made by LGEMM and Samsung, we used EP methodology, in accordance with section 772(a) of the Act, because the subject merchandise was sold directly to the first unaffiliated purchaser in the United States before the date of importation by the producer or exporter of the subject merchandise outside the United States, and CEP methodology was not otherwise warranted based on the facts of record.

For all U.S. sales made by Electrolux and Mabe and certain U.S. sales made by LGEMM and Samsung, we calculated CEP in accordance with section 772(b) of the Act because the subject merchandise was first sold (or agreed to be sold) in the United States after the date of importation by or for the account of the producer or exporter, or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter.

A. Electrolux

We based CEP on the packed prices to unaffiliated purchasers in the United States. We used the earlier of shipment or invoice date as the date of sale for Electrolux's CEP sales, in accordance with our practice. *See, e.g., Certain Frozen Warmwater Shrimp from Thailand: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 72 FR 52065 (September 12, 2007), and accompanying Issues and Decision Memorandum at Comment 11.

We adjusted the starting price by the amount of billing adjustments reported by Electrolux. We made deductions for rebates and discounts, as appropriate. We made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign customs fees, foreign and U.S. inland insurance, U.S. inland freight expenses (*i.e.,* freight from factory to warehouse and freight from warehouse to the customer), and pre-sale warehousing expenses. In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses, service fees paid to financing agents, advertising expenses, and warranty expenses), and indirect selling expenses (including inventory carrying costs).

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by Electrolux on its sales of the subject merchandise in the United States and the profit associated with those sales. *See* the Electrolux Calculation Memo.

B. LGEMM

We based EP on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments reported by LGEMM. We made deductions for discounts and rebates, as appropriate. We made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these expenses included, where appropriate, foreign inland freight, foreign brokerage and handling, and international freight.

We based CEP on the packed, ex-warehouse or delivered prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments reported by LGEMM. We made deductions for discounts and rebates, as appropriate.

We made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign brokerage and handling, international freight, U.S. brokerage and handling, U.S. warehousing, and U.S. inland freight expenses. In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses, bank charges, advertising expenses, and warranty expenses), and indirect selling expenses (including inventory carrying costs).

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by LGEMM and its U.S. affiliate on sales of the subject merchandise in the United States and the profit associated with those sales. *See* LGEMM Calculation Memo.

C. Mabe

Mabe sold bottom mount refrigerators to unaffiliated U.S. customers during the POI through its affiliated U.S. reseller, General Electric Company (GE).[5] Therefore, we used CEP methodology to calculate Mabe's antidumping margin, comparing Mabe's home market sales to unaffiliated customers to GE's sales to unaffiliated customers in the United States. We based CEP on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments. We made deductions for discounts and rebates, as appropriate. We reclassified one of Mabe's rebates as a discount, in accordance with the description of this expense in its September 26, 2011, supplemental questionnaire response (SQR).

In a supplemental questionnaire dated August 19, 2011, we instructed Mabe to report its rebates on a customer-specific basis, but Mabe did not do so arguing that its reporting methodology was reasonable. Based on information reported in Mabe's questionnaire responses, we believe that it is possible for Mabe to report its rebates, at a minimum, on a customer-specific basis and possibly on a product-specific and time period-specific basis. *See, e.g.,* pages 8–9 of the SQR which describes the various rebate programs. Therefore, pursuant to section 776(a)(2)(B) of the Act, we find that Mabe failed to provide information in the form and manner requested by the Department and that it is appropriate to resort to facts otherwise available to account for the unreported information. Moreover, we find that an adverse inference is appropriate because: (1) Mabe had the necessary information within its control and did not report this information; and (2) it failed to put forth the maximum effort to provide the requested information. Therefore, for this preliminary determination, pursuant to section 776(b) of the Act, we find that it is appropriate to apply adverse facts available (AFA) with respect to these rebates. Specifically, as AFA, we based the rebates reported for all of Mabe's U.S. rebate programs on the highest percentage reported for any of the programs. We intend to request additional information concerning Mabe's rebate programs, as well as its rebate reporting methodology, prior to verification for consideration in the final determination.

We made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, U.S. brokerage and handling, U.S. inland freight expenses (*i.e.,* freight from port to warehouse and freight from warehouse to the customer), and U.S. warehousing expenses. In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses, advertising expenses, and warranty expenses), and indirect selling expenses (including inventory carrying costs and other indirect selling expenses). We recalculated credit expenses by subtracting early payment discounts from gross unit price. *See* discussion below with respect to the calculation of indirect selling expenses and advertising expenses. With respect to the foreign inland freight expense from plant/warehouse to the port of export and inventory carrying costs incurred by Mabe for its U.S. sales to GE, we calculated an average expense. *See* Memorandum entitled ''Preliminary Margin Calculation for Controladora Mabe S.A. de C.V., Mabe S.A. de C.V.,

[5] *See* the Memorandum entitled, ''Investigation of Bottom Mount Combination Refrigerator-Freezers from Mexico: Finding of Affiliation Between Controladora Mabe S.A. de C.V., Mabe S.A. de C.V., and Leiser S. de R. (collectively ''Mabe'') and General Electric Company (''GE''), dated September 2, 2011.

and Leiser S. de R.L.,'' dated October 26, 2011 (Mabe Calculation Memo) for further discussion.

In its initial questionnaire response dated July 25, 2011, GE reported indirect selling and advertising expense ratios that were derived from a product-line management report. In its SQR, GE revised those ratios by substituting them with ratios that were derived from data in GE's Appliance Division accounts. As explanation, GE stated that the management report data used for the original ratios cannot be tied into its financial records. Moreover, the appliances-level records are the only available source of data from which GE can produce verifiable indirect selling and advertising ratios.

We have several outstanding questions regarding GE's claims with respect to both the original and the revised data, including how data was compiled and how expenses were allocated to product lines in the management report, and whether the appliance-level data include expenses that may be otherwise unaccounted for in Mabe's and GE's questionnaire responses. Moreover, GE has not explained why it has relied on the management report for other purposes besides the reporting of indirect selling and advertising expenses, such as in its sales reconciliation and the calculation of rebates. *See* Exhibit 2 of the SQR and Exhibit 2 of the July 25, 2011, questionnaire response, respectively. Therefore, for the preliminary determination we have used GE's originally-reported indirect selling and advertising expense ratios in the margin calculation for Mabe, as we prefer adjustments to be as product-specific as possible. We intend to ask for additional information concerning these expenses through a supplemental questionnaire to GE, which will be subject to verification, and will reconsider this issue for the final determination. *See* Mabe Calculation Memo.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by both Mabe and GE on sales of the subject merchandise in the United States and the profit associated with those sales.

D. Samsung

We based EP on the packed prices to unaffiliated purchasers in the United States. We made deductions for movement expenses in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign inland insurance, foreign brokerage and handling expenses, and U.S. customs duties (including merchandise processing fees and customs broker fees incurred in Mexico).

We based CEP on the packed prices to unaffiliated purchasers in the United States. We increased the starting price by the amount of billing adjustments reported by Samsung. We made deductions for discounts and rebates, as appropriate. We reclassified Samsung's early payment rebate as a discount, in accordance with the description of this expense in the October 5, 2011, supplemental questionnaire response.

In a supplemental questionnaire dated September 27, 2011, we instructed Samsung to report its rebates on as customer-specific, product-specific and time period-specific basis as possible. However, Samsung declined to report its U.S. rebates as instructed. While Samsung reported its U.S. rebates on a customer-specific basis, based on information reported in Samsung's supplemental questionnaire responses, we believe that it is possible for Samsung to report certain rebates (*i.e.,* REBATE3U and REBATE4U) on a product-specific and possibly a time period-specific basis, as well.[6] Therefore, pursuant to section 776(a)(2)(B) of the Act, we find that Samsung failed to provide information in the form and manner requested by the Department and that it is appropriate to resort to facts otherwise available to account for the unreported information. Moreover, we find that an adverse inference is appropriate because: (1) Samsung had the necessary information within its control and did not report this information; and (2) it failed to put forth the maximum effort to provide the requested information. Therefore, for this preliminary determination, pursuant to section 776(b) of the Act, we find that it is appropriate to apply adverse facts available (AFA) with respect to these rebates. Specifically, as AFA, we recalculated both of these rebates by assigning the highest customer-specific rebate percentage reported for each rebate program to all POI U.S. sales that were eligible for a rebate under that particular rebate program. We intend to request additional information concerning Samsung's rebate programs, as well as its rebate reporting methodologies, prior to verification for consideration in the final determination.

We made deductions for movement expenses, in accordance with section 772(c)(2)(A) of the Act; these included, where appropriate, foreign inland freight, foreign warehousing expenses, foreign inland insurance, foreign brokerage and handling expenses, ocean freight, U.S. customs duties (including merchandise processing fees and customs broker fees incurred in Mexico), U.S. inland insurance, U.S. inland freight expenses (*i.e.,* freight from port to warehouse and freight from warehouse to the customer), and post-sale warehousing expenses. In accordance with section 772(d)(1) of the Act and 19 CFR 351.402(b), we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (*i.e.,* imputed credit expenses, advertising expenses, and warranty expenses), and indirect selling expenses (including inventory carrying costs and other indirect selling expenses). We recalculated credit expenses by subtracting early payment discounts from gross unit price. We recalculated U.S. inventory carrying costs by using the Mexican peso short-term interest rate, consistent with our practice to match the currency of the interest rate to the currency of the cost being imputed. *See Certain Orange Juice from Brazil: Final Results of Antidumping Duty Administrative Review, Determination Not to Revoke Antidumping Duty Order in Part, and Final No shipment Determination,* 76 FR 50176 (August 12, 2011), and accompanying Issues and Decision Memorandum at Comment 5.

Pursuant to section 772(d)(3) of the Act, we further reduced the starting price by an amount for profit to arrive at CEP. In accordance with section 772(f) of the Act, we calculated the CEP profit rate using the expenses incurred by Samsung and its U.S. affiliate on their sales of the subject merchandise in the United States and the profit associated with those sales. *See* Samsung Calculation Memo.

Normal Value

A. Home Market Viability

In order to determine whether there is a sufficient volume of sales in the home market to serve as a viable basis for calculating NV (*i.e.,* the aggregate volume of home market sales of the foreign like product is equal to or greater than five percent of the aggregate volume of U.S. sales), we compared each respondent's volume of home

[6] *See, e.g.,* Exhibit SC–4 of Samsung's September 21, 2011, supplemental questionnaire response and Exhibit 1 of its October 5, 2011, supplemental questionnaire response.

market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with sections 773(a)(1)(A) and (B) of the Act.

In this investigation, we determined that Mabe's aggregate volume of home market sales of the foreign like product was greater than five percent of the aggregate volume of U.S. sales of the subject merchandise. Therefore, we used home market sales as the basis for NV in accordance with section 773(a)(1)(B) of the Act.

In this investigation, we determined that neither Electrolux's nor LGEMM's aggregate volume of home market sales of the foreign like product was sufficient to permit a proper comparison with U.S. sales of the subject merchandise. Therefore, where appropriate, we used sales to the respondent's largest third country market, comprised of merchandise that is similar to the subject merchandise exported to the United States, as the basis for comparison market sales in accordance with section 773(a)(1)(C) of the Act and 19 CFR 351.404. We used Canada as the third country market for Electrolux. Although Canada is LGEMM's largest third country market (comprised of merchandise that is similar to the subject merchandise exported to the United States) we performed the analysis discussed above under the ''MNC Provision'' section of this notice to determine the appropriate comparison market for LGEMM. As a result of our analysis, we determined Korea to be the appropriate comparison market for LGEMM. Furthermore, we determined that Samsung's aggregate volume of home and third country market sales of the foreign like product were insufficient to permit a proper comparison with U.S. sales of the subject merchandise.[7] Therefore, we used CV as the basis for calculating NV, in accordance with section 773(a)(4) of the Act.

B. Affiliated Party Transactions and Arm's-Length Test

During the POI, Mabe sold foreign like product to affiliated customers. To test whether these sales were made at arm's-length prices, we compared on a product-specific basis, the starting prices of sales to affiliated and unaffiliated customers, net of all applicable billing adjustments, discounts and rebates, movements charges, direct selling expenses, and packing expenses. Where the price to the affiliated party was, on average, within a range of 98 to 102 percent of the price of the same or comparable merchandise sold to unaffiliated parties, we determined that sales made to the affiliated party were at arm's-length. *See* 19 CFR 351.403(c); *see also e.g., Stainless Steel Sheet and Strip in Coils From Japan: Preliminary Results of Antidumping Duty Administrative Review,* 74 FR 39615 (August 7, 2009), unchanged in *Stainless Steel Sheet and Strip in Coils form Japan: Final Results of Antidumping Duty Administrative Review,* 75 FR 6631 (February 10, 2010). Sales to affiliated customers that were not made at arm's-length prices were excluded from our analysis because we considered them to be outside the ordinary course of trade. *See* section 771(15) of the Act and 19 CFR 351.102(b)(35).

C. Level of Trade

Section 773(a)(1)(B)(i) of the Act states that, to the extent practicable, the Department will calculate NV based on sales at the same LOT as the EP or CEP. Sales are made at different LOTs if they are made at different marketing stages (or their equivalent). *See* 19 CFR 351.412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stages of marketing. *Id; see also Certain Orange Juice From Brazil: Final Results of Antidumping Duty Administrative Review and Notice of Intent Not To Revoke Antidumping Duty Order in Part,* 75 FR 50999, 51001 (August 18, 2010), and accompanying Issues and Decision Memorandum at Comment 7 (*OJ from Brazil*). In order to determine whether the comparison market sales were at different stages in the marketing process than the U.S. sales, we reviewed the distribution system in each market (*i.e.,* the chain of distribution), including selling functions, class of customer (customer category), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying LOTs for EP and comparison market sales (*i.e.,* NV based on either home market or third country prices),[8] we consider the starting prices before any adjustments. For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. *See Micron Tech., Inc.* v. *United States,* 243 F.3d 1301, 1314–16 (Fed. Cir. 2001).

When the Department is unable to match U.S. sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the Department may compare the U.S. sale to sales at a different LOT in the comparison market. In comparing EP or CEP sales at a different LOT in the comparison market, where available data make it possible, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if the NV LOT is at a more advanced stage of distribution than the LOT of the CEP and there is no basis for determining whether the difference in LOTs between NV and CEP affects price comparability (*i.e.,* no LOT adjustment was possible), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. *See, e.g., OJ from Brazil,* 75 FR at 51001.

In this investigation, we obtained information from all four respondents regarding the marketing stages involved in making the reported comparison market and U.S. sales, including a description of the selling activities performed by each respondent for each channel of distribution. Company-specific LOT findings are summarized below.

1. Electrolux

Electrolux sold bottom mount refrigerators only to retailers and builders/wholesalers in both the Canadian and U.S. markets. Electrolux reported that it made CEP sales in the U.S. market through the following four channels of distribution: (1) The customer picks up the merchandise from its El Paso warehouse; (2) its U.S. affiliate (*i.e.,* Electrolux Major Appliances North America (UWA)) delivers the merchandise from the El Paso warehouse to the customer; (3) the customer picks up the merchandise from a UWA regional distribution center (RDC); and (4) UWA delivers the merchandise from the RDC to the customer. For purposes of examining the different selling activities reported by Electrolux for sales made through each U.S. channel of distribution, we grouped the selling activities into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support.

We compared the selling activities Electrolux performed in each channel, exclusive of the selling activities

[7] On July 8, 2011, the petitioner disputed Samsung's claim that it did not have a viable third country market during the POI and requested that Samsung report its third country sales. Based on our review of the record, we found no basis to require Samsung to report this data for consideration in the preliminary determination. However, we intend to verify Samsung's claims for purposes of the final determination.

[8] Where NV is based on CV, we determine the NV LOT based on the LOT of the sales from which we derive selling expenses, G&A expenses, and profit for CV, where possible.

performed by its U.S. affiliate, and found that either there is no difference in the selling functions performed by Electrolux between the channels (*i.e.,* freight and delivery services) or Electrolux did not perform the selling function at all (*i.e.,* sales and marketing, inventory maintenance and warehousing, and warranty and technical support) for each channel. As a result, we found that Electrolux performed the same selling functions for all four U.S. distribution channels. Accordingly, we determined that all CEP sales constitute one LOT. With respect to the Canadian market, Electrolux reported the following three channels of distribution: (1) Its Canadian affiliate (*i.e.,* Electrolux Canada Corp. (CDW)) delivers the merchandise from the El Paso warehouse to the customer; (2) the customer picks up the merchandise from CDW's RDC; and (3) CDW delivers the merchandise from the RDC to the customer. In determining whether separate LOTs exist in the Canadian market, we compared the selling functions performed by Electrolux and its affiliates CDW and UWA on behalf of the Canadian sales. For purposes of examining the different selling activities reported by Electrolux and its affiliates for sales made through each Canadian channel of distribution, we grouped the selling activities into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support.

We compared the selling activities Electrolux and its affiliates collectively performed in each channel, and found that there is no difference in the selling functions performed between the channels. As a result, we found that Electrolux performed the same selling functions for all three Canadian market distribution channels. Accordingly, we determined that all Canadian sales constitute one LOT.

Finally, we compared the CEP LOT to the Canadian market LOT and found that the selling functions performed for Canadian market sales are either not performed for CEP sales or are performed at a significantly higher degree of intensity compared to the selling functions performed for U.S. sales. Specifically, we found that three of the four selling functions (*i.e.,* sales and marketing, inventory maintenance and warehousing, and warranty and technical support) are performed by Electrolux in the Canadian market but not in the U.S. market, and the remaining selling function (*i.e.,* freight and delivery services) was performed by Electrolux in the Canadian market at a higher degree of intensity than in the U.S. market. Therefore, we determined that the NV LOT is at a more advanced stage of distribution than the CEP LOT and that no LOT adjustment was possible. Accordingly, we granted a CEP offset in accordance with section 733(a)(7)(B) of the Act. The CEP offset was calculated as the lesser of: (1) The indirect selling expenses incurred on the third country sales, or (2) the indirect selling expenses deducted from the starting price in calculating CEP.

2. LGEMM

LGEMM sold bottom mount refrigerators to original equipment manufacturers (OEMs), retailers and end users in the U.S. market. LGEMM reported that it made CEP sales in the U.S. market through the following two channels of distribution: (1) LGEMM's U.S. affiliate, LG Electronics USA (LGEUS), delivers the merchandise to the customer from one of its RDCs; and (2) the merchandise does not enter LGEUS' RDC but rather the merchandise is shipped from LGEMM to a trucking transit point where the customer takes delivery of the merchandise. LGEMM also reported that it made EP sales in the U.S. market through a single channel of distribution (*i.e.,* shipments of merchandise from LGEMM directly to the customer). For purposes of examining the different selling activities reported by LGEMM for sales made through each U.S. channel of distribution, we grouped the selling activities into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support.

We compared the selling activities LGEMM performed in each channel, exclusive of the selling activities performed by its U.S. affiliate, LGEUS, and found that either there is no difference in the selling functions performed by LGEMM between the channels (*i.e.,* sales and marketing, freight and delivery services, warranty and technical support) or LGEMM did not perform the selling function at all (*i.e.,* inventory maintenance and warehousing) for each channel. As a result, we found that LGEMM performed the same selling functions for all three U.S. distribution channels. Accordingly, we determined that all CEP and EP sales constitute one LOT.

As discussed above under ''MNC Provision'' section, we determined that the appropriate comparison market for LGEMM's sales to the United States was Korea. With respect to the Korean market, LGE reported that it made sales through three channels of distribution (*i.e.,* sales to construction companies, sales to unaffiliated retailers, and sales to unaffiliated retailers for which LGE was responsible for delivery and installation at the end-user's residence). Additionally, LGE reported a fourth channel of distribution for sales made to unaffiliated end-user customers by its affiliated retailer, HiPlaza. For its sales, LGE reported that it performed the following selling functions for sales to all home market customers: Sales forecasting, product development/market research, advertising, sales promotion, packing, inventory maintenance, order input direct sales personnel/sales support, warranty services, payment of commissions, and freight and delivery arrangement. In addition to these activities, LGE reported that its affiliated retailer maintained an extensive retail presence in Korea during the POI and performed the following additional selling functions for its sales: Sales forecasting, advertising, sales promotion, order input, direct sales personnel/sales support, and the payment of commissions.

We grouped these selling activities into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support. Accordingly, we found that LGE performed sales and marketing, freight and delivery services, and inventory maintenance and warehousing at the same relative level of intensity for all three of its reported sales channels in the home market. Regarding sales made by HiPlaza, HiPlaza also performed substantial sales and marketing activities for sales to its unaffiliated customers. We found that the nature and extent of these activities are sufficient to determine that the sales made by HiPlaza were at a more advanced stage of distribution than those made by LGE. Accordingly, we preliminarily determined that LGE had two LOTs in the Korean market.

Finally, we compared the U.S. LOT to the Korean LOTs and found that the selling functions performed for Korean customers (in both Korean LOTs) are substantially greater and/or are performed at a higher level of intensity than those performed for U.S. customers. For example, LGEMM did not perform any inventory maintenance and warehousing activities for sales to U.S. customers, whereas LGE performed this function for sales to Korean customers at a high level of intensity. Similarly, LGEMM performed sales and

marketing and warranty and technical support activities for sales to U.S. customers at a low level of intensity, whereas LGE performed these functions for sales to Korean customers at a high level of intensity. Therefore, we preliminarily determined that sales to Korea during the POI were made at different LOTs than sales to the United States. As a result, we matched U.S. sales with Korean sales at the most similar LOT. Additionally, because the home market LOTs are at a more advanced stage of distribution than the U.S. LOT and no LOT adjustment is possible, we determined that a CEP offset is warranted. Accordingly, we granted a CEP offset in accordance with section 773(a)(7)(B) of the Act. The CEP offset was calculated as the lesser of: (1) The indirect selling expenses incurred on the Korean sales, or (2) the indirect selling expenses deducted from the starting price in calculating CEP.

3. Mabe

Mabe sold bottom mount refrigerators to distributors, wholesalers, retailers, and end users in the home market, and its U.S. affiliate GE did the same in the U.S. market. GE reported that it made CEP sales in the U.S. market through the following two channels of distribution: (1) The customer picks up the merchandise from GE's warehouse; and (2) GE delivers the merchandise to the customer. For purposes of examining the different selling activities reported by Mabe for sales made through each U.S. channel of distribution, we grouped the selling activities into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support.

We compared the selling activities Mabe performed in each channel, exclusive of the selling activities performed by its affiliate GE, and found that either there is no difference in the selling functions performed by Mabe between the channels (*i.e.,* freight and delivery services) or Mabe did not perform the selling function at all (*i.e.,* sales and marketing, inventory maintenance and warehousing, and warranty and technical support) for each channel. As a result, we found that Mabe performed the same selling functions for both U.S. distribution channels. Accordingly, we determined that all CEP sales constitute one LOT.

With respect to the home market, Mabe reported the following two channels of distribution: (1) The customer picks up the merchandise from Mabe's distribution warehouse; and (2) the customer picks up the merchandise from Mabe's plant. In determining whether separate LOTs exist in the home market, we compared the selling functions performed by Mabe on behalf of the home market sales made to its different customer categories. For purposes of examining the different selling activities reported by Mabe for sales made through each home market channel of distribution, we grouped the selling activities into four selling function categories for analysis: (1) Sales and marketing; (2) freight and delivery services; (3) inventory maintenance and warehousing; and (4) warranty and technical support.

We compared the selling activities Mabe performed in each channel, and found that there is no difference in the selling functions performed between the channels. As a result, we found that Mabe performed the same selling functions for both home market distribution channels. Accordingly, we determined that all home market sales constitute one LOT.

Finally, we compared the CEP LOT to the home market LOT and found that the selling functions performed for home market sales are either not performed for U.S. sales or are performed at a significantly higher degree of intensity compared to the selling functions performed for U.S. sales. Specifically, we found that three of the four selling functions (*i.e.,* sales and marketing, inventory maintenance and warehousing, and warranty and technical support) are performed by Mabe in the home market but not in the U.S. market, and the remaining selling function (*i.e.,* freight and delivery services) was performed by Mabe in the home market at a higher degree of intensity than in the U.S. market. Therefore, we determined that the NV LOT is at a more advanced stage of distribution than the CEP LOT and that no LOT adjustment was possible. Accordingly, we granted a CEP offset in accordance with section 773(a)(7)(B) of the Act. The CEP offset was calculated as the lesser of: (1) The indirect selling expenses incurred on the home market sales, or (2) the indirect selling expenses deducted from the starting price in calculating CEP.

4. Samsung

Samsung had no viable home or third country market during the POI. Therefore, we based NV on CV. When NV is based on CV, the NV LOT is that of the sales from which we derive selling, general and administrative expenses and profit. (*See Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp from Brazil,* 69 FR 47081 (August 4, 2004) (*Shrimp from Brazil*), unchanged in *Notice of Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from Brazil,* 69 FR 76910 (December 23, 2004)). In accordance with 19 CFR 351.412(d), the Department will make its LOT determination under paragraph (d)(1) of this section on the basis of sales of the foreign like product by the producer or exporter. Because it is not possible in the instant case to make an LOT determination on the basis of sales of the foreign like product in the home or third country market, the Department may use sales of different or broader product lines, sales by other companies, or any other reasonable basis. Because we based the selling expenses and profit for Samsung on the weighted-average selling expenses incurred and profits earned by the other three respondents in the investigation on their comparison market sales (*i.e.,* home market sales for Mabe, Canadian market sales for Electrolux, and Korean market sales for LGEMM), we could not determine the LOT of the sales from which we derived selling expenses and profit for CV. As a result, we could not determine whether there is a difference in LOT between any U.S. sales and CV. Therefore, we did not make a LOT adjustment or CEP offset to NV in the case of Samsung. *See* ''Calculation of Normal Value Based on Constructed Value'' section of this notice below.

D. Cost of Production Analysis

Based on our analysis of an allegation contained in the petition, we found that there were reasonable grounds to believe or suspect that Mabe's sales of bottom mount refrigerators in the home market were made at prices below their COP. Accordingly, pursuant to section 773(b) of the Act, we initiated a country-wide sales-below-cost investigation to determine whether Mabe's sales were made at prices below their respective COPs.

Because Electrolux did not have a viable home market, on August 1, 2011, the petitioner alleged that it made third country sales below the COP and, therefore, requested that the Department initiate a sales-below-cost investigation. On August 24, 2011, the Department initiated a sales-below-cost investigation of Electrolux. *See* Memorandum entitled ''The Petitioner's Allegation of Sales below the Cost of Production for Electrolux Home Products, Corp. N.V. and Electrolux Home Products, Inc.,'' dated August 24, 2011.

As discussed above in the ''MNC Provision'' section of this notice, we have determined it appropriate to use the sales of bottom mount refrigerators produced and sold by LGE in Korea as the basis for LGEMM's NV. Based on our analysis of an allegation contained in the petition concerning bottom mount refrigerators from Korea, we found that there were reasonable grounds to believe or suspect that LGE's sales of bottom mount refrigerators in Korea were made at prices below their COP. Accordingly, pursuant to section 773(b) of the Act, we initiated a country-wide sales-below-cost investigation to determine whether LGE's sales were made at prices below their respective COPs.

1. Calculation of COP

In accordance with section 773(b)(3) of the Act, we calculated COP based on the sum of the cost of materials and fabrication for the foreign like product, plus an amount for G&A, interest expenses, and comparison market packing costs. *See* ''Test of Comparison Market Sales Prices'' section below for treatment of comparison market selling expenses. Based on the review of record evidence, none of the respondents appeared to experience significant changes in the COM during the POI. Therefore, we followed our normal methodology of calculating an annual weighted-average cost.

We relied on the COP data submitted by the respondents. We adjusted LGEMM's, Mabe's, and Samsung's COP data as follows:

A. LGEMM

We made adjustments to COP as discussed above under the ''MNC Provision'' section of this notice.

B. Mabe

We revised Mabe's G&A expense ratio to include employee profit sharing expenses in the numerator of the ratio. We applied the revised G&A expense ratio to the reported CONNUM-specific COM to determine the revised G&A expenses. *See* Memorandum entitled, ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—Controladora Mabe S.A. de C.V., Mabe S.A. de C.V., and Leiser S. de R.L.''

C. Samsung

We analyzed Samsung's transactions with certain affiliated parties in accordance with section 773(f)(2) of the Act (transactions disregarded rule) to determine whether the prices paid for the inputs used in the production of the merchandise under consideration reflect arm's-length prices. Where market prices were not available, we relied on the affiliate's COP as the market price. Based on our analysis, we found that the sum of the extended weighted-average prices paid by Samsung for inputs purchased from certain affiliates were at less than the sum of the extended weighted-average market prices. As such, we increased Samsung's reported COM to reflect market prices.

Because Samsung appears to have benefited from its parent's R&D activities associated with the production of the merchandise under consideration, we adjusted Samsung's reported costs to include R&D expenses incurred by its parent, Samsung Electronics Co. Ltd, for home appliances. We derived those expenses from the worksheets Samsung provided in reporting its affiliated parties' costs of inputs. We reduced the parent's R&D expenses for fees paid to the parent which were included in the reported costs.

We revised Samsung's G&A expenses to exclude offsets related to selling activities, financial income items, and prior year-adjustments.

See Memorandum entitled ''Cost of Production and Constructed Value Calculation Adjustments for the Preliminary Determination—Samsung Electronics Mexico S.A. de C.V.'' (Samsung Cost Calculation Memo), dated October 26, 2011.

2. Test of Comparison Market Sales Prices

On a product-specific basis, we compared the adjusted weighted-average COP to the comparison market sales of the foreign like product, as required under section 773(b) of the Act, in order to determine whether the sale prices were below the COP. The prices were exclusive of any applicable billing adjustments, discounts and rebates, movement charges, and actual direct and indirect selling expenses. In determining whether to disregard comparison market sales made at prices less than their COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act, whether such sales were made (1) Within an extended period of time in substantial quantities, and (2) at prices which permitted the recovery of all costs within a reasonable period of time.

3. Results of the COP Test

Pursuant to section 773(b)(2)(C) of the Act, where less than 20 percent of the respondent's sales of a given product during the POI are at prices less than the COP, we do not disregard any below-cost sales of that product, because we determine that in such instances the below-cost sales were not made in substantial quantities. Where 20 percent or more of the respondent's sales of a given product during the POI are at prices less than the COP, we disregard those sales of that product, because we determine that in such instances the below-cost sales represent substantial quantities within an extended period of time, in accordance with section 773(b)(1)(A) of the Act. In such cases, we also determine whether such sales were made at prices which would not permit recovery of all costs within a reasonable period of time, in accordance with section 773(b)(1)(B) of the Act.

We found that, for certain specific products, more than 20 percent of respondents' comparison market sales during the POI were at prices less than the COP and, in addition, the below-cost sales did not provide for the recovery of costs within a reasonable period of time. We therefore excluded these sales and used the remaining sales, if any, as the basis for determining NV, in accordance with section 773(b)(1) of the Act.

E. Calculation of Normal Value Based on Comparison Market Prices

Electrolux

We calculated NV based on packed prices to unaffiliated customers. We made deductions, where appropriate, from the starting price for discounts, rebates, and billing adjustments. We also made deductions for movement expenses, including inland freight, customs fees, brokerage and handling, insurance, and warehousing expenses, under section 773(a)(6)(B)(ii) of the Act. In addition, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for warranties, advertising and service fees paid to financing agents.

Furthermore, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also deducted third country packing costs and added U.S. packing costs in accordance with section 773(a)(6)(A) and (B) of the Act.

Finally, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses on the comparison market sales or the indirect selling expenses deducted from the starting price in calculating CEP. *See* Electrolux Calculation Memorandum.

LGEMM

We calculated NV based on LGE's sales in its Korean home market. We made adjustments for movement expenses under section 773(a)(6)(B)(ii) of the Act, as described in the ''MNC Provision'' section, above.

For comparisons to EP sales, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for direct selling expenses (including bank charges, direct advertising and promotional expenses, and warranties), and commissions. Regarding advertising expenses, LGE characterized certain home market advertising expenses as being direct in nature; however, we have reclassified these expenses as indirect because they are not product-specific (*i.e.,* they relate to a broader class of merchandise than is covered by this investigation). *See* LGEMM Calculation Memo for further discussion.

For comparisons to CEP sales, in accordance with section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410, we deducted from NV direct selling expenses (*i.e.,* imputed credit expenses, bank charges, direct advertising and promotional expenses, and warranties).

For all price-to-price comparisons, where commissions were granted in the comparison market but not in the U.S. market, we made an upward adjustment to NV for the lesser of: (1) The amount of commission paid in the comparison market; or (2) the amount of indirect selling expenses (including inventory carrying costs) incurred in the comparison market. *See* 19 CFR 351.410(e).

Furthermore, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also deducted home market packing costs and added U.S. packing costs in accordance with section 773(a)(6)(A) and (B) of the Act.

Finally, for comparisons to CEP sales, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses on the Korean market sales or the indirect selling expenses deducted from the starting price in calculating CEP. We reclassified certain advertising expenses as indirect, as discussed above. We also reclassified certain expenses incurred by LGE's affiliated retailer in maintaining its retail presence in the Korean market as indirect selling expenses because these expenses related to rent, sales staff salaries, and other overhead expenses and did not result from or bear a direct relationship to particular sales. We also recalculated LGE's home market inventory carrying costs using the company's reported COM, revised as stated above. *See* the LGEMM Calculation Memo for further discussion.

Mabe

We calculated NV based on ex-warehouse or delivered prices to unaffiliated customers. We made deductions, where appropriate, from the starting price for discounts and rebates. We also made deductions for movement expenses, including inland freight and warehousing expenses, under section 773(a)(6)(B)(ii) of the Act. In addition, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for imputed credit, warranties and royalties.

Furthermore, we made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. We also deducted home market packing costs and added U.S. packing costs in accordance with section 773(a)(6)(A) and (B) of the Act.

Finally, we made a CEP offset pursuant to section 773(a)(7)(B) of the Act and 19 CFR 351.412(f). We calculated the CEP offset as the lesser of the indirect selling expenses on the comparison market sales or the indirect selling expenses deducted from the starting price in calculating CEP. *See* Mabe Calculation Memo for further discussion.

F. Calculation of Normal Value Based on Constructed Value

In accordance with section 773(a)(4) of the Act, we based Samsung's NV on CV because it had no viable home or third country market.

In accordance with section 773(e) of the Act, we calculated CV based on the sum of Samsung's cost of materials and fabrication for the foreign like product, plus amounts for G&A and U.S. packing costs. We calculated the cost of materials and fabrication, G&A and interest based on the methodology described in the ''Calculation of COP'' section of this notice. For further details, *see* Samsung Cost Calculation Memo.

Because Samsung does not have a viable comparison market, the Department cannot determine selling expenses and profit under section 773(e)(2)(A) of the Act, which requires sales by the respondent in question in the ordinary course of trade in a comparison market. Therefore, we have relied on section 773(e)(2)(B) of the Act to determine Samsung's selling expenses and profit. In so doing, we used the weighted-average selling expenses and profit rates calculated for the other respondents in this investigation.

In situations where selling expenses and profit cannot be calculated under the preferred method, section 773(e)(2)(B) of the Act sets forth three alternatives. The statute does not establish a hierarchy for selecting among these alternative methodologies. *See* SAA at 840. Nonetheless, we examined each alternative in searching for an appropriate method. Alternative (i) of section 773(e)(2)(B) of the Act specifies that selling expenses and profit may be calculated based on ''actual amounts incurred by the specific exporter or producer * * * on merchandise in the same general category'' as subject merchandise. In considering this alternative, we examined the financial statements of Samsung. The sales revenues reported in Samsung's financial statements include sales to markets other than Mexico and include sales to affiliated parties.

Because there is insufficient information on the record of this case to determine the sales of the same general category of merchandise in the foreign country exclusive of the affiliated party sales, we determined that the selling expenses and profit calculated using Samsung's financial statements may not reflect the actual selling expenses and profit incurred by Samsung for sales to customers in the home market. Therefore, we did not rely on alternative (i) for purposes of this preliminary determination.

We considered relying on alternative 773(e)(2)(B)(ii) of the Act (alternative (ii)) which states that selling expenses and profit may be calculated based on the actual amounts incurred and realized by exporters or producers that are subject to the investigation in connection with sales for consumption in the foreign country. However, because Mabe is the only other respondent with viable home market sales, the Department cannot calculate profit under alternative (ii) because doing so would reveal the business-proprietary nature of that information. *See Shrimp from Brazil.*

Pursuant to alternative (iii) of section 773(e)(2)(B) of the Act, the Department has the option of using any other reasonable method to calculate CV

profit as long as the result is not greater than the amount realized by exporters or producers ''in connection with the sale, for consumption in the foreign country, of merchandise that is in the same general category of products as the subject merchandise'' (*i.e.,* the ''profit cap''). As a reasonable method, we relied on the weighted average of the profit and selling expenses incurred by the three other respondents in this investigation. Specifically, we calculated weighted-average selling expenses incurred and profit realized on home market sales by Mabe, and Canadian sales by Electrolux, and Korean sales by LGEMM's affiliate, LGE.

In the instant case, the profit cap cannot be calculated using the available data (*i.e.,* Electrolux, LGEMM, and Mabe), because LGEMM's and Electrolux's data would not result in a profit cap that is reflective of sales in the foreign country. Furthermore, using Mabe's home market data, the only information we have to allow us to calculate the amount normally realized in connection with the sale of merchandise in the same general category for consumption in the home market, would reveal the business-proprietary nature of that information. Therefore because there is no other information available on the record, as facts available, we are applying option (iii), without quantifying a profit cap.

For comparisons to EP, we made circumstances-of-sale adjustments for direct selling expenses. We deducted the weighted-average direct selling expenses of the other three respondents, as described above, and added U.S. direct selling expenses. For comparisons to CEP, we deducted from CV the weighted-average direct selling expenses incurred by the other three respondents on their comparison market sales.

Currency Conversion

We made currency conversions into U.S. dollars in accordance with section 773A(a) of the Act based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Critical Circumstances

On July 29, 2011, the petitioner filed a timely allegation, pursuant to section 733(e)(1) of the Act and 19 CFR 351.206, that critical circumstances exist with respect to imports of the merchandise under investigation. The petitioner subsequently amended its allegation to include only Electrolux, LGEMM and Samsung. In accordance with 19 CFR 351.206(c)(2)(i), because the petitioner submitted its critical circumstances allegation more than 20 days before the scheduled date of the preliminary determination, the Department must issue a preliminary critical circumstances determination not later than the date of the preliminary determination.

Section 733(e)(1) of the Act provides that the Department will preliminarily determine that critical circumstances exist if there is a reasonable basis to believe or suspect that: (A) (i) There is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise; or (ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales, and (B) there have been massive imports of the subject merchandise over a relatively short period. Section 351.206(h)(1) of the Department's regulations provides that, in determining whether imports of the subject merchandise under investigation have been ''massive,'' the Department normally will examine: (i) The volume and value of the imports; (ii) seasonal trends; and (iii) the share of domestic consumption accounted for by the imports. In addition, 19 CFR 351.206(h)(2) provides that an increase in imports of 15 percent during the ''relatively short period'' of time may be considered ''massive.'' Section 351.206(i) of the Department's regulations defines ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed) and ending at least three months later. The regulations also provide, however, that if the Department finds that importers, exporters, or producers had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely, the Department may consider a period of not less than three months from that earlier time.

In determining whether the above statutory criteria have been satisfied, we examined the evidence presented in the petitioner's submission of July 29, 2011, the ITC preliminary injury determination, and the respondents' shipment volume submissions.

To determine whether there is a history of injurious dumping of the merchandise under investigation, in accordance with section 733(e)(1)(A)(i) of the Act, the Department normally considers evidence of an existing antidumping duty order on the subject merchandise in the United States or elsewhere to be sufficient. *See Preliminary Determination of Critical Circumstances: Steel Concrete Reinforcing Bars From Ukraine and Moldova,* 65 FR 70696 (November 27, 2000). The petitioner did not identify any proceedings with respect to Mexican-origin bottom mount refrigerator products, nor are we aware of any existing antidumping duty order in any country on bottom mount refrigerators from Mexico. For this reason, the Department does not find a history of injurious dumping of the subject merchandise from Mexico pursuant to section 733(e)(1)(A)(i) of the Act.

To determine whether the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales in accordance with section 733(e)(1)(A)(ii) of the Act, the Department normally considers margins of 25 percent or more for EP sales or 15 percent or more for CEP transactions sufficient to impute knowledge of dumping. *See e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Lined Paper Products from Indonesia,* 71 FR 15162 (March 27, 2006) unchanged in *Final Determination of Sales at Less Than Fair Value and Affirmative Final Determination of Critical Circumstances: Certain Lined Paper Products from Indonesia,* 71 FR 47171 (August 16, 2006).

For Electrolux, we calculated a preliminary margin of 19.80 percent, which meets the threshold for imputing importer knowledge of dumping for CEP sales. Therefore, we find that the importer knowledge criterion, as set forth in section 733(e)(1)(A)(ii) of the Act, has been met for Electrolux. For LGEMM, we calculated a preliminary margin of 16.44 percent, which meets the 15-percent threshold necessary to impute knowledge of dumping for CEP sales, which are the vast majority of LGEMM's U.S. sales. Therefore, we find that importers of subject merchandise produced and/or exported by this company knew or should have known that this company was selling the subject merchandise at less than fair value. Finally, with regard to Samsung, we also find that importers of subject merchandise produced and/or exported by this company knew or should have known that this company was selling the subject merchandise at less than fair value because the preliminary dumping margin calculated for it, *i.e.,* 36.46 percent, is above the 15-percent and 25-percent thresholds for imputing

importer knowledge of dumping CEP and EP sales, respectively. Therefore, we find that the importer knowledge criterion, as set forth in section 733(e)(1)(A)(ii) of the Act, has met for Samsung.

In addition, if the ITC finds a reasonable indication of present material injury to the relevant U.S. industry, the Department will determine that a reasonable basis exists to impute importer knowledge that material injury is likely by reason of such imports. In the present case, the ITC preliminarily found reasonable indication that an industry in the United States is materially injured by imports of bottom mount refrigerators from Mexico. Based on the ITC's preliminary determination of injury, and the preliminary dumping margins for Electrolux, LGEMM, and Samsung, the Department finds that there is a reasonable basis to conclude that the importer knew or should have known that there was likely to be injurious dumping of subject merchandise by these companies.

In determining whether there are ''massive imports'' over a ''relatively short period,'' pursuant to section 733(e)(1)(B) of the Act, the Department normally compares the import volumes of the subject merchandise for at least three months immediately preceding the filing of the petition (*i.e.,* the ''base period'') to a comparable period of at least three months following the filing of the petition (*i.e.,* the ''comparison period''). Imports normally will be considered massive when imports during the comparison period have increased by 15 percent or more compared to imports during the base period.

The Department requested and obtained from each of the respondents monthly shipment data from January 2008 to July 2011. To determine whether imports of subject merchandise have been massive over a relatively short period, we compared, pursuant to 19 CFR 351.206(h)(1)(i), the respondents' export volumes for the four months before the filing of the petition (*i.e.,* December 2010–March 2011) to those during the four months after the filing of the petition (*i.e.,* April through July 2011). These periods were selected based on the Department's practice of using the longest period for which information is available from the month that the petition was filed through the effective date of the preliminary determination. According to the monthly shipment information, we found the volume of shipments of bottom mount refrigerators increased by more than 15 percent for Electrolux, LGEMM, and Samsung.

For purposes of our ''massive imports'' determination, we also considered the impact of seasonality on imports of bottom mount refrigerators based on interested party comments and information contained in the ITC's preliminary determination. In order to determine whether the seasonality factor accounted for the increase in imports observed for each of the respondents in the post-petition filing period (the comparison period), we analyzed company-specific shipment data for a historical three-year period, where possible, using the same base and comparison time periods noted above. As a result of this analysis, we found that there is a consistent pattern of seasonality, as shipments during the April–July time period were consistently higher than those in the December–March time period.

Furthermore, with respect to Electrolux and LGEMM, we found that the percentage increase in shipments during the comparison period is not related to the filing of the petition but rather to the consistent seasonal trends in the industry because the shipment increases observed in the April–July time period from year to year were relatively consistent or decreased. Therefore, we preliminarily find that imports from these companies during the period after the filing of the petition have not been massive in accordance with section 733(e)(1)(B) of the Act. However, with respect to Samsung, we found that the percentage increase in shipments during the comparison period is not entirely related to seasonal trends but also associated with the filing of the petition because the shipment increase observed in the April–July period between 2010 and 2011 was substantial. Accordingly, we preliminarily find that imports from Samsung during the period after the filing of the petition have been massive in accordance with section 733(e)(1)(B) of the Act. *See* Memorandum entitled ''Antidumping Duty Investigation of Bottom Mount Combination Refrigerator-Freezers from Mexico—Preliminary Determination of Critical Circumstances,'' dated October 26, 2011 (Critical Circumstances Memo).

In summary, we find that there is a reasonable basis to believe or suspect importers had knowledge of dumping and the likelihood of material injury with respect to bottom mount refrigerators produced and exported from Mexico by Electrolux, LGEMM, and Samsung. In addition, we find that there have been massive imports of bottom mount refrigerators over a relatively short period from Samsung, irrespective of seasonality. However, we do not find that there have been massive imports of bottom mount refrigerators over a relatively short period from Electrolux and LGEMM due to seasonality. Given the analysis summarized above, and described in more detail in the Critical Circumstances Memo, we preliminarily determine that critical circumstances do not exist with respect to imports of bottom mount refrigerators produced in and exported from Mexico by Electrolux and LGEMM. We preliminarily determine that critical circumstances do exist with respect to imports of bottom mount refrigerators produced in and exported from Mexico by Samsung.

Verification

As provided in section 782(i) of the Act, we will verify information relied upon in making our final determination.

Suspension of Liquidation

In accordance with section 733(e)(2) of the Act, we are directing Customs and Border Protection (CBP) to suspend liquidation of all imports of subject merchandise from Samsung that are entered, or withdrawn from warehouse, for consumption on or after 90 days prior to the date of publication of this notice in the **Federal Register**. In accordance with section 733(d)(2) of the Act, we are directing CBP to suspend liquidation of all imports of subject merchandise from Electrolux, LGEMM, Mabe, and ''All Others'' that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**.

We will instruct CBP to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the NV exceeds EP or CEP, as indicated in the chart below. These suspension-of-liquidation instructions will remain in effect until further notice. The weighted-average dumping margins are as follows:

Exporter/manufacturer	Weighted-average margin percentage	Critical circumstances
Electrolux Home Products, Corp. NV/Electrolux Home Products De Mexico, S.A. de C.V	19.80	No.

Exporter/manufacturer	Weighted-average margin percentage	Critical circumstances
LG Electronics Monterrey Mexico, S.A. de C.V	16.44	No.
Controladora Mabe, S.A. de C.V/Mabe, S.A. de C.V	36.21	NA.
Samsung Electronics Mexico, S.A. de C.V	36.65	Yes.
All Others	28.02	NA.

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

Disclosure

The Department will disclose to parties the calculations performed in connection with this preliminary determination within five days of the date of publication of this notice. *See* 19 CFR 351.224(b).

Public Comment

Case briefs for this investigation must be submitted to the Department no later than seven days after the date of the final verification report issued in this proceeding. Rebuttal briefs must be filed five days from the deadline date for case briefs. *See* 19 CFR 351.309(d). A list of authorities used, a table of contents, and an executive summary of issues should accompany any briefs submitted to the Department. Executive summaries should be limited to five pages total, including footnotes. Case briefs must present all arguments that continue to be relevant to the Department's final determination, in the submitter's view. See 19 CFR 351.309(c)(2). Section 774 of the Act provides that the Department will hold a public hearing to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs, provided that such a hearing is requested by an interested party. See 19 CFR 351.310(c). If a request for a hearing is made in this investigation, the hearing will tentatively be held two days after the rebuttal brief deadline date at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW, Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, within 30 days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the briefs.

We will make our final determination no later than 135 days after the publication of this notice in the **Federal Register**.

This determination is published pursuant to sections 733(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: October 26, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–28418 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[(A–570–973)]

Certain Steel Wheels From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value, Partial Affirmative Preliminary Determination of Critical Circumstances, and Postponement of Final Determination

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice.

DATES: *Effective Date:* November 2, 2011.

SUMMARY: The Department of Commerce (''Department'') preliminarily determines that certain steel wheels (''steel wheels'') from the People's Republic of China (''PRC'') are being, or are likely to be, sold in the United States at less than fair value (''LTFV''), as provided in section 733 of the Tariff Act of 1930, as amended (''the Act''). The estimated margins of sales at LTFV are shown in the ''Preliminary Determination'' section of this notice. Pursuant to requests from interested parties, we are postponing the final determination and extending the provisional measures from a four-month period to not more than six months. Accordingly, we will make our final determination not later than 135 days after publication of the preliminary determination.

FOR FURTHER INFORMATION CONTACT: Brendan Quinn or Raquel Silva, AD/CVD Operations, Office 8, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5848 or (202) 482–6475, respectively.

SUPPLEMENTARY INFORMATION:

Initiation

On March 30, 2011, the Department received an antidumping duty (''AD'') petition concerning imports of steel wheels from the PRC filed in proper form by Accuride Corporation and Hayes Lemmerz International, Inc. (collectively, ''Petitioners'').[1] Based on the Department's request, Petitioners filed supplements to the Petition on April 11, 14 and 15, 2011.

The Department initiated this investigation on April 19, 2011.[2] In the *Initiation Notice,* the Department notified parties of the application process by which exporters and producers may obtain separate rate status in non-market economy (''NME'') investigations. The process requires exporters and producers to submit a separate rate application (''SRA'')[3] and to demonstrate an absence of both *de jure* and *de facto* government control over their respective export activities. The SRA for this investigation was posted on the Department's Web site at *http://ia.ita.doc.gov/ia-highlights-and-news.html* on April 20, 2011. The due date for filing an SRA was June 27, 2011.

On May 16, 2011, the International Trade Commission (''ITC'') determined

[1] See the Petition for the Imposition of Antidumping and Countervailing Duties Pursuant to Sections 701 and 731 of the Tariff Act of 1930, as amended (''Petition''), filed on March 30, 2011.

[2] See *Certain Steel Wheels From the People's Republic of China: Initiation of Antidumping Duty Investigation,* 76 FR 23294 (April 26, 2011) (''Initiation Notice'').

[3] See Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries (April 5, 2005) (''Policy Bulletin 05.1''), available at *http://ia.ita.doc.gov/policy/bull05-1.pdf.*

that there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury by reason of imports of steel wheels from the PRC.[4]

Period of Investigation

The period of investigation (''POI'') is July 1, 2010, through December 31, 2010. This period corresponds to the two most recent fiscal quarters prior to the month of the filing of the petition, which was March 30, 2011. See 19 CFR 351.204(b)(1).

Postponement of Preliminary Determination

On August 5, 2011, Petitioners made a timely request, pursuant to section 733(c)(1)(A) of the Act and 19 CFR 351.205(b)(2) and (e) for a 50-day postponement of the preliminary determination. On August 17, 2011, the Department published a postponement of the preliminary AD determination on steel wheels from the PRC.[5]

Scope Comments

As discussed in the preamble to the regulations, we set aside a period for interested parties to raise issues regarding product coverage. See *Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997). The Department requested all interested parties to submit such comments within 20 calendar days of signature of the *Initiation Notice.* See *Initiation Notice.* As we stated in *Certain Steel Wheels From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination,* 76 FR 55012 (September 6, 2011) (''*CVD Prelim*''), the Department received scope comments on May 9, 2011,[6] from Blackstone/OTR LLC and OTR Wheel Engineering, Inc. (collectively, ''Blackstone/OTR''), U.S. importers of the subject merchandise. On May 18, 2011, Petitioners submitted their response to Blackstone/OTR's comments. The *CVD Prelim* states that the Department would be making a preliminary determination regarding the aforementioned scope comments with the issuance of the AD preliminary determination, and that the determination would be applied to the countervailing duty (''CVD'') and AD investigations moving forward. However, the Department intends to address Blackstone/OTR's scope comments and Petitioners' response after the AD preliminary determination is issued. In doing so, we intend to issue a questionnaire to Petitioners regarding whether they produce steel wheels suitable for use for particular applications. We also intend to request information with respect to whether there are any specifications that may differentiate the type of steel wheels Petitioners produce from other types of steel wheels that may be of the same diameters currently covered by the scope.

On June 7, 2011, the Department released a memorandum to the file requesting comment on additional HTSUS categories and language to include in the scope of the AD and CVD investigations, as proposed by U.S. Customs and Border Protection (''CBP'').[7] CBP's suggestion involved clarifying the scope's coverage by either adding HTSUS categories that cover steel wheels for non-vehicle applications (*e.g.,* elevators, manufacturing and agricultural machinery) or adding language that states the scope only covers steel wheels for vehicles.

On June 14[8] and 21,[9] 2011, Petitioners submitted comments and rebuttal comments agreeing with CBP's suggestion to include the additional HTSUS numbers to the scope language. In addition, Petitioners state that adding ''use'' (*e.g.,* ''for vehicles'') language to the scope is inappropriate, as the scope is intended to cover all steel wheels with a wheel diameter of 18 to 24.5 inches, regardless of use. Petitioners further state that specifying use in the scope language could present CBP classification problems, as well as enable steel wheels of the sizes covered by the scope to evade coverage by being entered as wheels for machinery and then used as wheels for vehicles.

On June 14[10] and 21,[11] 2011, we received comments and rebuttal comments from the government of the PRC (''GOC'') on the HTSUS Memorandum. The GOC supported CBP's proposal to clarify the scope language by stating that the scope is only intended to include steel wheels for vehicles. The GOC added that it would be inappropriate for the Department to include the Harmonized Tariff Schedule of the United States (''HTSUS'') numbers covering steel wheels for non-vehicle uses because those HTSUS numbers cover products beyond the scope of the investigation.

Because the language of the scope currently covers steel wheels ranging from 18 to 24.5 inches in diameter regardless of use, the Department has preliminarily determined to add all of the HTS categories suggested by CBP to the scope.

Scope of the Investigation

The products covered by this investigation are steel wheels with a wheel diameter of 18 to 24.5 inches. Rims and discs for such wheels are included, whether imported as an assembly or separately. These products are used with both tubed and tubeless tires. Steel wheels, whether or not attached to tires or axles, are included. However, if the steel wheels are imported as an assembly attached to tires or axles, the tire or axle is not covered by the scope. The scope includes steel wheels, discs, and rims of carbon and/or alloy composition and clad wheels, discs, and rims when carbon or alloy steel represents more than fifty percent of the product by weight. The scope includes wheels, rims, and discs, whether coated or uncoated, regardless of the type of coating.

Imports of the subject merchandise are provided for under the following categories of the HTSUS: 8708.70.05.00, 8708.70.25.00, 8708.70.45.30, and 8708.70.60.30. Imports of the subject merchandise may also enter under the following categories of the HTSUS: 8406.90.4580, 8406.90.7500, 8420.99.9000, 8422.90.1100, 8422.90.2100, 8422.90.9120, 8422.90.9130, 8422.90.9160, 8422.90.9195, 8431.10.0010, 8431.10.0090, 8431.20.0000, 8431.31.0020, 8431.31.0040, 8431.31.0060, 8431.39.0010,

[4] See Investigation Nos. 701–TA–478 and 731–TA–1182 (Preliminary): *Certain Steel Wheels from China,* 76 FR 29265 (May 20, 2011) (''ITC Preliminary Determination'').

[5] See *Certain Steel Wheels from the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation,* 76 FR 50995 (August 17, 2011).

[6] See Letter from Blackstone/OTR entitled ''Comments on Scope of Investigation: Certain Steel Wheels from the People's Republic of China,'' dated May 9, 2011.

[7] See Memorandum to the File entitled ''Suggested Additional Harmonized Tariff Schedule Categories,'' dated June 7, 2011(''HTSUS Memorandum'').

[8] See Letter from Petitioners entitled ''Certain Steel Wheels from the People's Republic of China: Response to Request to Add HTS Categories to Scope Definition,'' dated June 14, 2011.

[9] See Letter from Petitioners entitled ''Certain Steel Wheels from the People's Republic of China: Rebuttal to Comments from the Government of China Regarding the Addition of HTS Categories to the Scope Definition,'' dated June 21, 2011.

[10] See Letter from the GOC entitled ''Certain Steel Wheels from China: Comments on CBP Proposal for Additional HTS Categories,'' dated June 14, 2011.

[11] See Letter from the GOC entitled ''Certain Steel Wheels from China: Rebuttal Comments on CBP Proposal for Additional HTS Categories,'' dated June 21, 2011.

8431.39.0050, 8431.39.0070, 8431.39.0080, 8431.43.8060, 8431.49.1010, 8431.49.1060, 8431.49.1090, 8431.49.9030, 8431.49.9040, 8431.49.9085, 8432.90.0005, 8432.90.0015, 8432.90.0030, 8432.90.0080, 8433.90.1000, 8433.90.5020, 8433.90.5040, 8436.99.0020, 8436.99.0090, 8479.90.9440, 8479.90.9450, 8479.90.9496, 8487.90.0080, 8607.19.1200, 8607.19.1500, 8708.70.1500, 8708.70.3500, 8708.70.4560, 8708.70.6060, 8709.90.0000, 8710.00.0090, 8714.19.0030, 8714.19.0060, 8716.90.1000, 8716.90.5030, 8716.90.5060, 8803.20.0015, 8803.20.0030, and 8803.20.0060. These HTSUS numbers are provided for convenience and customs purposes only; the written description of the scope is dispositive.

Non-Market Economy Country

For purposes of initiation, Petitioners submitted an LTFV analysis for the PRC as an NME.[12] The Department's most recent examination of the PRC's market status determined that NME status should continue for the PRC.[13] Additionally, in two recent investigations, the Department also determined that the PRC is an NME country.[14] In accordance with section 771(18)(C)(i) of the Act, the NME status remains in effect until revoked by the Department. The Department has not revoked the PRC's status as an NME country, and we have therefore treated the PRC as an NME in this preliminary determination and applied our NME methodology.

Selection of Respondents

In accordance with section 777A(c)(2) of the Act, the Department selected the three largest exporters of steel wheels (*i.e.,* Jining Centurion Wheels Manufacturing (''Centurion''), Shanghai Yata Industry Company Limited (''Shanghai Yata'') and Zhejiang Jingu Company Limited (''Zhejiang Jingu'')), by volume, as the individually examined respondents in this investigation. The Department used volume data from the quantity and value (''Q&V'') information submitted by exporters/producers that were identified in the Petition, of which 11 firms filed timely Q&V questionnaire responses.[15] Of the 11 Q&V questionnaire responses, four companies (Zhejiang Jingu, Shanghai Yata, Xiamen Sunrise Wheel Group Co., Ltd. (''Xiamen Sunrise'') and Xiamen Topu Import & Export Co., Ltd. (''Xiamen Topu'')) filed timely documentation in support of their requests that the Department treat them as two single entities (i.e., 1) Zhejiang Jingu/Shanghai Yata and (2) Xiamen Sunrise/Xiamen Topu) for purposes of respondent selection. Three companies (Centurion, Shandong Xingmin Wheel Co., Ltd. (''Xingmin Wheel''), and Xiamen Sunrise) requested to be treated as voluntary respondents.

The Department issued its antidumping questionnaire to Centurion, Shanghai Yata, and Zhejiang Jingu on June 13, 2011. The Department requested that the respondents provide a response to section A of the Department's questionnaire by July 5, 2011, and a response to sections C and D of the questionnaire by July 20, 2011. From June 30, 2011, until October 6, 2011, the Department granted all respondents several extensions for their submissions.

Centurion submitted its responses to the section A, C and D questionnaires on July 5, July 27, and August 3, 2011, respectively. Centurion submitted responses to the supplemental section A, C and D questionnaires on August 9, September 9, and September 22, 2011, respectively. On September 28, 2011, the Department received Centurion's second supplemental section D questionnaire response. Finally, Centurion submitted its response to the Department's supplemental questionnaire regarding sections A, C, D and surrogate values in two parts: the first part on October 12 and the second on October 14, 2011.

Zhejiang Jingu and Shanghai Yata submitted their section A and C questionnaire responses on July 15, 2011 and July 27, 2011, respectively. Zhejiang Jingu and its wholly-owned subsidiary, Chengdu Jingu Wheel Co., Ltd., submitted responses to section D of the questionnaire on August 4, 2011. The Department received Zhejiang Jingu and Shanghai Yata's supplemental section A and C questionnaire responses on August 19 and August 29, 2011, respectively. Zhejiang Jingu submitted its supplemental section D questionnaire response in two parts: the first part on September 20 and second part on September 27, 2011. On October 11, 2011, Zhejiang Jingu submitted its response to the Department's supplemental questionnaire regarding surrogate value and factors of production (''FOP'') information. Last, on October 17, 2011, Zhejiang Jingu submitted its second supplemental section D questionnaire response.

On July 5, 2011, Xiamen Sunrise, Xiamen Topu, as well as Xingmin Wheel, entities that requested that we select them as voluntary respondents, submitted their responses to section A of the questionnaire. On July 20, 2011, Xiamen Sunrise, Xiamen Topu, as well as Xingmin Wheel submitted their responses to sections C and D of the questionnaire.

Postponement of Final Determination and Extension of Provisional Measures

Pursuant to section 735(a)(2) of the Act, on October 3 and October 7, 2011, respectively, Zhejiang Jingu, Shanghai Yata and Centurion requested that, in the event of an affirmative preliminary determination in this investigation, the Department postpone the final determination by 60 days. Zhejiang Jingu, Shanghai Yata, and Centurion also requested that the Department extend the application of the provisional measures prescribed under 19 CFR 351.210(e)(2) from a four-month period to a six-month period. In accordance with section 733(d) of the Act and 19 CFR 351.210(b), because (1) our preliminary determination is affirmative, (2) the requesting exporters account for a significant proportion of exports of the subject merchandise, and (3) no compelling reasons for denial exist, we are granting the request and are postponing the final determination until no later than 135 days after the publication of this notice in the **Federal Register**. Suspension of liquidation will be extended accordingly.

[12] See *Initiation Notice.*

[13] See the Department's memorandum entitled, ''Antidumping Duty Investigation of Certain Lined Paper Products from the People's Republic of China (''China'')—China's status as a non-market economy (''NME''),'' dated August 30, 2006. This document is available online at: *http://ia.ita.doc.gov/download/prc-nme-status/prc-lined-paper-memo-08302006.pdf.*

[14] See, *e.g., Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 74 FR 9591 (March 5, 2009) (''Kitchen Racks Prelim''), unchanged in *Certain Kitchen Appliance Shelving and Racks From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 36656 (July 24, 2009) (''Kitchen Racks Final''); and *Certain Tow Behind Lawn Groomers and Certain Parts Thereof from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination,* 74 FR 4929 (January 28, 2009), unchanged in *Certain Tow Behind Lawn Groomers and Certain Parts Thereof from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 74 FR 29167 (June 19, 2009).

[15] See the Department's memorandum entitled, ''Antidumping Duty Investigation of Certain Steel Wheels From the People's Republic of China: Respondent Selection,'' dated June 9, 2011 (''Respondent Selection Memo'').

Critical Circumstances

On August 22, 2011, Petitioners alleged that there is a reasonable basis to believe or suspect critical circumstances exist with respect to the antidumping investigation of steel wheels from the PRC.[16] On September 26, 2011, Zhejiang Jingu, Shanghai Yata, and Centurion [17] submitted information on their shipments of steel wheels from December 2010 through July 2011, as requested by the Department.[18] In accordance with 19 CFR 351.206(c)(2)(i), because Petitioners submitted critical circumstances allegations more than 20 days before the scheduled date of the preliminary determination, the Department must issue preliminary critical circumstances determinations not later than the date of the preliminary determination.

Section 733(e)(1) of the Act provides that the Department will preliminarily determine that critical circumstances exist if there is a reasonable basis to believe or suspect that: (A)(i) There is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise; or (ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales; and (B) there have been massive imports of the subject merchandise over a relatively short period. Section 351.206(h)(1) of the Department's regulations provides that, in determining whether imports of the subject merchandise have been ''massive,'' the Department normally will examine: (i) The volume and value of the imports; (ii) seasonal trends; and (iii) the share of domestic consumption accounted for by the imports. In addition, section 351.206(h)(2) of the Department's regulations provides that an increase in imports of 15 percent during the ''relatively short period'' of time may be considered ''massive.'' Section 351.206(i) of the Department's regulations defines ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed) and ending at least three months later (*i.e.,* the comparison period). The comparison period is normally compared to a corresponding period prior to the filing of the petition *(i.e.,* the base period).

In determining whether the above statutory criteria have been satisfied, we examined: (1) The evidence presented in Petitioners' August 22, 2011, Critical Circumstances Allegation, and (2) additional information obtained from Zhejiang Jingu, Shanghai Yata, Centurion, and the ITC.[19]

In accordance with section 733(e)(1)(A)(i) of the Act, to determine whether there is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise, the Department generally considers current or previous antidumping duty orders on subject merchandise from the country in question in the United States and current orders in any other country with regard to imports of subject merchandise. Petitioners noted that in 2007, India imposed antidumping duties on steel wheels from the PRC that are of a size subsumed within the scope of this petition.[20] The ITC Preliminary Report notes that in March 2007, ''India made final determinations and imposed antidumping duties on commercial steel wheels from China in sizes from 16 to 20 inches in nominal diameter.'' [21] We have reviewed these findings and found that the product coverage overlaps the product coverage of the Department's AD investigation of steel wheels from the PRC. We are not aware of the existence of any additional active antidumping orders or investigations on steel wheels from the PRC in other countries. As a result of the Indian order cited above, the Department finds there is a history of injurious dumping of steel wheels from the PRC pursuant to section 733(e)(1)(A)(i) of the Act.

In accordance with Section 733(e)(1)(A)(ii) of the Act, to determine whether importers of steel wheels from the PRC knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales, the Department must rely on the facts before it at the time the determination is made. The Department generally bases its decision with respect to knowledge on the margins calculated in the preliminary antidumping duty determination and the ITC preliminary injury determination.[22]

The Department normally considers margins of 25 percent or more for export price (''EP'') sales and 15 percent or more for constructed export price (''CEP'') sales sufficient to impute importer knowledge of sales at LTFV.[23] In this preliminary determination, Centurion has a combined margin of 110.58 percent for its EP and CEP sales.[24] Zhejiang Jingu and Shanghai Yata have a combined margin of 141.38 percent for their sales, all of which were EP transactions.[25] Consistent with Department practice, we based the margin for the separate rate respondents on the average of the margins calculated for the individually examined respondents, excluding any rates that are zero, *de minimis,* or based entirely on AFA.[26] Accordingly, we have preliminarily applied to the separate rate companies a margin of 125.98 percent. The PRC entity has a margin of 193.54 percent.[27] Accordingly, we find that the preliminary margins for Centurion, Zhejiang Jingu/Shanghai Yata, the separate rate companies, and

[16] See Letter from Petitioners entitled ''Certain Steel Wheels from the People's Republic of China,'' dated August 22, 2011 (''Critical Circumstances Allegation'').

[17] Though we did not request data from Xiamen Sunrise, it also submitted its monthly shipment data on September 26, 2011.

[18] See Letter from Zhejiang Jingu and Shanghai Yata entitled ''AD Investigation of Steel Wheels from China: Critical Circumstances Shipment Data,'' dated September 26, 2011 (''Zhejiang Jingu's and Shanghai Yata's Monthly Shipment Data'') at Exhibit I. See also Letter from Centurion, ''Antidumping Duty Investigation of Certain Steel Wheels from China: Response to Request for Monthly Shipment Information Questionnaire,'' dated September 26, 2011 (''Centurion's Monthly Shipment Data'').

[19] See Critical Circumstances Allegation. *See also* Zhejiang Jingu's and Shanghai Yata's Monthly Shipment Data and Centurion's Monthly Shipment Data. *See also* Memorandum to the File, ''Antidumping Duty Investigation of Certain Steel Wheels from the People's Republic of China, Critical Circumstances Data and Calculations for the Preliminary Determination,'' dated October 26, 2011 (''Critical Circumstances Calculation Memorandum''). *See also* U.S. ITC Publication 4233, *Certain Steel Wheels from China: Investigation Nos. 701–TA–478 and 731–TA–1182(Preliminary),* May 2011 (''ITC Preliminary Report'').

[20] See Volume I of the Petition at 12 and Exhibit I–9.

[21] See ITC Preliminary Report at 24 and VII–6.

[22] See, *e.g., Carbon and Alloy Steel Wire Rod From Germany, Mexico, Moldova, Trinidad and Tobago, and Ukraine: Notice of Preliminary Determination of Critical Circumstances,* 67 FR 6224, 6225 (February 11, 2002).

[23] *See id.*

[24] *See* Critical Circumstances Calculation Memorandum at Attachments II and III.

[25] *See id. See also* the *Affiliation* section of this notice, below.

[26] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006) (''PSF''), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007), *see also* the ''Separate Rates'' section.

[27] *See* Critical Circumstances Calculation Memorandum at Attachments II and III. See also, the *The PRC-Wide Entity and PRC-Wide Rate* section, below.

the PRC entity are sufficient to impute such knowledge.

In determining whether there is a reasonable basis to believe or suspect that an importer knew or should have known that there was likely to be material injury by reason of dumped imports, consistent with section 733(e)(1)(A)(ii) of the Act, the Department normally will look to the preliminary injury determination of the ITC.[28] On May 16, 2011, the ITC issued its preliminary affirmative determination for steel wheels from the PRC.[29] Accordingly, based on the above analysis, the Department finds that there is a reasonable basis to believe or suspect that the importers knew or should have known that there was likely to be material injury by reason of sales at LTFV of steel wheels from the PRC from Centurion, Zhejiang Jingu/Shanghai Yata, the separate rate companies, and the PRC entity.

In accordance with section 733(e)(1)(B) of the Act, the Department must determine whether there have been massive imports of the subject merchandise over a relatively short period. Pursuant to 19 CFR 351.206(h), we will not consider imports to be massive unless imports in the comparison period have increased by at least 15 percent over imports in the base period. As discussed above, the Department normally determines the comparison period for massive imports based on the filing date of the petition. Based on the March 30, 2011, filing date, we have determined that April 2011 is the month in which importers, exporters or producers knew or should have known an antidumping duty investigation was likely. Additionally, we have used a period of four months (*i.e.,* April through July 2011) as the period for comparison in preliminarily determining whether imports of the subject merchandise have been massive. We believe that a four-month period is most appropriate as the basis for analysis because using four months captures all data available at this time, based on April 2011 as the beginning of the comparison period. Additionally, a four-month period properly reflects the ''relatively short period'' set forth in the statute for determining whether imports have been massive.[30] It is our practice to base the critical circumstances analysis on all available data, using base and comparison periods of no less than three months.[31]

Therefore, we have used all available data in our critical-circumstances analysis for the preliminary determination. In applying the four-month period, we used a base period of December 2010 through March 2011, and a comparison period of April 2011 through July 2011.

Individually Examined Respondents

The Department used the shipment data of the three individually examined respondents, Zhejiang Jingu and Shanghai Yata (collapsed)[32] and Centurion, to examine the relevant base and comparison periods as identified above. When we compared Zhejiang Jingu and Shanghai Yata's shipment data during the comparison period with the base period, we found that imports of Zhejiang Jingu and Shanghai Yata's subject merchandise in the comparison period have not increased by at least 15 percent over imports in the base period, and we do not consider them to be massive, pursuant to section 351.206(h) of the Department's regulations.[33] When we compared Centurion's shipment data during the comparison period with the base period, we found that imports of Centurion's subject merchandise in the comparison period have increased by more than 15 percent over imports in the base period; hence we consider imports of Centurion's subject merchandise to be massive, pursuant to section 351.206(h) of the Department's regulations.[34]

Separate Rate Applicants

For the separate rate applicants, we did not request the monthly shipment information necessary to determine if there were massive imports. As the basis to measure whether massive imports existed for purposes of critical circumstances, we relied on the experience of the individually examined respondents receiving a separate rate.[35] We calculated the weighted-average percent change in imports in the comparison period over the base period for the individually examined respondents, and we do not find the imports of the separate rate applicants to be massive pursuant to section 351.206(h) of the Department's regulations.[36]

The PRC Entity

With respect to imports from the PRC entity, the Department's general approach is to examine U.S. import data from the ITC's DataWeb, adjusted to remove shipments by the respondents participating in the investigation.[37] By examining overall imports from the country in question, the Department tries to ascertain whether a massive increase in shipments occurred within a relatively short period following the point at which importers had reason to believe that a proceeding was likely. In this case, according to the Petitioners, the HTSUS numbers listed in the scope of the investigation include both subject merchandise and non-subject merchandise.[38] Thus, we cannot rely on these data in making our ''massive imports'' determination.[39] Lacking information on whether there was a massive import surge for the PRC entity, we are unable to determine whether there have been massive imports of steel

[28] *See, e.g., Lemon Juice from Argentina: Preliminary Determination of Sales at Less than Fair Value and Affirmative Preliminary Determination of Critical Circumstances,* 72 FR 20820, 20828 (April 26, 2007).

[29] *See* ITC Preliminary Determination.

[30] *See* section 733(e)(1)(B) of the Act.

[31] *See, e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Affirmative Preliminary Determination of Critical Circumstances: Certain Frozen and Canned Warmwater Shrimp from India,* 69 FR 47111 (August 4, 2004), unchanged in the final determination, (*Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Frozen and Canned Warmwater Shrimp From India,* 69 FR 76916 (December 23, 2004)); and *Notice of Final Determination of Sales at Less Than Fair Value and Negative Final Determination of Critical Circumstances: Certain Color Television Receivers From the People's Republic of China,* 69 FR 20594 (Apr. 16, 2004), and accompanying Issues and Decision Memorandum (''IDM'') at Comment 3.

[32] See the Department's Memorandum, ''Antidumping Duty Investigation of Certain Steel Wheels from the People's Republic of China: Affiliation and Collapsing of Zhejiang Jingu Company Limited and Shanghai Yata Industry Company Limited'' dated concurrently with this notice (''Affiliation and Collapsing Memorandum'') and the ''Affiliation'' section below.

[33] See Critical Circumstances Calculation Memorandum at Attachment I.

[34] See, id.

[35] See, *Certain Oil Country Tubular Goods From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value, Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination,* 74 FR 59117, 59121 (November 17, 2009), unchanged *in Certain Oil Country Tubular Goods from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, Affirmative Final Determination of Critical Circumstances and Final Determination of Targeted Dumping,* 75 FR 20335 (April 19, 2010) (''OCTG Investigation'').

[36] See *id.*

[37] See, *e.g., Laminated Woven Sacks From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value, Partial Affirmative Determination of Critical Circumstances, and Postponement of Final Determination,* 73 FR 5801 (January 31, 2008); and *Drill Pipe from the People's Republic of China: Notice of Preliminary Affirmative Determination of Critical Circumstances,* 75 FR 49891 (August 16, 2010).

[38] See Petition at Exhibit I–4. The Department's subsequent preliminary determination to add HTS numbers to the scope of the investigation does not affect the Petitioners' assertion or our resulting analysis.

[39] See OCTG Investigation.

wheels from the producers included in the PRC entity.[40]

Critical Circumstances Findings

Based on the above analysis, we preliminarily determine that critical circumstances do not exist for Zhejiang Jingu and Shanghai Yata (collapsed), the separate rate respondents, or the PRC entity. However, we preliminarily determine that critical circumstances do exist with respect to imports from Centurion. After issuance of the preliminary determination, we intend to request updated monthly shipment data from the mandatory respondents, and we will reevaluate our critical circumstances determination after the preliminary determination based on the updated data we receive.

Surrogate Country

Section 773(c)(1) of the Act directs the Department to base normal value (''NV'') on the NME producer's FOPs, valued in a surrogate market economy (''ME'') country or countries considered to be appropriate by the Department. In accordance with section 773(c)(4) of the Act, in valuing the FOPs, the Department shall use, to the extent possible, the prices or costs of the FOPs in one or more ME countries that are: (1) At a level of economic development comparable to that of the NME country; and (2) significant producers of comparable merchandise. The sources of the surrogate factor values are discussed under the ''Factor Valuations'' section below.[41]

The Department determined that Colombia, Indonesia, the Philippines, South Africa, Thailand and Ukraine are countries comparable to the PRC in terms of economic development.[42] Once we have identified the countries that are economically comparable to the PRC, we select an appropriate surrogate country by determining whether an economically comparable country is a significant producer of comparable merchandise and whether the data for valuing FOPs are both available and reliable.

Petitioners, in their August 8, 2011 comments on surrogate country, recommend that the Department select Indonesia as the primary surrogate country, as Indonesia is economically comparable to the PRC and a significant producer of steel and aluminum wheels. Zhejiang Jingu and Shanghai Yata, in their August 8, 2011 comments on surrogate country, state that based on the surrogate value and other information included in the petition, India appears to be a significant producer of identical merchandise and is a reliable source for deriving surrogate country data. Centurion, in its August 8, 2011 comments on surrogate country, recommends that the Department select India as the primary surrogate country. Centurion argues that India is a significant producer of comparable merchandise and represents the best choice in terms of the quality of data available. Centurion also argues that if the Department decides not to choose India as the primary surrogate country, Indonesia should be selected, as it is economically comparable and a significant producer of comparable merchandise. Additionally, Petitioners, Zhejiang Jingu and Shanghai Yata, and Centurion each put import data from Indonesia on the record of this proceeding.

Economic Comparability

As explained in the Surrogate Country Memorandum, the Department considers Colombia, Indonesia, the Philippines, South Africa, Thailand and Ukraine equally comparable to the PRC in terms of economic development.[43] Therefore, we consider all six countries as having satisfied this prong of the surrogate country selection criteria. Accordingly, unless we find that all of the countries determined to be equally economically comparable are not significant producers of comparable merchandise, do not provide a reliable source of publicly available surrogate data or are unsuitable for use for other reasons, we will rely on data from one of these countries.

Producers of Identical or Comparable Merchandise

Section 773(c)(4)(B) of the Act requires the Department to value FOPs in a surrogate country that is a significant producer of comparable merchandise. Neither the statute nor the Department's regulations provide further guidance on what may be considered comparable merchandise. Given the absence of any definition in the statute or regulations, the Department looks to other sources such as Policy Bulletin 04.1[44] for guidance on defining comparable merchandise. Policy Bulletin 04.1 states that ''the terms 'comparable level of economic development,' 'comparable merchandise,' and 'significant producer' are not defined in the statute.''[45] Policy Bulletin 04.1 further states that ''in all cases, if identical merchandise is produced, the country qualifies as a producer of comparable merchandise.''[46] Conversely, if identical merchandise is not produced, then a country producing comparable merchandise is sufficient in selecting a surrogate country.[47] Further, when selecting a surrogate country, the statute requires the Department to consider the comparability of the merchandise, not the comparability of the industry.[48] ''In cases where the identical merchandise is not produced, the Department must determine if other merchandise that is comparable is produced.''[49] In this regard, the Department recognizes that any analysis of comparable merchandise must be done on a case-by-case basis:

> In other cases, however, where there are major inputs, *i.e.,* inputs that are specialized or dedicated or used intensively, in the production of the subject merchandise, *e.g.,* processed agricultural, aquatic and mineral products, comparable merchandise should be identified narrowly, on the basis of a comparison of the major inputs, including energy, where appropriate.[50]

In evaluating which of the six countries are exporters or producers[51] of identical

[40] See, *e.g., Notice of Preliminary Affirmative Countervailing Duty Determination and Preliminary Negative Critical Circumstances Determination: Certain Lined Paper Products from India,* 71 FR 7916 (February 15, 2006) (making a preliminary negative critical circumstances determination for lack of a sufficient factual basis).

[41] *See* the Department's Memorandum, ''Antidumping Duty Investigation of Certain Steel Wheels from the People's Republic of China (''PRC''): Preliminary Determination Surrogate Value Memorandum,'' dated concurrently with this notice (''Surrogate Value Memorandum'').

[42] *See* the Department's Memorandum, ''Antidumping Duty Investigation of Certain Steel Wheels from the People's Republic of China: List of Surrogate Countries,'' dated June 24, 2011 (''Surrogate Country Memorandum'').

[43] *See* Surrogate Country Memorandum.

[44] *See* the Department's Policy Bulletin No. 04.1, regarding, ''Non-Market Economy Surrogate Country Selection Process,'' (March 1, 2004) (''Policy Bulletin 04.1''), available on the Department's Web site at *http://ia.ita.doc.gov/policy/bull04-.html.*

[45] *See* Policy Bulletin 04.1.

[46] *See id.*

[47] Policy Bulletin 04.1 also states that ''if considering a producer of identical merchandise leads to data difficulties, the operations team may consider countries that produce a broader category of reasonably comparable merchandise.'' *See id.,* at note 6.

[48] *See Sebacic Acid from the People's Republic of China; Final Results of Antidumping Duty Administrative Review,* 62 FR 65674 (December 15, 1997) and accompanying IDM at Comment 1 (to impose a requirement that merchandise must be produced by the same process and share the same end uses to be considered comparable would be contrary to the intent of the statute).

[49] See Policy Bulletin 04.1, at 2.

[50] *See id,* at 3.

[51] The Department has previously relied on production data for selecting the primary surrogate country. *See, e.g., Wooden Bedroom Furniture from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Review,* 75 FR 9581, 9584 (March 3, 2010), unchanged *in Wooden Bedroom Furniture from the People's Republic of China: Final Results of Antidumping Duty New Shipper Review,* 75 FR 44764 (July 29, 2010).

or comparable merchandise, the Department looked to export data obtained from Global Trade Atlas (''GTA'') for HTSUS 8708.70: Wheels Including Parts And Accessories For Motor Vehicles, which covers the merchandise under investigation. The GTA data for the comparable merchandise demonstrates that all the countries in the Surrogate Country Memorandum are producers of comparable merchandise.

Significant Producers of Identical or Comparable Merchandise

As noted above, Colombia, Indonesia, the Philippines, South Africa, Thailand and Ukraine were exporters of comparable merchandise in 2010. We find that the GTA data demonstrates that these countries were also significant producers of comparable merchandise.[52] Since all countries on the surrogate country list remain qualified, the Department looks to the availability of surrogate value data to determine the most appropriate surrogate country of the two remaining countries.

Data Availability

When evaluating surrogate value data, the Department considers several factors including whether the surrogate value is publicly available, contemporaneous with the POI, represents a broad market average, from an approved surrogate country, tax and duty-exclusive, and specific to the input. There is no hierarchy among these criteria; it is the Department's practice to carefully consider the available evidence in light of the particular facts of each industry when undertaking its analysis.[53] While the record does not contain appropriate surrogate value data from Colombia, the Philippines, South Africa, Thailand or Ukraine, in this case, the record does contain data and a surrogate financial statement for Indonesia. Accordingly, for purposes of the preliminary determination, there is no need for the Department to consider countries not as economically comparable as those identified in the Surrogate Country Memorandum, given the facts of this case. Therefore, we have selected Indonesia as the surrogate country to use in this investigation, and, accordingly, have calculated NV using Indonesian prices to value the respondent's FOPs, when available and appropriate. See Surrogate Value Memorandum. We have obtained and relied upon publicly available information wherever possible.

Surrogate Value Comments

Timely surrogate value submissions were filed on August 19, 2011, by Centurion, Zhejiang Jingu, Shanghai Yata, and Petitioners. Centurion filed rebuttal surrogate values comments on August 26, 2011. For a detailed discussion of the surrogate values used in this LTFV proceeding, *see* the ''Factor Valuation'' section below and the Surrogate Value Memorandum.

Affiliation

Based on the evidence presented in Zhejiang Jingu and Shanghai Yata's questionnaire responses, we preliminarily find that they are affiliated, pursuant to section 771(33)(E) of the Act. In addition, based on the evidence presented in their respective questionnaire responses, we preliminarily find that Zhejiang Jingu and Shanghai Yata should be treated as a single entity for the purposes of this investigation. This finding is based on the determination that Shanghai Yata, an exporter of subject merchandise, is a wholly-owned subsidiary of Zhejiang Jingu whose operations are fully integrated with those of Shanghai Yata. Further, we find that there is significant potential for manipulation of price or production between the parties pursuant to 19 CFR 351.401(f). For further discussion of the Department's affiliation and collapsing decision, *see* the Affiliation and Collapsing Memorandum.

Separate Rates

In the *Initiation Notice,* the Department notified parties of the application process by which exporters and producers may obtain separate rate status in NME investigations.[54] The process requires exporters and producers to submit an SRA.[55] The standard for eligibility for a separate rate is whether a firm can demonstrate an absence of both *de jure* and *de facto* government control over its export activities. In this instant investigation, the Department received timely-filed SRAs from eight separate rate applicants.[56] The three individually examined respondents (*i.e.,* Zhejiang Jingu, Shanghai Yata, and Centurion), and the separate rate applicants provided company-specific information, and each stated that it meets the criteria for the assignment of a separate rate.

In proceedings involving NME countries, the Department has a rebuttable presumption that all companies within the country are subject to government control and thus should be assessed a single antidumping duty rate.[57] It is the Department's policy to assign all exporters of merchandise subject to investigation in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate. Exporters can demonstrate this independence through the absence of both *de jure* and *de facto* governmental control over export activities. The Department analyzes each entity exporting the subject merchandise under a test arising from *Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China,* 56 FR 20588 (May 6, 1991) (''Sparklers''), as further developed in *Final Determination of Sales at Less Than Fair Value: Silicon Carbide from the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*''). As information on the record demonstrates that Wuxi Superior is wholly foreign-owned,[58] consistent with our practice, we have not conducted a separate rate analysis of Wuxi Superior.

a. Absence of De Jure Control

The Department considers the following de jure criteria in determining

[52] See Surrogate Value Memorandum.

[53] See Policy Bulletin 04.1.

[54] See *Initiation Notice.*

[55] See Policy Bulletin 05.1, which states: ''while continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME investigations will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applied both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question and produced by a firm that supplied the exporter during the period of investigation.'' See Policy Bulletin 05.1 at 6.

[56] The separate rate applicants are: (1) Shandong Land Star Import & Export Co., Ltd (''Shandong Land Star''), (2) Shandong Jining Wheel Factory (''Shandong Jining''); (3) Wuxi Superior Wheel Co., Ltd. (''Wuxi Superior''), (4) Xingmin Wheel, (5) Xiamen Sunrise, (6) Jiaxing Stone Wheel Co., Ltd. (''Jiaxing Stone''), (7) Xiamen Topu, and (8) China Dongfeng Motor Industry Imp. & Exp. Co., Ltd. (''Dongfeng Motor'').

[57] See, *e.g., Notice of Final Determination of Sales at Less Than Fair Value, and Affirmative Critical Circumstances, In Part: Certain Lined Paper Products From the People's Republic of China,* 71 FR 53079 (September 8, 2006), and *Final Determination of Sales at Less Than Fair Value and Final Partial Affirmative Determination of Critical Circumstances: Diamond Sawblades and Parts Thereof From the People's Republic of China,* 71 FR 29303 (May 22, 2006).

[58] See Wuxi Superior's SRA dated June 27, 2011.

whether an individual company may be granted a separate rate: (1) An absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; and (3) other formal measures by the government decentralizing control of companies. See *Sparklers,* 56 FR at 20589.

The evidence provided by all separate rate applicants supports a preliminary finding of *de jure* absence of government control based on the following: (1) an absence of restrictive stipulations associated with the individual exporter's business and export licenses; (2) applicable legislative enactments that decentralize control of the companies; and (3) formal measures by the government decentralizing control of companies. See Shandong Land Star's SRA submissions, dated June 24, 2011 and July 15, 2011; Shandong Jining's SRA submission dated July 6, 2011; Xingmin Wheel's SRA submissions, dated June 27, 2011 and July 21, 2011; Xiamen Sunrise's SRA submissions, dated June 24, 2011 and July 21, 2011; Jiaxing Stone's SRA submissions, dated June 28, 2011 and July 21, 2011; Xiamen Topu's SRA submissions, dated June 24, 2011 and July 21, 2011; and Dongfeng Motor's SRA submissions, dated June 24, 2011 and July 27, 2011; as well as Zhejiang Jingu and Shanghai Yata's SRA and section A questionnaire submissions, dated June 27, 2011, July 15, 2011 and August 19, 2011, respectively; and Centurion's section A questionnaire submissions, dated July 5, 2011 and August 8, 2011, where the individually examined respondents and separate rate applicants certified that they had no relationship with any level of the PRC government with respect to ownership, internal management, and business operations.

b. Absence of De Facto Control

Typically, the Department considers four factors in evaluating whether each respondent is subject to *de facto* government control of its export functions: (1) Whether the export prices are set by or are subject to the approval of a government agency; (2) whether the respondent has authority to negotiate and sign contracts and other agreements; (3) whether the respondent has autonomy from the government in making decisions regarding the selection of management; and (4) whether the respondent retains the proceeds of its export sales and makes independent decisions regarding disposition of profits or financing of losses. See *Silicon Carbide,* 59 FR at 22586–87; see also *Notice of Final Determination of Sales at Less Than Fair Value: Furfuryl Alcohol From the People's Republic of China,* 60 FR 22544, 22545 (May 8, 1995). The Department has determined that an analysis of *de facto* control is critical in determining whether respondents are, in fact, subject to a degree of government control which would preclude the Department from assigning separate rates.

In this investigation, each individually examined respondent and separate rate applicant asserted the following: (1) That the export prices are not set by, and are not subject to, the approval of a governmental agency; (2) they have authority to negotiate and sign contracts and other agreements; (3) they have autonomy from the government in making decisions regarding the selection of management; and (4) they retain the proceeds of their export sales and make independent decisions regarding disposition of profits or financing of losses. Additionally, each of these companies' SRA responses indicates that its pricing during the POI does not involve coordination among exporters.[59]

Evidence placed on the record of this investigation by Zhejiang Jingu, Shanghai Yata, Centurion, and the separate rate applicants demonstrate an absence of *de jure* and *de facto* government control with respect to their respective exports of the merchandise under investigation, in accordance with the criteria identified in *Sparklers* and *Silicon Carbide.* Therefore, we are preliminarily granting a separate rate to these entities.

Margin for Separate Rate Companies

As discussed above, the Department received timely and complete separate rate applications from (1) Shandong Land Star, (2) Shandong Jining, (3) Wuxi Superior, (4) Xingmin Wheel, (5) Xiamen Sunrise, (6) Jiaxing Stone, (7) Xiamen Topu and (8) Dongfeng Motor, all of which were exporters of steel wheels from the PRC during the POI and were not selected as individually examined respondents in this investigation. Through the evidence in their respective SRAs, these companies have demonstrated their eligibility for a separate rate. Consistent with the Department's practice, we have established a margin for the separate rate applicants based on the average of the rates we calculated for the individually examined respondents, Centurion and Zhejiang Jingu/Shanghai Yata, excluding any rates that were zero, de minimis, or based entirely on AFA.[60]

Application of Facts Otherwise Available and Adverse Facts Available

The PRC-Wide Entity and PRC-Wide Rate

We issued our request for Q&V information to 19 potential Chinese exporters of the subject merchandise, in addition to posting the Q&V questionnaire on the Department's Web site. See Respondent Selection Memo. While information on the record of this investigation indicates that there are numerous producers/exporters of steel wheels in the PRC, we received only eleven timely filed Q&V responses. Although all exporters were given an opportunity to provide Q&V information, not all exporters provided a response to the Department's Q&V letter. Therefore, the Department has preliminarily determined that there were exporters/producers of the subject merchandise during the POI from the PRC that did not respond to the Department's request for information. We have treated these PRC producers/exporters as part of the PRC-wide entity because they did not apply for a separate rate.[61]

Section 776(a)(2) of the Act provides that, if an interested party (A) withholds information that has been requested by the Department, (B) fails to provide such information in a timely manner or in the form or manner requested, subject to subsections 782(c)(1) and (e) of the Act, (C) significantly impedes a proceeding under the antidumping statute, or (D) provides such information but the information cannot be verified, the Department shall, subject to subsection 782(d) of the Act, use facts otherwise

[59] See Shandong Land Star's SRA submissions dated June, 24, 2011 and July 15, 2011; Shandong Jining's SRA submission dated July 6, 2011; Xingmin Wheel's SRA submissions dated June 27, 2011 and July 21, 2011; Xiamen Sunrise's SRA submissions, dated June 24, 2011 and July 21, 2011; Jiaxing Stone's SRA submissions, dated June 28, 2011 and July 21, 2011; Xiamen Topu's SRA submissions dated June 24, 2011 and July 21, 2011; and Dongfeng Motor's SRA submissions, dated June 24, 2011 and July 27, 2011; as well as Zhejiang Jingu and Shanghai Yata's SRA and section A questionnaire submissions, dated June 27, 2011, July 15, 2011 and August 19, 2011, respectively; and Centurion's section A questionnaire submissions, dated July 5, 2011 and August 8, 2011.

[60] See, *e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in Final Determination of Sales at Less Than Fair Value and *Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[61] See, *e.g., Kitchen Racks Prelim,* unchanged in *Kitchen Racks Final.*

available in reaching the applicable determination.

Information on the record of this investigation indicates that the PRC-wide entity was non-responsive. Certain companies did not respond to our questionnaire requesting Q&V information. As a result, pursuant to section 776(a)(2)(A) of the Act, we find that the use of facts available (''FA'') is appropriate to determine the PRC-wide rate.[62]

Section 776(b) of the Act provides that, in selecting from among the facts otherwise available, the Department may employ an adverse inference if an interested party fails to cooperate by not acting to the best of its ability to comply with requests for information.[63] We find that, because the PRC-wide entity did not respond to our requests for information, it has failed to cooperate to the best of its ability. Furthermore, the PRC-wide entity's refusal to provide the requested information constitutes circumstances under which it is reasonable to conclude that less than full cooperation has been shown.[64] Therefore, the Department preliminarily finds that, in selecting from among the facts available, an adverse inference is appropriate.

When employing an adverse inference, section 776 of the Act indicates that the Department may rely upon information derived from the petition, the final determination from the LTFV investigation, a previous administrative review, or any other information placed on the record. In selecting a rate for adverse facts available (''AFA''), the Department selects a rate that is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it had fully cooperated. It is the Department's practice to select, as AFA, the higher of the (a) highest margin alleged in the petition, or (b) the highest calculated rate of any respondent in the investigation.[65] As AFA, we have preliminarily assigned to the PRC-wide entity a rate of 193.54 percent, the highest calculated rate from the *Initiation Notice.*[66] The Department preliminarily determines that this information is the most appropriate from the available sources to effectuate the purposes of AFA. The Department's reliance on the petition rate to determine an AFA rate is subject to the requirement to corroborate secondary information, discussed in the Corroboration section below.

Corroboration

Section 776(c) of the Act provides that, when the Department relies on secondary information rather than on information obtained in the course of an investigation as facts available, it must, to the extent practicable, corroborate that information from independent sources reasonably at its disposal. Secondary information is described as ''information derived from the petition that gave rise to the investigation or review, the final determination concerning merchandise subject to this investigation, or any previous review under section 751 concerning the merchandise subject to this investigation.''[67] To ''corroborate'' means that the Department will satisfy itself that the secondary information to be used has probative value. Independent sources used to corroborate may include, for example, published price lists, official import statistics and customs data, and information obtained from interested parties during the particular investigation. To corroborate secondary information, the Department will, to the extent practicable, examine the reliability and relevance of the information used.[68]

The AFA rate that the Department used is from the *Initiation Notice.* To corroborate the AFA margin that we have selected, we compared this margin to the margin we found for the individually examined respondents. We calculated that the margin of 193.54 percent has probative value because it is in the range of the control number (CONNUM)-specific margins that we found for the Centurion and Zhejiang Jingu/Shanghai Yata during the period of investigation.[69] Given that numerous PRC-wide entities did not respond to the Department's requests for information, the Department concludes that the petition rate of 193.54 percent, as total AFA for the PRC-wide entity, is sufficiently adverse to prevent the PRC-wide entity from benefitting from its lack of cooperation.[70] Accordingly, we find that the rate of 193.54 percent is corroborated to the extent practicable within the meaning of section 776(c) of the Act.

Date of Sale

19 CFR 351.401(i) states that, ''in identifying the date of sale of the merchandise under consideration or foreign like product, the Secretary normally will use the date of invoice, as recorded in the exporter or producer's records kept in the normal course of business.'' In *Allied Tube,* the CIT noted that a ''party seeking to establish a date of sale other than invoice date bears the burden of producing sufficient evidence to 'satisf{y}' the Department that 'a different date better reflects the date on which the exporter or producer establishes the material terms of sale.''' *Allied Tube & Conduit Corp.* v. *United States,* 132 F. Supp. 2d 1087, 1090 (CIT 2001) (quoting 19 CFR 351.401(i)) (''*Allied Tube*''). Additionally, the Secretary may use a date other than the date of invoice if the Secretary is satisfied that a different date better reflects the date on which the exporter

[62] See *Preliminary Determination of Sales at Less Than Fair Value, Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 68 FR 4986 (January 31, 2003), unchanged in *Final Determination of Sales at Less Than Fair Value and Affirmative Critical Circumstances: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam,* 68 FR 37116 (June 23, 2003).

[63] See *Statement of Administrative Action,* accompanying the Uruguay Round Agreements Act (''URAA''), H.R. Rep. No. 103–316, 870 (1994) (''SAA''); see also *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon-Quality Steel Products from the Russian Federation,* 65 FR 5510, 5518 (February 4, 2000).

[64] See *Nippon Steel Corporation* v. *United States,* 337 F.3d 1373, 1383 (Fed. Cir. 2003) (''*Nippon Steel*'') (providing an explanation of the ''failure to act to the best of its ability'' standard and noting that the Department need not show intentional conduct existed on the part of the respondent, but merely that a ''failure to cooperate to the best of a respondent's ability'' existed (*i.e.,* information was not provided ''under circumstances in which it is reasonable to conclude that less than full cooperation has been shown'')).

[65] See *Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Carbon Quality Steel Products from the People's Republic of China,* 65 FR 34660 (May 31, 2000), and accompanying IDM, at ''Facts Available.''

[66] See *Initiation Notice,* 76 FR 23297.

[67] See *Final Determination of Sales at Less Than Fair Value: Sodium Hexametaphosphate From the People's Republic of China,* 73 FR 6479, 6481 (February 4, 2008), quoting SAA at 870.

[68] See *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Preliminary Results of Antidumping Duty Administrative Reviews and Partial Termination of Administrative Reviews,* 61 FR 57391, 57392 (November 6, 1996), unchanged in *Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From Japan, and Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Components Thereof, From Japan; Final Results of Antidumping Duty Administrative Reviews and Termination in Part,* 62 FR 11825 (March 13, 1997).

[69] See Memorandum from the Department entitled ''Investigation of Certain Steel Wheels from the People's Republic of China: Analysis of the Preliminary Determination Margin Calculation for Zhejiang Jingu Company Limited (''Jingu'') and Shanghai Yata Industry Company Limited (''Yata''),'' dated October 26, 2011; *see also* Memorandum from the Department entitled ''Investigation of Certain Steel Wheels from the People's Republic of China: Analysis of the Preliminary Determination Margin Calculation for Jining Centurion Wheels Manufacturing Co., Ltd. and Centurion Wheel Manufacturing Company,'' dated October 26, 2011.

[70] See SAA at 870.

or producer establishes the material terms of sale.[71] The date of sale is generally the date on which the parties agree upon all substantive terms of the sale. This normally includes the price, quantity, delivery terms and payment terms.[72]

For sales by all three respondents, consistent with 19 CFR 351.401(i), we used the commercial invoice date as the sale date because record evidence indicates that the terms of sale were set atuntil the time when the commercial invoice was issued.[73]

Fair Value Comparisons

To determine whether sales of steel wheels to the United States by the respondents were made at LTFV, we compared EP and CEP to NV, as described in the ''Constructed Export Price,'' ''Export Price,'' and ''Normal Value'' sections of this notice.

U.S. Price

Constructed Export Price

In accordance with section 772(a) of the Act, CEP is the price at which the subject merchandise is first sold (or agreed to be sold) in the United States before or after the date of importation by or for the account of the producer or exporter of such merchandise or by a seller affiliated with the producer or exporter, to a purchaser not affiliated with the producer or exporter, as adjusted under subsections (c) and (d). In accordance with section 772(a) of the Act, we used CEP for a portion of Centurion's U.S. sales because the merchandise subject to this investigation was sold directly to an affiliated purchaser located in the United States.

We calculated CEP for Centurion based on delivered prices to unaffiliated purchasers in the United States. We made deductions from the U.S. sales price, where applicable, for movement expenses in accordance with section 772(c)(2)(A) of the Act. These included such expenses as foreign inland freight from the plant to the port of exportation, international freight, marine insurance, other U.S. transportation, U.S. customs duty, U.S. inland freight from port to the warehouse, and U.S. inland freight from the warehouse to the customer. In accordance with section 772(d)(1) of the Act, the Department deducted credit expenses, inventory carrying costs and indirect selling expenses from the U.S. price, all of which relate to commercial activity in the United States. Finally, we deducted CEP profit, in accordance with sections 772(d)(3) and 772(f) of the Act.[74]

Export Price

In accordance with section 772(a) of the Act, we used EP for Zhejiang Jingu's, Shanghai Yata's, and Centurion's U.S. sales, where applicable. We calculated EP based on the packed prices to unaffiliated purchasers in, or for exportation to, the United States. We made deductions, as appropriate, for any movement expenses (*e.g.,* foreign inland freight from the plant to the port of exportation, domestic brokerage, etc.) in accordance with section 772(c)(2)(A) of the Act. Where foreign inland freight or foreign brokerage and handling fees were provided by PRC service providers or paid for in renminbi, we based those charges on surrogate value rates from Indonesia. Where U.S. inland freight or U.S. brokerage and handling fees were provided by PRC service providers or paid for in renminbi, we based those charges on surrogate value rates for those U.S. services. See ''Factor Valuation'' section below for further discussion of surrogate value rates.

In determining the most appropriate surrogate values to use in a given case, the Department's stated practice is to use period-wide price averages, prices specific to the input in question, prices that are net of taxes and import duties, prices that are contemporaneous with the POI, and publicly available data.[75] We valued foreign brokerage and handling using a price list of export procedures necessary to export a standardized cargo of goods from Indonesia where foreign brokerage and handling were provided by PRC service providers or paid for in renminbi. The price list is compiled based on a survey case study of the procedural requirements for trading a standard shipment of goods by truck in Indonesia as reported in ''Doing Business 2011: Indonesia'' published by the World Bank.[76] We used a similar price list from ''Doing Business 2011: United States'' to value brokerage and handling fees incurred in the United States. To value truck freight, the Department used a price list for domestic shipments from the Indonesian shipping company, PT Mantap Abiah Abadi. We determined the average cost for shipment from 12 cities to Jakarta by truck, using Google maps to determine overland distance. To value domestic water freight, the Department also used PT Mantap Abiah Abadi's price list. We determined the average price of shipment from 11 cities to Jakarta by boat, using *http://www.sea-distances.com,* to calculate the port-to-port sailing distance.

To value international ocean freight and U.S. inland freight, the Department used quotes from China Container Line Ltd. (a Hong Kong company) for the shipment of various consumer products, as obtained on the Descartes Carrier Rate Retrieval Database (''Descartes''). For international ocean freight, the Department used departure and destination ports, container size and gross shipment weight of three reported shipments of subject merchandise by respondents. For U.S. inland freight, the Department used ports of import and customer city locations, container size, and gross shipment weight of three reported shipments of subject merchandise by respondents. The data obtained from Descartes can be accessed via *http://www.descartes.com/*. The Descartes database is a Web-based service, which publishes the ocean freight rates of numerous carriers. In prior proceedings, we rejected the Descartes database as an ocean freight surrogate value source because the data did not appear to be publicly available.[77] Upon reexamination, however, we found that this database is accessible to government agencies without charge, in compliance with Federal Maritime Commission regulations and, thus, we now find that this is a publicly-available source. In addition to being publicly available, the Descartes data reflect rates for multiple carriers, report rates on a daily basis, additionally, the price data obtained are based on routes that closely correspond to those used by respondents, and are specific to the merchandise subject to this investigation. Therefore, the Descartes data is product-specific, publicly available, a broad-market average, and contemporaneous with the period of the segment. Accordingly, the

[71] See 19 CFR 351.401(i); see also *Allied Tube,* 132 F. Supp. 2d 1087, 1090–1092.

[72] See *Carbon and Alloy Steel Wire Rod from Trinidad and Tobago: Final Results of Antidumping Duty Administrative Review,* 72 FR 62824 (November 7, 2007), and accompanying IDM at 5; *Notice of Final Determination of Sales at Less Than Fair Value: Certain Cold-Rolled Flat-Rolled Carbon Quality Steel Products from Turkey,* 65 FR 15123 (March 21, 2000), and accompanying IDM at Comment 2.1.

[73] See, *e.g.,* Zhejiang Jingu's section A response at 24–25 and Exhibit 6; *see also* Shanghai Yata's section A response at 22 and Exhibit 4; see also Centurion's section A response at A–22—A–23 and Exhibit A–2.

[74] See Surrogate Value Memorandum.

[75] See, *e.g., Certain Cased Pencils from the People's Republic of China; Final Results and Partial Rescission of Antidumping Duty Administrative Review,* 71 FR 38366 (July 6, 2006), and accompanying IDM at Comment 1.

[76] See Surrogate Value Memorandum.

[77] See, *e.g., Fresh Garlic from the People's Republic of China: Final Results and Partial Rescission of Antidumping Duty Administrative Review and Final Results of New Shipper Reviews,* 71 FR 26329 (May 4, 2006) and accompanying IDM at Comment 7.

Descartes data is the best available source for valuing international freight on the record because it provides rates that are representative of the entire period of the investigation and a broad representation of product-specificity.

However, while the Department finds that the Descartes data is the most superior source for valuing international freight on the record, to make the source less impractical, we had to define certain parameters in our selection of data. The Department has calculated the period-average international freight rate by obtaining rates from multiple carriers for a single day in each quarter of the period of the segment. For any rate that the Department determined was from a non-market economy carrier, the Department has not included that rate in the period-average international freight calculation. Additionally, any charges included in the rate that are covered by brokerage and handling charges that the respondent incurred or are included in the reported market economy purchase or the appropriate surrogate value, the Department has not included these charges in the calculation.[78]

Normal Value

Section 773(c)(1) of the Act provides that the Department shall determine the NV using an FOP methodology if the merchandise is exported from an NME and the information does not permit the calculation of NV using home-market prices, third-country prices, or constructed value under section 773(a) of the Act. The Department bases NV on the FOPs because the presence of government controls on various aspects of NMEs renders price comparisons and the calculation of production costs invalid under the Department's normal methodologies. See, *e.g., Kitchen Racks Prelim,* 71 FR at 19703 (unchanged in *Kitchen Racks Final*).

In accordance with 19 CFR 351.408(c)(1), the Department normally will use publicly available information to find an appropriate surrogate value to value FOPs, but when a producer sources an input from an ME and pays for it in an ME currency, the Department may value the factor using the actual price paid for the input. See 19 CFR 351.408(c)(1); *see also Shakeproof Assembly Components Div of Ill* v. *United States,* 268 F.3d 1376, 1382–1383 (Fed. Cir. 2001) (affirming the Department's use of market-based prices to value certain FOPs).

Factor Valuations

In accordance with section 773(c) of the Act, we calculated NV based on FOP data reported by respondents during the POI. To calculate NV, we multiplied the reported per-unit factor-consumption rates by publicly available surrogate values (except as discussed below). In selecting the surrogate values, we considered the quality, specificity, and contemporaneity of the data.[79] As appropriate, we adjusted input prices by including freight costs to make them delivered prices. Specifically, we added to Indonesian import surrogate values a surrogate freight cost using the shorter of the reported distance from the domestic supplier to the factory or the distance from the nearest seaport to the factory where appropriate. This adjustment is in accordance with the Court of Appeals for the Federal Circuit's decision in *Sigma Corp.* v. *United States,* 117 F.3d 1401, 1407–08 (Fed. Cir. 1997). A detailed description of all surrogate values used for Centurion and Zhejiang Jingu/Shanghai Yata can be found in the Surrogate Value Memorandum.

For the preliminary determination, in accordance with the Department's practice, we used data from the Indonesian Import Statistics and other publicly available Indonesian sources in order to calculate surrogate values for Centurion's and Zhejiang Jingu's FOPs (direct materials, energy, and packing materials) and certain movement expenses. In selecting the best available information for valuing FOPs in accordance with section 773(c)(1) of the Act, the Department's practice is to select, to the extent practicable, surrogate values which are non-export average values, most contemporaneous with the POI, product-specific, and tax-exclusive.[80] The record shows that data in the Indonesian import statistics, as well as those from the other Indonesian sources, are contemporaneous with the POI, product-specific, and tax-exclusive.[81] In those instances where we could not obtain publicly available information contemporaneous to the POI with which to value factors, we adjusted the surrogate values using, where appropriate, the Indonesian WPI as published in the Organization for Economic Co-operation and Development's StatExtracts database library, accessed via *http://www.stats.oecd.org/Index.aspx.*[82]

Furthermore, with regard to the Indonesian import-based surrogate values, we have disregarded import prices that we have reason to believe or suspect may be subsidized. We have reason to believe or suspect that prices of inputs from India, South Korea, and Thailand may have been subsidized. We have found in other proceedings that these countries maintain broadly available, non-industry-specific export subsidies and, therefore, it is reasonable to infer that all exports to all markets from these countries may be subsidized.[83]

Further, guided by the legislative history, it is the Department's practice not to conduct a formal investigation to ensure that such prices are not subsidized.[84] Rather, the Department bases its decision on information that is available to it at the time it makes its determination.[85] In addition, there exists no record evidence in this case to suggest that these prices are not subsidized. Therefore, we have not used prices from these countries in calculating the Indonesian import-based surrogate values. Additionally, we disregarded prices from NME countries. Finally, imports that were labeled as originating from an ''unspecified'' country were excluded from the average value, because the Department could

[78] See Surrogate Value Memorandum.

[79] See, *e.g., Fresh Garlic From the People's Republic of China: Final Results of Antidumping Duty New Shipper Review,* 67 FR 72139 (December 4, 2002), and accompanying IDM at Comment 6; and *Final Results of First New Shipper Review and First Antidumping Duty Administrative Review: Certain Preserved Mushrooms From the People's Republic of China,* 66 FR 31204 (June 11, 2001), and accompanying IDM at Comment 5.

[80] See, *e.g., Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 42672, 42682 (July 16, 2004), unchanged in *Final Determination of Sales at Less Than Fair Value: Certain Frozen and Canned Warmwater Shrimp from the Socialist Republic of Vietnam,* 69 FR 71005 (December 8, 2004).

[81] See Surrogate Value Memorandum.

[82] See, *e.g., Kitchen Racks Prelim,* 74 FR at 9600, unchanged in *Kitchen Racks Final.*

[83] See, *e.g., Carbazole Violet Pigment 23 from India: Final Results of the Expedited Five-Year (Sunset) Review of the Countervailing Duty Order,* 75 FR 13257 (March 19, 2010), and accompanying IDM at 4–5; *Corrosion-Resistant Carbon Steel Flat Products from the Republic of Korea: Final Results of Countervailing Duty Administrative Review,* 74 FR 2512 (January 15, 2009), and accompanying IDM at 17, 19–20; and *Final Affirmative Countervailing Duty Determination: Certain Hot-Rolled Carbon Steel Flat Products from Thailand,* 66 FR 50410 (October 3, 2001), and accompanying IDM at 23.

[84] See Omnibus Trade and Competitiveness Act of 1988, Conference Report to accompany H.R. Rep. 100–576 at 590 (1988) reprinted in 1988 U.S.C.C.A.N. 1547, 1623–24; see also *Preliminary Determination of Sales at Less Than Fair Value: Coated Free Sheet Paper from the People's Republic of China,* 72 FR 30758 (June 4, 2007), unchanged in *Final Determination of Sales at Less Than Fair Value: Coated Free Sheet Paper from the People's Republic of China,* 72 FR 60632 (October 25, 2007).

[85] See *Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 73 FR 24552, 24559 (May 5, 2008), unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 73 FR 55039 (September 24, 2008).

not be certain that they were not from either an NME country or a country with general export subsidies.[86]

Previously, the Department used regression-based wages that captured the worldwide relationship between *per capita* GNI and hourly manufacturing wages, pursuant to 19 CFR 351.408(c)(3), to value the respondent's cost of labor in NME cases. However, on May 14, 2010, the Court of Appeals for the Federal Circuit (''CAFC''), in *Dorbest Ltd.* v. *United States,* 604 F.3d 1363, 1372 (Fed. Cir. 2010) (''*Dorbest*''), invalidated 19 CFR 351.408(c)(3). As a consequence of the CAFC's ruling in *Dorbest,* the Department no longer relies on the regression-based wage rate methodology described in its regulations.

On June 21, 2011, the Department revised its methodology for valuing the labor input in NME antidumping proceedings.[87] In *Labor Methodologies,* the Department determined that the best methodology to value the labor input is to use industry-specific labor rates from the primary surrogate country. Additionally, the Department determined that the best data source for industry-specific labor rates is Chapter 6A: Labor Cost in Manufacturing, from the International Labor Organization (ILO) Yearbook of Labor Statistics (''Yearbook'').

In this preliminary determination, the Department calculated direct, indirect, and packing labor inputs using the wage method described in *Labor Methodologies.* To value respondents' labor inputs, the Department relied on data reported by Indonesia to the ILO in Chapter 5B of the Yearbook because Indonesia's 6A data is not available. The Department further finds the two-digit description under ISIC–Revision 3 (''34—Manufacture of motor vehicles, trailers, and semi-trailers'') to be the best available information on the record, as it includes a four-digit description (''3430—Manufacture of parts and accessories for motor vehicles and their engines''), which is specific to the industry being examined, and is therefore derived from industries that produce comparable merchandise. Accordingly, relying on Chapter 5B of the Yearbook, the Department calculated the labor input using labor data reported by Indonesia to the ILO under Sub-Classification 34 of the ISIC–Revision 3 standard, in accordance with Section 773(c)(4) of the Act. For this preliminary determination, the calculated industry-specific wage rate is 9,830.98 Rupiah per hour. Because this wage rate does not separate the labor rates into different skill levels or types of labor, the Department has applied the same wage rate to all skill levels and types of labor reported by respondents.[88] A more detailed description of the wage rate calculation methodology is provided in the Surrogate Value Memorandum.

We valued electricity using the average electricity rate for industry in 2009, obtained from the Indonesia Ministry of Energy and Mineral Resources' ''2010 Handbook of Energy & Economic Statistics of Indonesia.''

The Department valued natural gas using data obtained from EnergyBiz Magazine's January/February 2006 edition, in which the American Chemistry Council's data for Indonesian natural gas prices of January 2006 are cited. To value steam, the Department calculated 14.52 percent of the value of natural gas (obtained as described above), by volume.[89]

To value factory overhead, selling, general, and administrative expenses, and profit, we used the audited financial statement of PT Prima Alloy Steel Universal Tbk, a producer of comparable merchandise, covering the fiscal period January 1, 2010, through December 31, 2010. The Department may consider other publicly available financial statements for the final determination, as appropriate.

Currency Conversion

Where necessary, we made currency conversions into U.S. dollars, in accordance with section 773A(a) of the Act, based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Verification

As provided in section 782(i)(1) of the Act, we intend to verify the information from Zhejiang Jingu, Shanghai Yata, and Centurion, upon which we will rely in making our final determination.

Combination Rates

In the *Initiation Notice,* the Department stated that it would calculate combination rates for certain respondents that are eligible for a separate rate in this investigation.[90] This practice is described in Policy Bulletin 05.1.

Preliminary Determination

The weighted-average dumping margin percentages are as follows:

Exporter	Producer	Percent margin
Zhejiang Jingu Company Limited	Zhejiang Jingu Company Limited	141.38
Shanghai Yata Industry Company Limited	Zhejiang Jingu Company Limited	141.38
Jining Centurion Wheels Manufacturing Co., Ltd	Jining Centurion Wheels Manufacturing Co., Ltd	110.58
Shandong Land Star Import & Export Co., Ltd	Shandong Shengtai Wheel Co., Ltd	125.98
Shandong Jining Wheel Factory	Shandong Jining Wheel Factory	125.98
Wuxi Superior Wheel Co., Ltd	Wuxi Superior Wheel Co., Ltd	125.98
Shandong Xingmin Wheel Co. Ltd	Shandong Xingmin Wheel Co. Ltd	125.98
Xiamen Sunrise Wheel Group Co., Ltd	Jining Centurion Wheels Manufacturing Co., Ltd	125.98
Jiaxing Stone Wheel Co., Ltd	Jiaxing Stone Wheel Co., Ltd	125.98
Xiamen Topu Import & Export Co., Ltd	Xiamen Sunrise Wheel Group Co., Ltd	125.98
Xiamen Topu Import & Export Co., Ltd	Jining Centurion Wheels Manufacturing Co., Ltd	125.98
China Dongfeng Motor Industry Imp. & Exp. Co., Ltd	Dongfeng Automotive Wheel Co., Ltd	125.98
PRC-Wide Entity		193.54

[86] See id.

[87] See *Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor,* 76 FR 36092 (June 21, 2011) (''Labor Methodologies'').

[88] See Surrogate Value Memorandum.

[89] See, *e.g., Certain Preserved Mushrooms from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Reviews,* 74 FR 14772 (April 1, 2009), unchanged in *Certain Preserved Mushrooms From the People's Republic of China: Final Results of Antidumping Duty New Shipper Review,* 74 FR 65520 (December 10, 2009).

[90] See *Initiation Notice.*

Disclosure

We will disclose the calculations performed to parties in this proceeding within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

In accordance with section 733(d) of the Act, we will instruct U.S. Customs and Border Protection (''CBP'') to suspend liquidation of all entries of steel wheels from the PRC as described in the ''Scope of Investigation'' section, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register** with the exception of those exported by Centurion. Because we have preliminarily found that critical circumstances exist with regard to exports by Centurion, we will instruct CBP to suspend liquidation of covered entries entered, or withdrawn from warehouse, for consumption up to 90 days prior to the date of publication of this notice in the **Federal Register**. We will instruct CBP to require a cash deposit or the posting of a bond equal to the weighted-average amount by which the normal value exceeds U.S. price, as follows: (1) The rate for the exporter/producer combinations listed in the chart above will be the rate we have determined in this preliminary determination; (2) for all PRC exporters of subject merchandise which have not received their own rate, the cash-deposit rate will be the PRC-wide rate; and (3) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash-deposit rate will be the rate applicable to the PRC exporter/producer combination that supplied that non-PRC exporter. These suspension of liquidation instructions will remain in effect until further notice.

Additionally, as the Department has determined in its Certain Steel Wheels From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination, 76 FR 55012 (September 6, 2011) (''CVD Prelim'') that the merchandise under investigation exported by Zhejiang Jingu and Shanghai Yata benefitted from export subsidies, we will instruct CBP to require an antidumping cash deposit or posting of a bond equal to the amount by which the NV exceeds the U.S. price for Zhejiang Jingu and Shanghai Yata, as indicated above, minus the amount determined to constitute an export subsidy. See, *e.g., Notice of Final Determination of Sales at Less Than Fair Value: Carbazole Violet Pigment 23 From India,* 69 FR 67306, 67307 (November 17, 2007).

International Trade Commission Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our preliminary affirmative determination of sales at LTFV and our partial affirmative decision of critical circumstances. Section 735(b)(2) of the Act requires the ITC to make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of coated paper, or sales (or the likelihood of sales) for importation, of the merchandise under consideration within 45 days of our final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Import Administration no later than seven days after the date on which the final verification report is issued in this proceeding and rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline date for case briefs. See 19 CFR 351.309. A table of contents, list of authorities used and an executive summary of issues should accompany any briefs submitted to the Department. This summary should be limited to five pages total, including footnotes.

In accordance with section 774 of the Act, we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Interested parties, who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, filed electronically using Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern Time (ET) within 30 days after the date of publication of this notice. See 19 CFR 351.310(c). Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230, at a time and location to be determined. See 19 CFR 351.310. Parties should confirm by telephone the date, time, and location of the hearing.

We will make our final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act.

Dated: October 26, 2011.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2011–28413 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Science Advisory Board

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of open meeting.

SUMMARY: The Science Advisory Board (SAB) was established by a Decision Memorandum dated September 25, 1997, and is the only Federal Advisory Committee with responsibility to advise the Under Secretary of Commerce for Oceans and Atmosphere on strategies for research, education, and application of science to operations and information services. SAB activities and advice provide necessary input to ensure that National Oceanic and Atmospheric Administration (NOAA) science programs are of the highest quality and provide optimal support to resource management.

TIME AND DATE: The meeting will be held Tuesday, November 29, 2011 from 9 a.m. to 5:30 p.m. and Wednesday, November 30, 2011, from 8:30 a.m. to 2:30 p.m. These times and the agenda topics described below are subject to change. Please refer to the Web page *http://www.sab.noaa.gov/Meetings/meetings.html* for the most up-to-date meeting agenda.

PLACE: The meeting will be held at the Embassy Row Hotel, 2015 Massachusetts Avenue NW., Washington, DC Please check the SAB Web site *http://www.sab.noaa.gov* for directions to the meeting location.

Status: The meeting will be open to public participation with a 15 minute

public comment period on November 29 at 5:15 p.m. (check Web site to confirm time). The SAB expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of five (5) minutes. Individuals or groups planning to make a verbal presentation should contact the SAB Executive Director by November 22, 2011 to schedule their presentation. Written comments should be received in the SAB Executive Director's Office by November 22, 2011 to provide sufficient time for SAB review. Written comments received by the SAB Executive Director after November 22, 2011 will be distributed to the SAB, but may not be reviewed prior to the meeting date. Seating at the meeting will be available on a first-come, first-served basis.

Matters To Be Considered: The meeting will include the following topics: (1) SAB Data Archive and Access Requirements Working Group White Paper on Management of External Data; (2) Draft Report from the SAB Environmental Information Services Working Group (EISWG), ''Toward Open Weather and Climate Services;'' (3) Review of EISWG Proposed New Members; (4) External Review of the Cooperative Institute for Alaska Research; (5) A Proposal for Engaging the Science Advisory Board in Reviewing NOAA's Research and Development Portfolio-Presentation and Discussion; (6) NOAA Report on Needs Assessment for Science Advisory Board Working Groups; (7) NOAA Response to the SAB Coastal and Marine Spatial Planning Report; (8) Proposed Members and Chair for the SAB Satellite Task Force; and (9) Updates from SAB Working Groups.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, Science Advisory Board, NOAA, Rm. 11230, 1315 East-West Highway, Silver Spring, Maryland 20910. *Phone:* (301) 734–1156, *Fax:* (301) 713–1459, *Email: Cynthia.Decker@noaa.gov;* or visit the NOAA SAB Web site at *http://www.sab.noaa.gov.*

Dated: October 27, 2011.

Mark E. Brown,

Chief Financial Officer/Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2011–28334 Filed 11–1–11; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Partially Exclusive Patent License; ReconRobotics, Inc.

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of its intent to grant to ReconRobotics, Inc., a revocable, nonassignable, partially exclusive license in the United States to practice the Government-owned invention described in Navy Case No. 101027—Magnetic Wheel.

DATES: Anyone wishing to object to the grant of this license must file written objections along with supporting evidence, if any, not later than November 17, 2011.

ADDRESSES: Written objections are to be filed with the Office of Research and Technology Applications, Space and Naval Warfare Systems Center Pacific, Code 72120, 53560 Hull St., Bldg. A33 Room 2531, San Diego, CA 92152–5001.

FOR FURTHER INFORMATION CONTACT: Brian Suh, Office of Research and Technology Applications, Space and Naval Warfare Systems Center Pacific, Code 72120, 53560 Hull St., Bldg. A33 Room 2531, San Diego, CA 92152–5001, telephone (619) 553–5118, email: *brian.suh@navy.mil.*

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: October 26, 2011.

L. M. Senay,

Lieutenant, Office of the Judge Advocate, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 2011–28359 Filed 11–1–11; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Secretary of Energy Advisory Board

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Secretary of Energy Advisory Board (SEAB). SEAB was reestablished pursuant to the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) (the Act). This notice is provided in accordance with the Act.

DATES: Monday, November 14, 2011, 2 p.m.–3:30 p.m.

LOCATION: Teleconference.

FOR FURTHER INFORMATION CONTACT: Amy Bodette, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. Phone (202) 586–0383; facsimile (202) 586–1441; or email: *seab@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Board was reestablished to provide advice and recommendations to the Secretary on the Department's basic and applied research, economic and national security policy, educational issues, operational issues, and other activities as directed by the Secretary.

Purpose of the Meeting: The Natural Gas Subcommittee will present their final report to the Board.

Tentative Agenda: The meeting will start at 2 p.m. on November 14, 2011. The meeting agenda includes presentation of the final report from the Natural Gas Subcommittee and discussion of the recommendations. A draft of the report will be made available at *www.shalegas.energy.gov* and *www.energy.gov/seab* no later than Thursday, November 10, 2011. The meeting will conclude at 3:30 p.m.

Public Participation: The meeting will be conducted by teleconference and is open to the public. Individuals who would like to call in must RSVP to Amy Bodette no later than 5 p.m. on Wednesday, November 9, 2011, at *seab@hq.doe.gov.* There will be a limited number of call-in ports and RSVP is required to obtain dial-in information. Call-in ports will be made available to members of the public on a first come, first served basis. Individuals and representatives of organizations who would like to offer comments and suggestions may do so at the meeting on Monday, November 14, 2011. Approximately 30 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak, but will not exceed 5 minutes. Public Comment will be available on a first come, first served basis and will be queued by the call operator. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

Those not able to call in to the meeting or have insufficient time to address the committee are invited to send a written statement to Amy Bodette, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; or email to *seab@hq.doe.gov.* Timely comments may also be posted online at *www.shalegas.energy.gov.* This notice is being published less than 15 days prior to the meeting date due to programmatic issues and members' availability that had to be resolved prior to the meeting date.

Minutes: The minutes of the meeting will be available on the SEAB Web site: *http://www.energy.gov/SEAB* or by contacting Ms. Bodette. She may be reached at the postal address or email address above.

Issued in Washington, DC, on October 28, 2011.

Carol A. Matthews,

Committee Management Officer.

[FR Doc. 2011–28433 Filed 11–1–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Nuclear Energy Advisory Committee

AGENCY: Department of Energy, Office of Nuclear Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Nuclear Energy Advisory Committee (NEAC). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Tuesday December 13, 2011; 8:30 a.m.–3:30 p.m.

ADDRESSES: L'Enfant Plaza Hotel, 480 L'Enfant Plaza, SW., Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Kenneth Chuck Wade, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue SW., Washington DC 20585. Phone (301) 903–6509 or email: *Kenneth.wade@nuclear.energy.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Nuclear Energy Advisory Committee (NEAC), formerly the Nuclear Energy Research Advisory Committee (NERAC), was established in 1998 by the U.S. Department of Energy (DOE) to provide advice on complex scientific, technical, and policy issues that arise in the planning, managing, and implementation of DOE's civilian nuclear energy research programs. The committee is composed of 16 individuals of diverse backgrounds selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to nuclear energy.

Purpose of the Meeting: Introduction of new members to the committee; briefing the committee on recent developments and current status of research programs and projects pursued by the Department of Energy's Office of Nuclear Energy; and receiving advice and comments in return from the committee.

Tentative Agenda: The meeting is expected to include the introduction of seven new members to the Committee, presentations that cover such topics as the Office of Nuclear Energy's 2012 Budget and the status of Nuclear Energy's Small Modular Reactor Program. In addition, there will be presentation by five Nuclear Energy Advisory Committee subcommittees and a presentation on the Nexus of Nuclear Power with Renewable Technology. Finally, Nuclear Regulatory Commissioner, William Magwood will be giving a presentation on the early beginnings of the Nuclear Energy Advisory Committee. The agenda may change to accommodate committee business. For updates, one is directed to the NEAC Web site: *http://www.ne.doe.gov/neac/neNeacMeetings.html.*

Public Participation: Individuals and representatives of organizations who would like to offer comments and suggestions may do so on the day of the meeting, Tuesday December 13, 2011. Approximately thirty minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak, but is not expected to exceed 5 minutes. Anyone who is not able to make the meeting or has had insufficient time to address the committee is invited to send a written statement to Kenneth Chuck Wade, U.S. Department of Energy 1000 Independence Avenue SW., Washington DC 20585, or email: *Kenneth.wade@nuclear.energy.gov.*

Minutes: The minutes of the meeting will be available by contacting Mr. Wade at the address above or on the Department of Energy, Office of Nuclear Energy Web site at *http://www.ne.doe.gov/neac/neNeacMeetings.html.*

Issued in Washington, DC, on October 28, 2011.

Carol A. Matthews,

Committee Management Officer.

[FR Doc. 2011–28439 Filed 11–1–11; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14297–000]

Placer County Water Agency; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, Protests, Recommendations, and Terms and Conditions

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Conduit Exemption.

b. *Project No.:* 14297–000.

c. *Date filed:* September 29, 2011.

d. *Applicant:* Placer County Water Agency.

e. *Name of Project:* Gold Run Pipeline Small Hydroelectric Project.

f. *Location:* The proposed Gold Run Pipeline Small Hydroelectric Project would be located along the Placer County Water Agency's (PCWA) Boardman Canal, near the Towns of Gold Run and Auburn, Placer County, California. The land on which all the project structures are located is owned by the applicant.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Brian C. Martin, Director of Technical Services, Placer County Water Agency, P.O. Box 6570, Auburn, CA 95604, phone (530) 823–4886.

i. *FERC Contact:* Linda Jemison, (202) 502–6363, *linda.jemison@ferc.gov*

j. *Status of Environmental Analysis:* This application is ready for environmental analysis at this time, and the Commission is requesting comments, reply comments, recommendations, terms and conditions, and prescriptions.

k. Deadline for filing responsive documents: Due to the small size of the proposed project, as well as the resource agency consultation letters filed with the application, the 60-day timeframe specified in 18 CFR 4.34(b) for filing all comments, motions to intervene, protests, recommendations, terms and conditions, and prescriptions is shortened to 30 days from the issuance date of this notice. All reply comments filed inresponse to comments submitted by any resource agency, Indian tribe, or person, must be filed with the Commission within 45 days from the issuance date of this notice.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; see 18

CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site under the *http://www.ferc.gov/docs-filing/efiling.asp.* The Commission strongly encourages electronic filings.

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 in 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.

l. *Description of Project:* The proposed Gold Run Pipeline Small Hydroelectric Project would consist of a proposed powerhouse containing one proposed generating unit with an installed capacity of 300 kilowatts. The applicant estimates the project would have an average annual generation of 1,062 MWh per year.

m. This filing is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street, NE., Washington, DC 20426. The filing may also be viewed on the web at *http://www.ferc.gov/docs-filing/elibrary.asp* using the ''eLibrary'' link. Enter the docket number, here P–14297, in the docket number field to access the document. For assistance, call toll-free 1–(866)–208–3676 or email *FERCOnlineSupport@ferc.gov*. For TTY, call (202) 502–8659. A copy is also available for review and reproduction at the address in item h above.

n. Development Application—Any qualified applicant desiring to file a competing application must submit to the Commission, on or before the specified deadline date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified deadline date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

o. *Notice of Intent*—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, and must include an unequivocal statement of intent to submit a competing development application. A notice of intent must be served on the applicant(s) named in this public notice.

p. Protests or Motions to Intervene—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests 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 protests or motions to intervene must be received on or before the specified deadline date for the particular application.

q. All filings must (1) bear in all capital letters the title ''PROTEST'', ''MOTION TO INTERVENE'', ''NOTICE OF INTENT TO FILE COMPETING APPLICATION'', ''COMPETING APPLICATION'', ''COMMENTS'', ''REPLY COMMENTS,'' ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (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, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Any of these documents must be filed by providing the original and seven copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Office of Energy Projects, Federal Energy Regulatory Commission, at the above address. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. 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.

r. *Waiver of Pre-filing Consultation:* On July 27, 2011, the applicant informed agencies and affected Indian Tribes of its request to waive the Commission's consultation requirements under 18 CFR 4.38(c). The following agencies and Indian Tribes support the waiver request: (1) Shingle Springs Rancheria and (2) United Auburn Indian Community. On July 13, 2011, Placer County Water Agency held a joint meeting with the pertinent agencies to which the public was invited to attend. No other comments were received. Therefore, we intend to accept the consultation that has occurred on this project during the pre-filing period and we intend to waive pre-filing consultation under section 4.38(c), which requires, among other things, conducting studies requested by resource agencies, and distributing and consulting on a draft exemption application.

Dated: October 27, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28397 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–3519–001.

Applicants: NedPower Mount Storm, L.L.C.

Description: NedPower Mount Storm, L.L.C. submits tariff filing per 35: Compliance Filing—MBR Tariff Order of Affiliate Restrictions to be effective 10/26/2011.

Filed Date: 10/26/2011.

Accession Number: 20111026–5019.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER11–4128–000.

Applicants: Michigan Electric Transmission Company, LLC.

Description: Michigan Electric Transmission Company, LLC submits tariff filing per 35.19a(b): Filing of a Refund Report to be effective N/A.

Filed Date: 10/26/2011.

Accession Number: 20111026–5043.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER11–4479–001.

Applicants: Endure Energy, L.L.C.

Description: Endure Energy, L.L.C. submits tariff filing per 35: Compliance filing to baseline refile to be effective 10/26/2011.

Filed Date: 10/26/2011.

Accession Number: 20111026–5002.

Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER12–191–000.

Applicants: ISO New England Inc.

Description: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii): 2012 Administrative Cost Filing to be effective 1/1/2012.

Filed Date: 10/26/2011.
Accession Number: 20111026–5013.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER12–192–000.
Applicants: Liberty Electric Power, LLC.
Description: Liberty Electric Power, LLC submits tariff filing per 35: Revisions to Market-Based Rate Tariff to be effective 12/25/2011.
Filed Date: 10/26/2011.
Accession Number: 20111026–5018.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER12–193–000.
Applicants: Fowler Ridge Wind Farm LLC.
Description: Fowler Ridge Wind Farm LLC submits tariff filing per 35: Compliance Filing—MBR Tariff Order of Affiliate Restrictions to be effective 10/26/2011.
Filed Date: 10/26/2011.
Accession Number: 20111026–5020.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER12–194–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Original Service Agreement No. 3083—Queue No. W3–136 to be effective 9/26/2011.
Filed Date: 10/26/2011.
Accession Number: 20111026–5065.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

Docket Numbers: ER12–195–000.
Applicants: PJM Interconnection, L.L.C.
Description: Request for Waiver of PJM Interconnection, L.L.C..
Filed Date: 10/26/2011.
Accession Number: 20111026–5068.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 2, 2011.

Docket Numbers: ER12–196–000.
Applicants: PJM Interconnection, L.L.C.
Description: PJM Interconnection, L.L.C. submits tariff filing per 35.13(a)(2)(iii): Original Service Agreement No. 3084—Queue No. W3–138 to be effective 9/26/2011.
Filed Date: 10/26/2011.
Accession Number: 20111026–5082.
Comment Date: 5 p.m. Eastern Time on Wednesday, November 16, 2011.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: October 26, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28341 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP11–2559–000.
Applicants: Gulf South Pipeline Company, LP.
Description: Gulf South Pipeline Company, LP submits tariff filing per 154.204: Chesapeake 35040–3 Amendment to Negotiated Rate Agreement to be effective 9/8/2011.
Filed Date: 09/08/2011.
Accession Number: 20110908–5145.
Comment Date: 5 p.m. Eastern Time on Tuesday, September 20, 2011.

Docket Numbers: RP11–2560–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: Gulf Crossing Pipeline Company LLC submits tariff filing per 154.204: Housekeeping for Agreements Volume to be effective 9/12/2011.
Filed Date: 09/12/2011.
Accession Number: 20110912–5064.
Comment Date: 5 p.m. Eastern Time on Monday, September 26, 2011.

Docket Numbers: RP11–2561–000.
Applicants: East Cheyenne Gas Storage, LLC.
Description: East Cheyenne Gas Storage, LLC submits tariff filing per 154.203: East Cheyenne Compliance filing to be effective 12/31/9998.
Filed Date: 09/13/2011.
Accession Number: 20110913–5000.
Comment Date: 5 p.m. Eastern Time on Monday, September 26, 2011.

Docket Numbers: RP11–2562–000.
Applicants: Trunkline Gas Company, LLC.
Description: Trunkline Gas Company, LLC submits tariff filing per 154.601: Negotiated Rates Filing—1 to be effective 9/14/2011.
Filed Date: 09/13/2011.
Accession Number: 20110913–5088.
Comment Date: 5 p.m. Eastern Time on Monday, September 26, 2011.

Docket Numbers: RP11–2563–000.
Applicants: Northwest Pipeline GP.
Description: Northwest Pipeline GP submits tariff filing per 154.204: NWP 2011 Housekeeping Filing to be effective 10/14/2011.
Filed Date: 09/13/2011.
Accession Number: 20110913–5112.
Comment Date: 5 p.m. Eastern Time on Monday, September 26, 2011.

Docket Numbers: CP11–542–000.
Applicants: UGI Storage Company.
Description: Abbreviated Application of UGI Storage Company to Amend Certificate of Public Convenience and Necessity, for Blanket Certificate Authority and for Approval of Market-Based Rates under Section 7 of the Natural Gas Act.
Filed Date: 08/31/2011.
Accession Number: 20110831–5193.
Comment Date: 5 p.m. Eastern Time on Friday, September 23, 2011.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP11–2467–001.
Applicants: Kern River Gas Transmission Company.
Description: Kern River Gas Transmission Company submits tariff filing per 154.205(b): 2011 SoCal Non-conforming Agreement Amendment to be effective 9/1/2011.
Filed Date: 09/09/2011.
Accession Number: 20110909–5105.
Comment Date: 5 p.m. Eastern Time on Wednesday, September 21, 2011.

Docket Numbers: RP11–2471–001.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: Transcontinental Gas Pipe Line Company, LLC submits tariff filing per 154.205(b): Amendment to Previous Filing in Docket No. RP11–2471–000 to be effective 9/30/2011.
Filed Date: 09/08/2011.
Accession Number: 20110908–5124.
Comment Date: 5 p.m. Eastern Time on Tuesday, September 20, 2011.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, and service can be found at: *http://www.ferc.gov*/docs-filing/efiling/filing-req.pdf. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: September 14, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28363 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PR11–106–002]

DCP Guadalupe Pipeline, LLC; Notice of Compliance Filing

Take notice that on October 27, 2011, DCP Guadalupe Pipeline, LLC filed a revised Statement of Operating Conditions including a revised stand-alone rate sheet in compliance with the September 27, 2011, unpublished Delegated Letter Order approving a Stipulation and Agreement of Settlement and pursuant to section 284.123(e) of the Commission's regulations, as more fully described in the filing.

Any person desiring to participate in this rate filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 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 date as indicated below. Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not 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 7 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 p.m. Eastern Time on Monday, November 14, 2011.

Dated: October 27, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28393 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14136–000; Project No. 14139–000]

Lock+ Hydro Friends Fund XXXV; Riverbank Hydro No. 4, LLC; Notice Announcing Filing Priority for Preliminary Permit Applications

On October 27, 2011, the Commission held a drawing to determine priority among competing preliminary permit applications with identical filing times. In the event that the Commission concludes that neither of the applicants' plans is better adapted than the other to develop, conserve, and utilize in the public interest the water resources of the region at issue, the priority established by this drawing will serve as the tiebreaker. Based on the drawing, the order of priority is as follows:

1. Lock+ Hydro Friends Fund XXXV—Project No. 14136–000
2. Riverbank Hydro No. 4, LLC—Project No. 14139–000

Dated: October 27, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28365 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–164–000]

Bishop Hill Energy III LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bishop Hill Energy III LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 15, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 26, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28338 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–162–000]

Bishop Hill Energy II LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bishop Hill Energy II LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 15, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 26, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28339 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–186–000]

PNE Energy Supply, LLC;

Supplemental Notice that Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PNE Energy Supply, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure

(18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 15, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 26, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28342 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–161–000]

Bishop Hill Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Bishop Hill Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard

to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 15, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 26, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28340 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–178–000]

PPL Energy Supply, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of PPL Energy Supply, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 15, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 26, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28343 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–199–000]

Coram California Development, L.P.; Supplemental Notice that Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Coram California Development, L.P.'s application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 16, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 27, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28367 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER12–204–000]

Trupro Energy LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Trupro Energy LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 16, 2011.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also 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.

Dated: October 27, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28366 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12576–007]

CRD Hydroelectric, LLC; Notice of Application To Amend License and 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. *Type of Application:* Amendment to License.

b. *Project No:* 12576–007.

c. *Date Filed:* July 27, 2011.

d. *Applicant:* CRD Hydroelectric, LLC.

e. *Name of Project:* Red Rock Hydroelectric Project.

f. *Location:* The project is located at the U.S. Army Corps of Engineers Lake Red Rock Dam on the Des Moines River in Marion County, Iowa.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Douglas Spaulding PE, Nelson Energy LLC, 8441 Wayzata Blvd., Suite 101, Golden Valley MN, 55426, Phone: (952) 544–8133.

i. *FERC Contact:* Mr. Steven Sachs (202) 502–8666 or *Steven.Sachs@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests, is 30 days from the issuance date of this notice. 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–12576–007) on any comments, motions, or recommendations filed.

k. *Description of Request:* The applicant proposes to amend the unconstructed project's license to modify the design of the intake and reduce the number of penetrations through the existing U.S. Army Corps of Engineers' Lake Red Rock Dam. The applicant's proposal also includes the installation of two turbine/generator units rather than the previously approved three units. The applicant does not propose any change to the authorized installed capacity or maximum hydraulic capacity.

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 (P–12576–007) 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 comments, motions to intervene, or protests should relate to project works which are the subject of the license surrender. 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: October 27, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28396 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2698–052]

Duke Energy Carolinas, LLC; Notice of Application for Amendment of License and 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. *Application Type:* Amendment of license.

b. *Project No:* 2698–052.

c. *Date Filed:* August 22, 2011.

d. *Applicant:* Duke Energy Carolinas, LLC.

e. *Name of Project:* East Fork Project.

f. *Location:* The project is located on the East Fork Tuckasegee River and Wolf Creek in Jackson County, North Carolina .

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a—825r.

h. *Applicant Contact:* Jeffrey G. Lineberger, Duke Energy Carolinas, LLC, 526 South Church Street, P.O. Box 1006, Charlotte, NC 28202, (704) 382–5942.

i. *FERC Contact:* Rebecca Martin, (202) 502–6012, *Rebecca.martin@ferc.gov*.

j. *Deadline for filing comments, motions to intervene, and protests:* November 28, 2011.

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–2698–052) on any comments or motions filed.

k. *Description of Application:* Duke Energy Carolina, LLC is requesting Commission approval to install and operate a new small turbine for providing minimum flows to the Tuckasegee River from the Cedar Cliff Development, as required by article 404 of the project's license. The licensee also requests to adjust the project's authorized installed capacity (AIC) to agree with the definition in 18 CFR 11.1(i). The AIC would change from 26,175 KW specified in the license, to 24,280 KW, which includes a 395KW increase from the minimum flow unit and adjustments to AIC for all three developments at the project to account for differences in net head resulting from operations under the new license for the project.

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–2698) 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 comments, motions to intervene, or protests should relate to project works which are the subject of the amendment 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: October 27, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28395 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PL10–4–000]

Technical Conference on Penalty Guidelines; Second Notice of Technical Conference on Penalty Guidelines

On September 21, 2011, the staff of the Federal Energy Regulatory Commission (Commission) issued a Notice of Technical Conference on Penalty Guidelines to be held on November 17, 2011. The conference will be held from 1 p.m. to 4:30 p.m. Eastern Standard Time in the Commission Meeting Room at the Commission's headquarters located at 888 First Street NE., Washington, DC 20426.

The purpose of the conference is to discuss the impact of the Penalty Guidelines, which the Commission issued on September 17, 2010,[1] on compliance and enforcement matters. The schedule and topics for the conference are as follows:[2]

1 p.m.–1:30 p.m.—Opening Remarks by Commission Members

1:30 p.m.–2:45 p.m.—First Panel—*Compliance Efforts Since Issuance of Penalty Guidelines*

2:45 p.m.–3 p.m.—Break

3 p.m.–4:15 p.m.—Second Panel—*Various Issues Affecting Penalty Calculations*

4:15 p.m.–4:30 p.m.—Closing Remarks by Commission Members

The first panel will focus on organizations' compliance efforts since issuance of the Penalty Guidelines. Section 1B2.1 of the Penalty Guidelines provides guidance to industry on compliance, describing seven elements organizations should follow to establish effective compliance programs. This panel will explore whether and how this guidance has helped organizations prioritize their compliance efforts. It will also discuss steps organizations have taken to modify their compliance programs in light of the Penalty Guidelines. Finally, this panel will provide an opportunity for industry to raise comments and questions for staff and the Commission on specific aspects of the compliance-related sections in the Penalty Guidelines.

The second panel will focus on certain issues affecting penalty calculations under the Penalty Guidelines. In particular, it will address three issues that have received significant attention since the Penalty Guidelines were issued. First, this panel will examine the function and usefulness of Penalty Guidelines section 2B1.1(b)(2), which accounts for the scope of violations by considering the volume of energy involved in a violation as well as the violation's duration. As part of this examination, the panel will consider whether volume and duration are already sufficiently accounted for in the ''loss'' calculation contained in section 2B1.1(b)(1). Second, this panel will discuss whether the Penalty Guidelines should account for situations in which the entity that committed a violation passed any of the gain it received from the violation to its ratepayers. Third, this panel will address the treatment of multiple violations under section 1A1.1, which states: ''Where an organization has engaged in multiple acts of fraud, anti-competitive conduct, or other rule, tariff, and order violations * * * or made multiple misrepresentations or false statements * * * each act will be treated as a separate violation. But in calculating the harm for purposes of determining the penalty, it is the cumulative harm of the multiple violations that is taken into account.'' Specifically, this panel will explore whether penalties should be calculated based on each separate act or based on the conduct as a whole—or whether it should depend on the type of violation or the particular facts and circumstances of the investigation.

The Commission will accept comments related to the Penalty Guidelines and their application for thirty days after the conference.

A revised notice will be issued before the conference if there are changes to the conference format, schedule, or panelists. All interested persons are invited to attend the conference, and there is no registration and no fee to attend. The conference will not be transcribed but will be webcast. A free webcast of this event will be available through *http://www.ferc.gov.* Anyone with Internet access who desires to view this event can do so by navigating to *http://www.ferc.gov's* Calendar of Events and locating this event in the Calendar. The event will contain a link to its webcast. The Capitol Connection provides technical support for the webcasts and offers access to the meeting via phone bridge for a fee. If you have any questions, you may visit *http://www.CapitolConnection.org.*

FERC conferences and meetings are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an email to *accessibility@ferc.gov* or call toll free (866) 208–3372 (voice) or (202) 502–8659 (TTY), or send a fax to (202) 208–2106 with the required accommodations.

Questions about the technical conference may be directed to Jeremy Medovoy by email at *Jeremy.Medovoy@ferc.gov* or by telephone at (202) 502–6768, or to David Applebaum by email at *David.Applebaum@ferc.gov* or by telephone at (202) 502–8186.

Dated: October 27, 2011.

Kimberly D. Bose,

Secretary.

Agenda

1 p.m.–1:30 p.m.—Opening Remarks by Commission Members

1:30 p.m.–2:45 p.m.—First Panel—*Compliance Efforts Since Issuance of Penalty Guidelines*

Andrew K. Soto—Senior Managing Counsel, American Gas Association

Nancy Bagot—Vice President of Regulatory Policy, Electric Power Supply Association

Shari Gribbin—Assistant General Counsel and Manager, FERC Compliance, Exelon Corporation; Member, Edison Electric Institute

Susan N. Kelly—Vice President of Policy Analysis and General Counsel, American Public Power Association

Richard Meyer—Senior Regulatory Counsel, National Rural Electric Cooperative Association

Joan Dreskin—General Counsel, Interstate Natural Gas Association of America

2:45 p.m.– 3 p.m.—Break

3 p.m.– 4:15 p.m.—Second Panel—*Various Issues Affecting Penalty Calculations*

[1] *Enforcement of Statutes, Orders, Rules, and Regulations,* 132 FERC ¶ 61,216 (2010).

[2] A list of panelists is included in the attached agenda.

Joseph T. Kelliher—Executive Vice President, Federal Regulatory Affairs, NextEra Energy, Inc
William L. Massey—Partner, Covington & Burling LLP
Max Minzner—Associate Professor of Law, University of New Mexico School of Law
Frank R. Lindh—General Counsel, California Public Utilities Commission
4:15 p.m.–4:30 p.m.—Closing Remarks by Commission Members

[FR Doc. 2011–28398 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14222–000]

Natural Currents Energy Services, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On July 13, 2011, Natural Currents Energy Services, LLC filed an application, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the BW2 Tidal Energy Project, which would be located on the Maurice River in Cumberland County, New Jersey. The proposed project would not use a dam or impoundment. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of: (1) Installation of 2 NC Sea Dragon or Red Hawk tidal turbines at a rated capacity of 150 kilowatts, (2) an estimated 250 meters in length of additional transmission infrastructure, and (3) appurtenant facilities. The project is estimated to have an annual minimum generation of 700,800 kilowatt-hours with the installation of 2 units.

Applicant Contact: Mr. Roger Bason, Natural Currents Energy Services, LLC, 24 Roxanne Boulevard, Highland, New York 12561, (845) 691–4009.

FERC Contact: Woohee Choi (202) 502–6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *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 also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14222–000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: October 26, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28345 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14223–000]

Natural Currents Energy Services, LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On July 13, 2011, Natural Currents Energy Services, LLC filed an application, pursuant to section 4(f) of the Federal Power Act, proposing to study the feasibility of the Dorchester—Maurice Tidal Energy Project, which would be located on the Maurice River in Cumberland County, New Jersey. The proposed project would not use a dam or impoundment. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of: (1) Installation of 1 to 10 NC Sea Dragon or Red Hawk tidal turbines at a rated capacity of 100 kilowatts, (2) an estimated 700 meters in length of additional transmission infrastructure, and (3) appurtenant facilities. The project is estimated to have an annual minimum generation of 3,504,000 kilowatt-hours with the installation of 10 units.

Applicant Contact: Mr. Roger Bason, Natural Currents Energy Services, LLC, 24 Roxanne Boulevard, Highland, New York 12561, (845) 691–4009.

FERC Contact: Woohee Choi (202) 502–6336.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36. Comments, motions to intervene, notices of intent, and competing applications may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site *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 also be paper-filed. To paper-file, mail an original and seven copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14223–000) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: October 26, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28344 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for review at the Commission in the Public Reference Room or may 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 to access the document. For assistance, please contact FERC, Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Exempt:

Docket No.	File date	Presenter or requester
1. CP11–72–000	10–14–11	Hon. Mary L. Landrieu, *et al.*
2. CP10–477–000	10–18–11	Mayor Otis S Johnson, Ph.D.
3. Project No. 1256–029	10–18–11	Paul Makowski, et al.[1]
4. Project No. 2851–016	10–20–11	John Baummer.[2]
5. Project No. 13551–000	10–25–11	Lee Emery.[3]

[1] Record of teleconference.
[2] Telephone record.
[3] Telephone record.

Dated: October 27, 2011.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2011–28364 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Attendance at the Entergy Regional State Committee Work Group and Stakeholder Meeting

The Federal Energy Regulatory Commission hereby gives notice that members of its staff may attend the meeting noted below. Their attendance is part of the Commission's ongoing outreach efforts.

Entergy Regional State Committee Meeting

November 2, 2011 (1 p.m.–5 p.m.)
November 3, 2011 (8 a.m.–12 p.m.)

This meeting will be held at the New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130. The hotel phone number is (504) 581–1000.

The discussions may address matters at issue in the following proceedings:

Docket No. OA07–32	Entergy Services, Inc.
Docket No. EL00–66	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL01–88	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL07–52	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–51	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL08–60	*Ameren Services Co.* v. *Entergy Services, Inc.*
Docket No. EL09–43	*Arkansas Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–50	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL09–61	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–55	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL10–65	*Louisiana Public Service Commission* v. *Entergy Services, Inc.*
Docket No. EL11–34	Midwest Independent System Transmission Operator, Inc.
Docket No. ER05–1065	Entergy Services, Inc.
Docket No. ER07–682	Entergy Services, Inc.
Docket No. ER07–956	Entergy Services, Inc.
Docket No. ER08–1056	Entergy Services, Inc.

Docket No. ER09–833	Entergy Services, Inc.
Docket No. ER09–1224	Entergy Services, Inc.
Docket No. ER10–794	Entergy Services, Inc.
Docket No. ER10–1350	Entergy Services, Inc.
Docket No. ER10–1676	Entergy Services, Inc.
Docket No. ER10–2001	Entergy Arkansas, Inc.
Docket No. ER10–2161	Entergy Texas, Inc.
Docket No. ER10–2748	Entergy Services, Inc.
Docket No. ER10–3357	Entergy Arkansas, Inc.
Docket No. ER11–2131	Entergy Arkansas, Inc.
Docket No. ER11–2132	Entergy Gulf States, Louisiana, LLC
Docket No. ER11–2133	Entergy Gulf States, Louisiana, LLC
Docket No. ER11–2134	Entergy Mississippi, Inc.
Docket No. ER11–2135	Entergy New Orleans, Inc.
Docket No. ER11–2136	Entergy Texas, Inc.
Docket No. ER11–2161	Entergy Texas, Inc.
Docket No. ER11–3156	Entergy Arkansas, Inc.
Docket No. ER11–3157	Entergy Arkansas, Inc.
Docket No. ER11–3274	Entergy Arkansas, Inc.
Docket No. ER11–3728	Midwest Independent Transmission System Operator, Inc.
Docket No. ER11–3657	Entergy Arkansas, Inc.
Docket No. ER11–3658	Entergy Arkansas, Inc.

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

Dated: October 27, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–28394 Filed 11–1–11; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9485–8]

Proposed Settlement Agreement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''Act''), 42 U.S.C. 7413(g), notice is hereby given of a proposed settlement agreement to address a lawsuit filed by the Engine Manufacturers Association, in the United States Court of Appeals for the District of Columbia Circuit: *Engine Manufacturers Association* v. *EPA,* No. 10–1331 (DC Cir.). Petitioners filed a petition for review of an EPA rule that revised the National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines (the RICE NESHAP). Under the terms of the proposed settlement agreement, EPA anticipates that, by June 15, 2012, the Agency will sign a notice of proposed rulemaking that includes a proposal to revise the RICE NESHAP to allow owners and operators of spark-ignition 4-stroke rich burn engines that meet an emission standard requiring a 76 percent or greater reduction of the pollutant formaldehyde, to prove compliance with the standard based on approved testing that shows at least a thirty percent reduction in total hydrocarbons and that, by March 14, 2013, the Administrator of EPA will sign a final action on this proposal, which may include signature of a final rule by the Administrator. If EPA promulgates in final form an amendment to the RICE NESHAP that includes changes that are substantially the same substance as that set forth in the settlement agreement, then EMA shall promptly file a stipulation of dismissal of No. 10–1331.

DATES: Written comments on the proposed settlement agreement must be received by December 2, 2011.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2011–0869, online at *www.regulations.gov* (EPA's preferred method); by email to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Michael Horowitz, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone: (202) 564–5583; fax number (202) 564–5603; email address: *horowitz.michael@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Settlement Agreement

This proposed settlement agreement would potentially resolve a petition for judicial review filed by Engine Manufacturers Association (EMA) for review of a rule promulgating standards that revised the National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines (the RICE NESHAP), 75 FR 51570 (August 20, 2010). The RICE NESHAP requires certain subcategories of four-stroke rich burn spark-ignition RICE to meet an emission standard requiring a 76 percent or greater reduction of the pollutant formaldehyde.

EMA filed a petition for review regarding these provisions. Discussions with EMA indicate that compliance with the standard can be proven based on approved testing that shows at least a thirty percent reduction in total hydrocarbons.

Under the terms of the proposed settlement agreement, EPA states that it anticipates that, by June 15, 2012, it will sign a notice of proposed rulemaking that includes a proposal to revise these provisions to allow owners and operators of spark-ignition four-stroke rich burn engines that meet an emission standard requiring a 76 percent or greater reduction of the pollutant formaldehyde, to prove compliance with the standard based on approved testing that shows at least a thirty percent reduction in total hydrocarbons

and that by March 14, 2013, the Administrator of EPA will sign a final action on this proposal, which may include signature of a final rule by the Administrator. Under the proposed settlement agreement, if EPA fails to sign the proposal by June 15, 2012, or to take final action on the proposal by March 14, 2013, EMA may move the Court to lift the order staying proceedings and establish a briefing schedule. Petitioners shall have no further remedy under the agreement.

Under the proposed settlement agreement, if the relevant provisions of the final rule are in substantial conformance with the revisions in the proposed agreement, then EMA agrees to dismiss the petition for review.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed settlement agreement from persons who were not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed settlement agreement if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines, based on any comment submitted, that consent to this settlement agreement should be withdrawn, the terms of the agreement will be affirmed.

II. Additional Information About Commenting on the Proposed Settlement Agreement

A. How can I get a copy of the settlement agreement?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2011–0869) contains a copy of the proposed settlement agreement. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use the *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search''.

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an ''anonymous access'' system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: October 20, 2011.

Kevin McLean,

Acting Associate General Counsel.

[FR Doc. 2011–28389 Filed 11–1–11; 8:45 am]

BILLING CODE 6560–50–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 (a) 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; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; (d) 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 (e) 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 December 2, 2011. 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, 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: 3060–0685.

Title: Updating Maximum Permitted Rates for Regulated Services and Equipment, FCC Form 1210; Annual Updating of Maximum Permitted Rates for Regulated Cable Services, FCC Form 1240.

Form Number: FCC Forms 1210 and 1240.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; State, Local or Tribal Government.

Number of Respondents and Responses: 3,400 respondents; 5,350 responses.

Estimated Time per Response: 1 hour to 15 hours.

Frequency of Response: Annual reporting requirement; Quarterly reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 4(i) and 623 of the Communications Act of 1934, as amended.

Total Annual Burden: 44,800 hours.

Total Annual Cost: $2,034,375.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Cable operators use FCC Form 1210 to file for adjustments in maximum permitted rates for regulated services to reflect external costs. Regulated cable operators submit this form to local franchising authorities or the Commission, in situations where the FCC has assumed jurisdiction. FCC Form is filed by cable operators quarterly.

FCC Form 1240 is filed by cable operators seeking to adjust maximum permitted rates for regulated cable services to reflect changes in external costs. Cable operators submit FCC Form 1240 to their respective local franchising authorities (''LFAs'') to justify rates for the basic service tier and related equipment or with the Commission, in situations where the Commission has assumed jurisdiction. FCC Form 1240 is a filing alternative to FCC Form 1210. FCC Form 1240 is filed by cable operators annually.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of Managing Director.

[FR Doc. 2011–28392 Filed 11–1–11; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel-Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR part 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573, by telephone at (202) 523–5843 or by email at *OTI@fmc.gov.*

Astral Freight Services, Inc. (NVO & OFF) 1418 NW 82nd Avenue, #1625, Doral, FL 33126, Officers: Eliane Lessa, Secretary/Director (Qualifying Individual) Ney Lessa, President/Treasurer/Director, Application Type: Add OFF Service

Encore International Corp. (NVO & OFF), 12280 SW 130th Street, #4, Miami, FL 33186, Officers: Fatima G. Lopes, President (Qualifying Individual), Caetano R. Lopes, Vice President, Application Type: Add NVO Service

Eztrans Logistics Ltd. (NVO), 5889 Coopers Avenue Unit 101, Mississauga, ON L4Z 1R9 Canada, Officer: Xin Wang, President (Qualifying Individual), Application Type: New NVO License

Fletmar International Corp. (NVO & OFF), 8121 NW. 60 Street, Miami, FL 33166, Officer: Maria M. Conde, President/Director/Secretary/Treasurer (Qualifying Individual), Application Type: Add NVO Service

G Max Distributors Inc. (NVO), 6979 NW 84 Avenue Miami, FL 33166, Officers: Hugo D. Carmona, Secretary (Qualifying Individual), Victor Lopez, President, Application Type: New NVO & OFF License

Kimberly Ann Martin dba KNJs Shipping Solutions (OFF), 951 Denton Court, Suite 201, Crystal Lake, IL 60014, Officer: Kimberly A. Martin, Sole Proprietor (Qualifying Individual), Application Type: New OFF License

LF Freight USA LLC dba LF Logistics dba LF Freight dba IDS Logistics USA, dba IDS Freight Services, dba AGI Logistics USA, dba AGI Logistics, 230–59 International Airport Center Blvd., #270, Jamaica, NY 11413, Officers: James Minutello, Vice President (Qualifying Individual), Simon Oxley, President, Application Type: Name Change/Trade Name Change

Lion Transport, Inc. dba Amex Logistics (NVO & OFF), 10630 NW 27th Street, #102, Miami, FL 33122, Officers: Silvia E. Bustamante, President/Secretary (Qualifying Individual), Maria Bustamante, Vice President, Application Type: Trade Name Change

Oceanstar Express Company, Inc. (NVO & OFF), 929 E. Pacific Coast Hwy., Wilmington, CA 90744, Officers: Paul D. Conolly, Secretary (Qualifying Individual), Sigmund H. Ting, CEO, Application Type: New NVO & OFF License

Pegasus Maritime, Inc. (NVO & OFF), 250 W. 39th Street, #501 (501–505), New York, NY 10018, Officers: Mohtashum Mahmood, Vice President for Sales and Marketing (Qualifying Individual), Khurram Mahmood, President/Secretary, Application Type: QI Change

Sintra USA LLC (NVO & OFF), 21 Fadem Road, Unit #14, Springfield, NJ 07081, Officers: Alex Tralha, Secretary (Qualifying Individual), Morten Olesen, President, Application Type: New NVO & OFF License

STC Worldwide Inc. (NVO & OFF), 111 Town Square Plaza, Jersey City, NJ 07310, Officers: William F. Woods,Jr., Vice President (Qualifying Individual), Nick Ferlito, Executive Director, Application Type: New NVO & OFF License,

United Transport Services, Corp. (NVO), 6947 NW 82nd Avenue Miami, FL 33166, Officers: Oscar Nova, Secretary (Qualifying Individual), Augusto Villegas, President, Application Type: New NVO License

V R Logistics Incorporated (NVO & OFF), 30 Sheryl Drive, Edison, NJ 08820, Officers: Govind Bhagat, Vice President/Treasurer (Qualifying Individual), Vanita G. Bhagat, President, Application Type: New NVO & OFF License

Dated: October 28, 2011.

Karen V. Gregory,

Secretary.

[FR Doc. 2011–28419 Filed 11–1–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License; Revocation

The Federal Maritime Commission hereby gives notice that the following Ocean Transportation Intermediary license has been revoked pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515, effective on the corresponding date shown below:

License Number: 020542n.

Name: Overseas Transport USA Corp.

Address: 3107 Stirling Road, Suite 107, Fort Lauderdale, FL 33312.

Date Revoked: September 29, 2011.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2011–28423 Filed 11–1–11; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL RESERVE SYSTEM

Federal Open Market Committee; Domestic Policy Directive of September 20 and 21, 2011

In accordance with Section 271.7(d) of its rules regarding availability of information (12 CFR part 271), there is set forth below the domestic policy directive issued by the Federal Open Market Committee at its meeting held on September 20 and 21, 2011.[1]

''The Federal Open Market Committee seeks monetary and financial conditions that will foster price stability and promote sustainable growth in output. To further its long-run objectives, the Committee seeks conditions in reserve markets consistent with federal funds trading in a range from 0 to ¼ percent. The Committee directs the Desk to purchase, by the end of June 2012, Treasury securities with remaining maturities of approximately 6 years to 30 years with a total face value of $400 billion, and to sell Treasury securities with remaining maturities of 3 years or less with a total face value of $400 billion. The Committee also directs the Desk to maintain its existing policy of rolling over maturing Treasury securities into new issues and to reinvest principal payments on all agency debt and agency mortgage-backed securities in the System Open Market Account in agency mortgage-backed securities in order to maintain the total face value of domestic securities at approximately $2.6 trillion. The Committee directs the Desk to engage in dollar roll transactions as necessary to facilitate settlement of the Federal Reserve's agency MBS transactions. The System Open Market Account Manager and the Secretary will keep the Committee informed of ongoing developments regarding the System's balance sheet that could affect the attainment over time of the Committee's objectives of maximum employment and price stability.''

[1] Copies of the Minutes of the Federal Open Market Committee at its meeting held on September 20 and 21, 2011, which includes the domestic policy directive issued at the meeting, are available upon request to the Board of Governors of the Federal Reserve System, Washington, DC 20551. The minutes are published in the Federal Reserve Bulletin and in the Board's Annual Report.

By order of the Federal Open Market Committee, October 20, 2011.

William B. English,

Secretary, Federal Open Market Committee.

[FR Doc. 2011–28431 Filed 11–1–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of the Surgeon General of the United States Public Health Service.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), notice is hereby given that a Web meeting is scheduled to be held for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the ''Advisory Group''). The Web meeting will be open to the public. Information about the Advisory Group and the agenda for this meeting can be obtained by accessing the following Web site: *http://www.healthcare.gov/prevention/nphpphc/advisorygrp/index.html*

DATES: The meeting will be held on November 21, 2011, 3 p.m. to 5 p.m.

ADDRESSES: The meeting will be held online via WebEx software. For detailed instructions about how to make sure that your windows computer and browser is set up for WebEx and to register for the meeting, please email the designated contact at *prevention.council@hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, 200 Independence Ave. SW., Hubert H. Humphrey Building, Room 701H, Washington, DC 20001; (202) 205–9517; *prevention.council@hhs.gov*.

SUPPLEMENTARY INFORMATION: On June 10, 2010, the President issued Executive Order 13544 to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. This legislation mandated that the Advisory Group was to be established within the Department of Health and Human Services. The charter for the Advisory Group was established by the Secretary of Health and Human Services on June 23, 2010; the charter was filed with the appropriate Congressional committees and Library of Congress on June 24,

2010. The Advisory Group has been established as a non-discretionary Federal advisory committee.

The Advisory Group has been established to provide recommendations and advice to the National Prevention, Health Promotion and Public Health (the ''Council''). The Advisory Group shall provide assistance to the Council in carrying out its mission.

The Advisory Group membership shall consist of not more than 25 non-Federal members to be appointed by the President. The membership shall include a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) Worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine. There are currently 17 members of the Advisory Group. This will be the fourth meeting of the Advisory Group.

Public attendance at the Web meeting is limited. Members of the public who wish to attend the Web meeting must register by 12 p.m. EST November 17, 2011. Individuals should notify the designated contact to register for public attendance at *prevention.council@hhs.gov.* Individuals who plan to attend the Web meeting and need special assistance and/or accommodations should notify the designated contact for the Advisory Group. The public will have opportunity to provide electronic written comments to the Advisory Group on November 21, 2011 during the Web meeting. Any member of the public who wishes to have printed material distributed to the Advisory Group for this scheduled Web meeting should submit material to the designated point of contact for the Advisory Group no later than 12 p.m. EST November 10, 2011.

Dated: October 24, 2011.

Corinne M. Graffunder,

Acting Designated Federal Officer, Office of the Surgeon General, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health.

[FR Doc. 2011–28422 Filed 11–1–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Nursing Home Survey on Patient Safety Culture Comparative Database.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by January 3, 2012.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Nursing Home Survey on Patient Safety Culture Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Nursing Home Survey on Patient Safety Culture (Nursing Home SOPS) Comparative Database. The Nursing Home SOPS Comparative Database consists of data from the AHRQ Nursing Home Survey on Patient Safety Culture. Nursing homes in the U.S. are asked to voluntarily submit data from the survey to AHRQ through its contractor, Westat. The Nursing Home SOPS Database is modeled after the Hospital SOPS Database [OMB No. 0935–0162, approved 05/04/2010] that was originally developed by AHRQ in 2006 in response to requests from hospitals interested in knowing how their patient safety culture survey results compare to those of other hospitals.

In 1999, the Institute of Medicine called for health care organizations to develop a ''culture of safety'' such that their workforce and processes focus on improving the reliability and safety of care for patients (IOM, 1999; To Err is Human: Building a Safer Health System). To respond to the need for tools to assess patient safety culture in nursing homes, AHRQ developed and pilot tested the Nursing Home Survey on Patient Safety Culture with OMB approval (OMB No. 0935–0132; Approved July 5, 2007).

The survey is designed to enable nursing homes to assess provider and staff opinions about patient safety issues, medical error, and error reporting and includes 42 items that measure 12 dimensions of patient safety culture. AHRQ released the survey into the public domain along with a Survey User's Guide and other toolkit materials in November 2008 on the AHRQ Web site (located at *http://www.ahrq.gov/qual/patientsafetyculture/nhsurvindex.htm*). Since its release, the survey has been voluntarily used by hundreds of nursing homes in the U.S.

The Nursing Home SOPS and the Comparative Database are supported by AHRQ to meet its goals of promoting improvements in the quality and safety of health care in nursing home settings. The survey, toolkit materials, and preliminary comparative database results are all made available in the public domain along with technical assistance provided by AHRQ through its contractor at no charge to nursing homes, to facilitate the use of these materials for nursing home patient safety and quality improvement.

The goal of this project is to create the Nursing Home SOPS Comparative Database. This database will (1) allow nursing homes to compare their patient safety culture survey results with those of other nursing homes; (2) provide data to nursing homes to facilitate internal assessment and learning in the patient safety improvement process; and (3) provide supplemental information to help nursing homes identify their strengths and areas with potential for improvement in patient safety culture. De-identified data files will also be available to researchers conducting patient safety analysis. The database will include 42 items that measure 12 areas, or composites of patient safety culture.

This study is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the

delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement, and database development. 42 U.S.C. 299a(a)(1) and (2), and (a)(8).

Method of Collection

To achieve the goal of this project the following activities and data collections will be implemented:

(1) Nursing Home Eligibility and Registration Form—The purpose of this form is to determine the eligibility status and initiate the registration process for nursing homes seeking to voluntarily submit their NH SOPS data to the NH SOPS Comparative Database. The nursing home (or parent organization) point of contact (POC) will complete the form. The POC is either a corporate level health care manager for a Quality Improvement Organization (QIO), a survey vendor who contracts with a nursing home to collect their data, or a nursing home Director of Nursing or nurse manager. Many nursing homes are part of a QIO or larger nursing home or health system that includes many nursing home sites.

(2) Data Use Agreement—The purpose of this form is to obtain authorization from nursing homes to use their voluntarily submitted NH SOPS data for analysis and reporting according to the terms specified in the Data Use Agreement (DUA). The nursing home POC will complete the form.

(3) Nursing Home Site Information Form — The purpose of this form is to obtain basic information about the characteristics of the nursing homes submitting their NH SOPS data to the NH SOPS Comparative Database (e.g., bed size, urbanicity, ownership, and geographic region). The nursing home POC will complete the form.

(4) Data Submission—After the nursing home POC has completed the Nursing Home Eligibility and Registration Form, the Data Use Agreement and the Nursing Home Site Information Form, they will submit their data from the NH SOPS to the NH SOPS Comparative Database.

Data from the AHRQ Nursing Home Survey on Patient Safety Culture are used to produce three types of products: (1) A Nursing Home SOPS Comparative Database Report that is produced periodically and made available in the public domain on the AHRQ Web site (see *http://www.ahrq.gov/qual/nhsurveyll/nhsurv111.pdf* for the 2011 report); (2) Nursing Home Survey Feedback Reports that are confidential, customized reports produced for each nursing home that submits data to the database; and (3) Research data sets of staff-level and nursing home-level de-identified data that enable researchers to conduct additional analyses.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the nursing home to participate in the Nursing Home SOPS Comparative Database. The POC completes a number of data submission steps and forms, beginning with completion of the online Nursing Home SOPS Database Eligibility and Registration form and Data Use Agreement, which will be completed for 85 nursing homes or groups of affiliated nursing homes annually. The Nursing Home Site Information Form will be completed for each individual nursing home; since each POC represents an average of 5 nursing homes a total of 425 Information Forms will be completed annually and requires about 5 minutes to complete. The POC will submit data for all of the nursing homes they represent which will take about 5 and ½ hours, including the amount of time POCs typically spend deciding whether to participate in the database and preparing their materials and data set for submission to the database, and performing the submission. The total annual burden hours are estimated to be 511.

Nursing homes administer the AHRQ Nursing Home Survey on Patient Safety Culture on a periodic basis. Hospitals submitting to the Hospital SOPS Comparative Database administer the survey every 16 months on average. Similarly, the number of nursing home submissions to the database is likely to vary each year because nursing homes do not administer the survey and submit data every year. The 85 respondents/POCs shown in Exhibit 1 are based on an estimate of nursing homes submitting data in the coming years, with the following assumptions:

- 30 POCs for QIOs submitting on behalf of 10 nursing homes each
- 5 POCs for vendors outside of QIOs submitting on behalf of 10 nursing homes each
- 50 independent nursing homes submitting on their own behalf

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/POCs	Number of responses per POC	Hours per response	Total burden hours
Eligibility/Registration Forms	85	1	3/60	4
Data Use Agreement	85	1	3/60	4
Nursing Home Site Information Form	85	5	5/60	35
Data Submission	85	1	5.5	468
Total	340	NA	NA	511

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to submit their data. The cost burden is estimated to be $21,152 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COSY BURDEN

Form name	Number of respondents/POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Eligibility/Registration Forms	85	4	$41.39	$166
Data Use Agreement	85	4	41.39	166
Nursing Home Site Information Form	85	35	41.39	1,449

EXHIBIT 2—ESTIMATED ANNUALIZED COSY BURDEN—Continued

Form name	Number of respondents/ POCs	Total burden hours	Average hourly wage rate*	Total cost burden
Data Submission	85	468	41.39	19,371
Total	340	511	NA	21,152

*The wage rate in Exhibit 2 is based on May 2009 National Industry-Specific Occupational Employment and Wage Estimates Bureau o Labor Statistics, U.S. Dept of Labor. Mean hourly wages for nursing home POCs are located at *http://www.bls.gov/oes/2009/may/naics4* 623100.htm and *http://www.bls.gov/oes/2009/may/naics2* 62.htm. The hourly wage of $41.39 is the weighted mean of $41.94 (General and Operations Managers; N = 25), $37.29 (Medical and Health Services Managers; N = 25), $42.89 (General and Operations Managers; N = 30) and $50.00 (Computer and Information Systems Managers; N = 5).

Estimated Annual Costs to the Federal Government

The estimated annualized cost to the government for developing, maintaining, and managing the database and analyzing the data and producing reports is shown below. The cost is estimated to be $310,000 annually. The total cost over the three years of this information collection request is $930,000.

EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$59,715	$19,905
Data Collection Activities	82,107	27,369
Data Processing and Analysis	111,963	37,321
Publication of Results	111,966	37,322
Project Management	7,464	2,488
Overhead	556,785	185,595
Total	930,000	310,000

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 25, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–28403 Filed 11–1–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''MEPS Cancer Self Administrated Questionnaire.'' In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by January 3, 2012.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *dorislefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

MEPS Cancer SAQ

The Medical Expenditure Panel Survey (MEPS) is a nationally representative survey of the civilian noninstitutionalized population of all ages in the United States that collects comprehensive data on health care and health care expenditures from all payors (including private payors, Medicaid, the VA, and out-of-pocket) over a two-year period. The MEPS has been conducted annually since 1996. The OMB Control Number for the MEPS is 0935–0118, with an expiration date of January 31st, 2013. All of the supporting documents for the MEPS can be downloaded from *http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=200910-0935-001.*

The purpose of this request is to integrate the new self-administered questionnaire (SAQ) entitled, ''Experiences with Cancer,'' into the MEPS. Once the SAQ is integrated it will be completed by MEPS participants identified as ever having cancer. The

Cancer SAQ will be included in the MEPS in 2012; it will be subsequently removed from the MEPS in 2013.

The work is being conducted by AHRQ through its contractor, Westat, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including the use of surveys to collect data on the cost, use and quality of such care. 42 U.S.C. 299b–2; 42 U.S.C. 299a(a)(1), (2), (3), and (8).

Method of Collection

MEPS respondents identified as having cancer will be given the paper questionnaire to complete themselves. If the cancer SAQ respondent is available at the time of the MEPS interview, we ask that he/she complete the SAQ and give it to the interviewer before she leaves the household after completing the MEPS interview. If the cancer SAQ is not collected before the interviewer leaves the household (including those cases where the SAQ respondent is not available at the time of the MEPS interview), he/she will either arrange a time to come back to pick it up (if it is mutually convenient for the respondent and interviewer) or we ask that the SAQ be returned in a postage-paid envelope left at the household.

There are several benefits to administering this SAQ nationally as a supplement to the MEPS. First, the accompanying over sample of persons with cancer will improve the cost estimates for patients with this disease and will allow AHRQ to conduct analysis on the long term costs of cancer for survivors. Since the survey is about the lasting effects of cancer and cancer treatments on the lives of those who have been diagnosed with cancer, the data will also allow research directed at long-term consequences of cancer and overall medical expenses. Finally, this activity will allow AHRQ to examine the feasibility of using MEPS as a vehicle for in depth analysis of other specific conditions. The questionnaire is being funded by the National Cancer Institute (NCI) and was developed through a collaboration among the Centers for Disease Control and Prevention, NCI, the National Institutes of Health, AHRQ, the American Cancer Society, and the Lance Armstrong Foundation.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for respondents' time to participate in this research. The Cancer SAQ will be completed by 3,500 persons and is estimated to require 30 minutes to complete. The total annualized burden is estimated to be 1,750 hours.

Exhibit 2 shows the estimated annualized cost burden associated with respondents' time to participate in this research. The total cost burden is estimated to be $37,363 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Activity	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
MEPS Cancer SAQ	3,500	1	30/60	1,750
Total	3,500	n/a	n/a	1,750

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Activity	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
MEPS Cancer SAQ	3,500	1,750	$21.35	$37,363
Total	3,500	1,750	n/a	37,363

*Based on the mean average hourly rate for all occupations (00–0000), National Compensation Survey: Occupational Wages in the United States May 2010, "U.S. Department of Labor, Bureau of Labor Statistics".

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total cost for the Cancer SAQ. Since the SAQ will only be used once in 2012 the total and annual costs are identical. The total cost is approximately $1,050,000.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Sampling Activities	$20,000	$20,000
Interviewer Recruitment and Training	0	0
Data Collection Activities	300,000	300,000
Data Processing	600,000	600,000
Production of Public Use Data Files	80,000	80,000
Project Management	50,000	50,000
Total	1,050,000	1,050,000

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ' s estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 27, 2011.

Carolyn M. Clancy,

Director.

[FR Doc. 2011–28402 Filed 11–1–11; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket NIOSH–219]

Implementation of Section 2695 (42 U.S.C. 300ff–131) of Public Law 111–87: Infectious Diseases and Circumstances Relevant to Notification Requirements

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Final notice.

SUMMARY: The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87) addresses notification procedures for medical facilities and state public health officers and their designated officers regarding exposure of emergency response employees (EREs) to potentially life-threatening infectious diseases. The Secretary of Health and Human Services (Secretary) has delegated authority to the Director of the Centers for Disease Control and Prevention (CDC) to issue a list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which EREs may be exposed in responding to emergencies (including a specification of those infectious diseases that are routinely transmitted through airborne or aerosolized means); guidelines describing circumstances in which employees may be exposed to these diseases; and guidelines describing the manner in which medical facilities should make determinations about exposures. On December 13, 2010, CDC invited comment on a draft list of covered infectious diseases and both sets of guidelines (75 FR 77642). In consideration of the comments received, this notice sets forth CDC's final list of diseases, final guidelines describing circumstances under which exposure to listed diseases may occur, and final guidelines for determining whether an exposure to the listed diseases has occurred.

DATES: The list of diseases and guidelines in this notice will be effective December 2, 2011.

FOR FURTHER INFORMATION CONTACT: James Spahr, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, 1600 Clifton Road, NE., M/S E20, Atlanta, GA 30333, telephone (404) 498–6185.

SUPPLEMENTARY INFORMATION:

Preamble Table of Contents

Introduction
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Part II. Guidelines Describing the Circumstances in Which Emergency Response Employees May Be Exposed to Such Diseases
Part III. Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purposes of Section 2695B(d) [42 U.S.C. 300ff–133(d)]

Introduction

The Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87) amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii), including the addition of a Part G to Title XXVI, which addresses notification procedures and requirements for medical facilities and state public health officers and their designated officers regarding exposure of EREs to potentially life-threatening infectious diseases. (See Title XXVI, Part G of the PHS Act, codified as amended at 42 U.S.C. 300ff–131 to 300ff–140.)

For purposes of these notification requirements, sec. 2695 [42 U.S.C. 300ff–131] requires the Secretary to develop and disseminate:

1. A list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which EREs may be exposed in responding to emergencies (including a specification of those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means);

2. guidelines describing the circumstances in which such employees may be exposed to such diseases, taking into account the conditions under which emergency response is provided; and

3. guidelines describing the manner in which medical facilities should make determinations for purposes of sec. 2695B(d) [Evaluation and Response Regarding Request to Medical Facility, 42 U.S.C. 300ff–133(d)].

On July 7, 2010, the Secretary issued a PHS Act Delegation of Authority (Delegation of Authority), which assigned to the Director of CDC the authority vested in the Secretary of HHS (Secretary) under sec. 2695 of Title XXVI (42 U.S.C. 300ff–131) ''as it pertains to the functions assigned to the [CDC]'' (75 FR 40842, July 14, 2010). On December 13, 2010, CDC invited comment on a draft list of covered infectious diseases and two sets of guidelines developed pursuant to this Delegation of Authority and 42 U.S.C. 300ff–131 through a general notice and request for comments published in the **Federal Register** (75 FR 77642).

Response to Comments

In response to the December 2010 notice, CDC received a total of 83 comments from 22 individuals and/or organizations. The comments are addressed below.

Emergency Response Employees (EREs)

Comment: CDC received two comments regarding EREs. One commenter wanted to make it clear that police were included among the group of people considered EREs. The other commenter wanted there to be a specification that EREs included volunteer and paid emergency medical services.

CDC response: ''Emergency response employee'' is not defined in the PHS Act, and CDC's authority for purposes of this notice is limited to those duties set out in the Delegation of Authority (75 FR 40842). The duties of an individual considered an ERE are described in 42 U.S.C. 300ff–133(a):

[i]f an emergency response employee believes that the employee may have been exposed to an infectious disease by a victim of an emergency who was transported to a medical facility as a result of the emergency and if the employee attended, treated, assisted, or transported the victim pursuant to the emergency, then the designated officer of the employee shall, upon the request of the employee, carry out the duties described in subsection (b) regarding a determination of whether the employee may have been exposed to an infectious disease by the victim.

Non-compliance

Comment: CDC received one comment regarding non-compliance. The commenter noted that there was no mention of an administrative contact person or a process regarding non-compliance.

CDC response: The PHS Act addresses this issue in section 2695H [42 U.S.C. 300ff–139], which is outside the scope of this notice covering the Secretary's duties under sec. 2695 [42 U.S.C. 300ff–131]. The December 13, 2010, **Federal Register** notice was limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842).

Designated officers

Comment: CDC received one comment regarding designated officers. The commenter noted that the designated officer position needs to be better developed.

CDC response: The PHS Act does not provide a definition of ''designated officer,'' except that 42 U.S.C. 300ff–136 provides for selection of such officer by the public health officer of each state. The December 13, 2010, **Federal Register** notice was limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842). Development of the designated officer position is beyond the scope of the Delegation and this notice.

Definitions

The December 13, 2010, general notice and request for comments provided definitions only where such were necessary for clarification of CDC's approach to developing the disease list and guidelines as assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842). CDC received five comments regarding definitions. One commenter approved of the definitions.

Comment: Two commenters wanted to either use the word ''communicable'' instead of ''infectious'' or to add the word ''communicable'' in front of ''infectious.''

CDC response: To ensure consistency in interpretation of terms used in the PHS Act and in the guidelines, CDC is mirroring the Act's language in its guidelines to the extent feasible. Title XXVI, Part G of the PHS Act refers only to the word ''infectious'' and not to the word ''communicable.'' Furthermore, the ability of the infectious diseases included in the draft to be transmitted from person to person is addressed in their specification as ''transmitted by contact or body fluid exposures,'' ''transmitted through aerosolized airborne means,'' or ''transmitted through aerosolized droplet means.'' In addition, Part III, ''Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purpose of Section 2695B(d) [42 U.S.C. 300ff–133(d)],'' in several places requires consideration of ''infectious disease that was possibly contagious at the time of the potential exposure incident.'' Therefore the requested wording change was not made.

Comment: Two commenters requested that the word ''exposed'' be redefined as ''any contact direct or indirect with a person in which there is a risk of transmission of an infectious agent to an ERE.''

CDC response: CDC did not redefine ''exposed.'' The existing definition is clear and there was concern that the word ''contact'' could lead to misinterpretations.

List of Potentially Life-Threatening Infectious Diseases (Part I)

Under sec. 2695 of Title XXVI (42 U.S.C. 300ff–131), CDC, through the Delegation of Authority by the Secretary of HHS, must issue a list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which EREs may be exposed in responding to emergencies (including a specification of those infectious diseases that are routinely transmitted through airborne or aerosolized means). CDC received 45 comments regarding its proposed disease list.

CDC received a number of positive comments in support of the proposed disease list. For example, one commenter was pleased to see the addition of hepatitis C to the disease list. Another commenter supported finalization of the disease list. Two commenters stated that they agreed with the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted by Contact or Body Fluid Exposures* and the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Airborne Means.* Two commenters appreciated the language in the document permitting amendments to the list in the future as warranted by new scientific information or emerging diseases.

Comment: Two commenters felt that there should not be two separate lists, one listing diseases with aerosolized airborne transmission and the other listing diseases with aerosolized droplet transmission. They requested there be a single specification for the list of life-threatening infectious diseases that identifies disease routinely transmitted through airborne or aerosolized means. In contrast, others supported this approach. One commenter ''agrees with these definitions [regarding aerosolized airborne and aerosolized droplet transmission and the corresponding lists] and appreciates the thoroughness and clarity in which they are written,'' and stated that ''[t]his will permit our members to implement the revised requirements with accuracy and consistency.'' Two other commenters provided very similar supportive comments.

CDC response: CDC holds that having two separate lists most accurately represents the epidemiology of the diseases on the respective lists and mirrors usual infection control terminology, which will facilitate comprehension and optimal implementation of the Act. Therefore, the two separate lists (aerosolized airborne transmission and aerosolized droplet transmission) have been retained.

Commenters also asked CDC to consider amending the disease list by adding or removing conditions.

Comment: One commenter recommended that all multi-drug-resistant organisms (MDROs) be added to the disease list to establish documentation and surveillance for these organisms. Five other commenters specifically wanted methicillin-resistant *Staphylococcus aureus* (MRSA) and other resistant organisms [for example *E. coli* ST131 and vancomycin-resistant enterococci (VRE)] to be added to the disease list.

CDC response: Because documentation and surveillance activities are beyond the scope of 42 U.S.C. 300ff–131, the addition of MDROs for the purpose of documentation and surveillance to the disease list is not warranted. CDC's authority for purposes of this final notice is limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842).

Regarding the addition of MRSA and other resistant organisms (ST131 and VRE) for the purposes of notification, exposure alone without clinical infection would not necessitate any type

of screening or prophylactic treatment.[1] MRSA, in particular, has become common and contemporary treatment of clinical conditions such as wound infections or cellulitis associated with abscesses, carbuncles, or furuncles routinely covers for MRSA until culture results allow for the narrowing of antibiotic coverage.[2] Therefore, CDC has not added MRSA, ST131, VRE, or MDROs in general to the list of diseases.

Comment: Five commenters wanted anthrax to be added to the disease list.

CDC response: Anthrax remains an endemic public health threat through annual epizootics in certain areas of the United States. Cutaneous anthrax can be transmitted human to human via drainage from lesions and is potentially fatal if left untreated;[3] therefore, cutaneous anthrax has been added to the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted by Contact or Body Fluid Exposures.* Inhalation and gastrointestinal anthrax are not contagious from human to human and are not included in this list; they are, however, addressed in a newly added list of *Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare.*

Comment: One commenter requested that syphilis be added to the disease list.

CDC response: While the transmission of syphilis via accidental needlestick injury may be a theoretical concern, there is only one case report of its occurrence in the medical literature, and even in that case, it is not clear whether active infection was due to a needlestick injury. Syphilis due to needlestick injury does not pose a significant public health risk to health care workers, and syphilis has not been added to the list.

Comment: Eight commenters desired that seasonal influenza and/or novel influenza be added to the disease list.

CDC response: CDC recognizes that influenza infections are potentially life-threatening. Therefore, CDC has expanded the influenza viruses included on the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means* to broaden them beyond just avian influenza A viruses, but still avoid overburdening the reporting system. To achieve this, CDC has modified the list to specify novel influenza A viruses, as defined by the Council of State and Territorial Epidemiologists (CSTE).[4] This specification includes avian influenza and adds other influenza A strains of animal origin and other new or unique reassortments. Regarding over-burdening the reporting system, sec. 2695G(e) [42 U.S.C. 300ff–138(e)] states:

> In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to section 319(a), individuals or public or private entities are unable to comply with the requirements of this part, the Secretary may, not withstanding any other provision of law, temporarily suspend, in whole or in part, the requirements of this part as the circumstances reasonably require.

Comment: Eight commenters suggested that pertussis be added to the disease list.

CDC response: CDC recognizes that pertussis is a highly communicable disease and is potentially life-threatening. Pertussis has been associated with significant adult morbidity.[5] Additionally, an exposed and subsequently infected ERE might carry this highly contagious disease home to young children, and pertussis is associated with an increased number of fatalities in the very young.[6] Therefore, CDC has added pertussis to the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means.*

Comment: One commenter noted that bioterrorist agents were not specifically mentioned in the disease list.

CDC response: The Select Agents list maintained by HHS[7] lists biological agents that have the potential to pose a severe threat to human health and that may be used or adapted for bioterrorist attacks. Those agents on the list that are routinely transmitted human to human are already listed in Part I ''List of Potentially Life-Threatening Infectious Diseases to Which EREs Might be Exposed.'' CDC recognizes that the other agents on the Select Agents list would not typically exhibit human-to-human transmission or be considered contagious threats. However, in the setting of potential intentional modification to artificially increase transmissibility or lethality and deployment as bioweapons (potentially in quantities far greater than would naturally be encountered), atypical pathways of transmission may occur. In this case, EREs may be exposed by entering contaminated environments to care for victims and by exposure to contaminated individuals from those environments. Thus, CDC has added to the definition of exposed (''or, in the case of a select agent, from a surface or environment contaminated by the agent to an ERE.'') and created the disease list category *Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare.* This disease list category includes diseases caused by any transmissible agent included in the HHS Select Agents List including those that are not routinely transmitted human to human but may be transmitted via exposure to contaminated environments.[8]

Comment: One commenter requested rabies be removed from the disease list or that CDC add an explanation of its presence on the list.

CDC response: Rabies is an almost universally fatal viral disease that has no reliable treatment; therefore, if an exposure to the rabies virus has occurred, the best hope for prevention of the disease is timely post-exposure immunization (i.e., rabies vaccine with or without Human Rabies Immunoglobulin). Rabies virus is present in the saliva, nervous tissue, and spinal fluid of humans with the disease, and it is recommended protocol that a contact investigation be conducted and recommendations for any necessary post-exposure immunization be made any time there has been a diagnosis of rabies in a human patient.[9] Thus, a brief explanation has been added regarding rabies exposure, and CDC will retain rabies on the list of *Potentially Life-Threatening Infectious Diseases:*

[1] Liu C, *et al.* Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children. Infectious Disease Society of America Guidelines. January 4, 2011. *http://cid.oxfordjournals.org/content/early/2011/01/04/cid.ciq146.full.pdf+html.* Accessed July 14, 2011.

[2] Liu C, *et al.* Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* Infections in adults and children. Infectious Disease Society of America Guidelines. January 4, 2011. *http://cid.oxfordjournals.org/content/early/2011/01/04/cid.ciq146.full.pdf+html.* Accessed July 14, 2011.

[3] Gold H. Anthrax: a report of 117 cases. AMA Arch Int Med 1955;96:387–96.

[4] Council of State and Territorial Epidemiologists. Novel influenza A virus infections: 2010 Case Definition. CSTE Position Statement Number: 09–ID–43. *http://www.cdc.gov/osels/ph_surveillance/nndss/casedef/novel_influenzaA.htm.* Accessed July 18, 2011.

[5] De Serres G, *et al.* Morbidity of pertussis in adolescents and adults. J Infect Dis 2000;182:174–9.

[6] CDC. Pertussis—United States, 2001—2003. MMWR 2005;54:1283–6.

[7] 42 CFR 73.3, 73.4.

[8] **Note:** 42 CFR 73 specifies special reporting requirements for Select Agents independent of these guidelines.

[9] CDC. Human Rabies Prevention—United States, 2008: Recommendations of the Advisory Committee on Immunization Practices. MMWR 2008;57:1–26,28.

Routinely Transmitted by Contact or Body Fluid Exposures.

Comment: Two commenters recommended that certain diseases such as SARS–CoV, smallpox, avian influenza, and aerosolizable spores (*i.e.*, anthrax) be listed on a separate list rather than on the main list.

CDC response: CDC appreciates this comment. Accordingly, anthrax (except for the cutaneous manifestation) and smallpox (Variola virus) have been placed in the disease list category *Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare.* SARS–CoV and avian influenza (now included as a ''novel influenza'') will remain under *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means* because this accurately reflects their mode of transmission.

Guidelines Describing the Circumstances in Which Employees May Be Exposed (Part II).

In this final notice, ''exposed'' is defined as ''to be in circumstances in which there is recognized risk for transmission of an infectious agent from a human source to an ERE [10] or, in the case of a Select Agent, from a surface or environment contaminated by the agent to an ERE.'' See discussion of the inclusion of Select Agents, above. CDC received three comments regarding this section.

One commenter supported the way that Part I ''List of Potentially Life-threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed'' clearly outlined the various methods of disease transmission (contact or body fluid exposures, aerosolized airborne, and aerosolized droplet) that are utilized in determining risk of exposure. The other two commenters made substantive requests.

Comment: One commenter requested that aerosolized airborne and aerosolized droplet means of transmission be addressed separately in Part II ''Guidelines Describing the Circumstances in Which Such Employees May Be Exposed to Such Diseases'' as they were in Part I.

CDC response: CDC determined that there was benefit in the current approach to discussing aerosolized airborne and aerosolized droplet transmission in the same section in Part II, limiting redundancy by providing language common to the two modes of transmission only once.

Comment: The final commenter requested that CDC provide more information about exposures, but did not specify what additional information was desired.

CDC response: There was not enough specificity provided with this comment for CDC to formulate a response. Additionally, CDC believes that the current content of the exposures description is sufficient.

Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations (Part III)

Section 2695B(d) [42 U.S.C. 300ff–133(d)] specifies that medical facilities shall evaluate the facts submitted in an ERE's request to make a determination of whether, on the basis of the medical information possessed by the facility regarding the victim involved, the emergency response employee was exposed to an infectious disease included on the list issued pursuant to sec. 2695(a)(1) [42 U.S.C. 300ff–131(a)(1)] and sets certain parameters on these responses. CDC received six comments regarding medical facilities.

Two commenters were supportive of the medical facility guidelines. One supported making the proposed guidelines final. The other was in agreement with the proposed criteria for making determination of exposure when responding to appropriate requests by an employer; the individual felt such interaction would result in the best determination.

Comment: Three commenters did not feel comfortable with the medical facilities' authority to determine exposure. One commenter felt that the guidance should not allow a medical facility to overrule the designated officer's determination that an exposure had occurred. Two commenters noted that Part III ''Guidelines Describing the Manner in Which Medical Facilities Should Make Determination for Purposes of Section 2695B(d) [42 U.S.C. 300ff–133(d)]'' appears to require medical facilities to conduct a second exposure evaluation, and they felt that the role of a medical facility should be solely to determine if a patient had a disease transmissible by aerosols, and if so, to provide information to the designated officer who would notify all potentially exposed EREs. One commenter stated that medical facility management and exposure guidelines are not adequate and will not work well.

CDC response: CDC notes that the role and responsibilities of medical facilities are specified in some detail in the statute in sec. 2695B(d), (e), (f) [42 U.S.C. 300ff–133(d), (e), (f)]. In addition, sec. 2695B(g) [42 U.S.C. 300ff–133(g)] specifies the role of the public health officer in resolving differences of opinion between designated officers and medical facilities.

Notification

Under sec. 2695B(c)(2) [42 U.S.C. 300ff–133(c)(2)], a request for notification with respect to victims assisted shall be in writing and signed by the designated officer involved, and shall contain a statement of the facts collected pursuant to subsection (b)(1). Additionally, under sec. 2695B(e) [42 U.S.C. 300ff–133(e)], after receiving a request, a medical facility must make the applicable response as soon as is practicable, but not later than 48 hours after receiving the request. CDC received nine comments regarding notification.

Comment: Three commenters felt that the requirement for a written request was not practical. Of these commenters, two advocated for the use of modern technology allowing requests to be in a documented verbal or electronic form followed by a written communication. Three commenters felt that the 48-hour time frame for response by the medical facility is too long and that this time frame may unnecessarily restrict or delay notifications to EREs. One commenter felt there was a problem with medical facilities taking responsibility for notifying exposed EREs of lab results that were available a day or two after the victim arrived at the facility.

CDC response: Processes specified in the PHS Act cannot be altered through the guidelines published in this final notice. Moreover, the scope of this final notice is limited to those duties assigned to CDC through the Secretary's Delegation of Authority (75 FR 40842).

Comment: One commenter requested additional clarification or emphasis that the statute requires medical facilities to notify EREs of possible exposure to TB and that the facilities notify the designated officers of the ERE agencies regarding the newly added airborne and droplet transmitted diseases.

CDC response: CDC has placed TB on the list of *Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Airborne Means;* thus it will require routine notification. Additionally, sec. 2695(c) of Title XXVI [42 U.S.C. 300ff–131(c)] addresses dissemination by requiring that CDC, as delegated by the Secretary of HHS, shall transmit to State public health officers copies of the list and guidelines it developed with the request that the officers disseminate

[10] Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.* Accessed September 23, 2010.

such copies as appropriate throughout the State and make such copies available to the public.

Comment: One commenter felt that non-transporting emergency response employees should be included in notifications.

CDC response: As previously noted, ''emergency response employee'' is not defined in the PHS Act and CDC's authority for purposes of this notice is limited to those duties set out in the Delegation of Authority (75 FR 40842). The duties of an individual considered an ERE are described in 42 U.S.C. 300ff–133(a) as having ''attended, treated, assisted, or transported the victim pursuant to the emergency.''

HIPAA

CDC received three comments regarding the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which provides confidentiality for patients' protected health information, including health conditions, treatments, or payment records. In general, HIPAA rules would apply to EREs and medical facilities caring for the victims of emergencies.

Comment: One commenter recommended the addition of a statement directing ERE companies to provide appropriate requests to medical facilities while also adhering to HIPAA rules in the process.

CDC response: CDC, in consultation with the HHS Office for Civil Rights, notes that the HIPAA rules regarding privacy of individually identifiable health information apply to HIPAA covered entities and, to some extent, to their business associates. Those ERE companies that are HIPAA covered entities or business associates must adhere to the relevant HIPAA rules. While ERE companies that are neither HIPAA covered entities nor their business associates are not subject to HIPAA, we expect that the designated officers of all ERE companies will only request relevant information of medical facilities; i.e., whether there was sufficient information to determine whether the emergency response employee involved had been exposed and, if so, what determination did the facility make. What information can be requested and reported can be found in sec. 2695C(a)(1), (2) [42 U.S.C. 300ff–134(a)(1), (2)] and sec. 2695D(a)(1), (2) and (b)(1)–(3) [42 U.S.C. 300ff–135(a)(1), (2) and (b)(1)–(3)]. Section 2695G(c) [42 U.S.C. 300ff–138(c)] states that ''[t]his part may not be construed to authorize or require any medical facility, any designated officer of emergency response employees, or any such employee, to disclose identifying information with respect to a victim of an emergency or with respect to an emergency response employee.''

Comment: Two commenters recommended a clear statement that notification of source patient test results or other information is not a HIPAA violation.

CDC response: CDC, in consultation with the HHS Office for Civil Rights, notes that under the HIPAA Privacy Rule, if a law requires the disclosure of individually identifiable health information, a covered entity (such as a medical facility) may comply with such statute provided that the disclosure complies with and is limited to the relevant requirements of such law. Public Law 111–87 requires medical facilities that make determinations as to whether EREs have been exposed to an infectious disease to notify the designated officer who submitted the request. If the determination is that the employee has been exposed, the medical facility shall provide the name of the infectious disease involved and the date on which the victim of the emergency was transported by EREs to the facility. Other than this information, Public Law 111–87 does not authorize medical facilities to disclose identifying information with respect to either a victim of an emergency or an ERE. A medical facility would not violate HIPAA by complying with this requirement of the PHS Act.

Patient Testing

CDC received four comments regarding testing victims of emergencies for potentially life-threatening infectious diseases. Results of such tests are generally needed for medical facilities to make definitive determinations about potential ERE exposures.

Comment: Three commenters noted that there are state laws allowing for the testing of victims if an ERE can document an exposure; one of these three commenters recommended it be stated that State and local laws be used when they are more expansive than the Federal law.

CDC response: CDC has not added that specific statement to this final notice, because it is outside the scope of this notice, which is limited to those duties assigned to CDC through the Secretary's Delegation of Authority. However, Section 2695G(f) [42 U.S.C. 300ff–138(f)] states that ''[n]othing in this part shall be construed to limit the application of State or local laws that require the provision of data to public health authorities.''

Comment: One commenter requested that CDC strongly recommend patient testing.

CDC response: Patient testing is not authorized under sec. 2695G(b) [42 U.S.C. 300ff–138(b)], which specifically states that ''this part may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for an infectious disease.''

General

CDC received 7 general comments not focused on a specific part of the December 13, 2010, **Federal Register** notice.

Comment: Two commenters stated that the Act is important and urged CDC to move as quickly as possible to implement.

CDC response: CDC agrees and is working toward that end.

Comment: Two commenters recommended that more research is needed regarding how to protect EREs, and encouraged the National Institute for Occupational Safety and Health (NIOSH) to conduct more research.

CDC response: CDC agrees that this remains an important area of investigation.

Comment: One commenter recommended that Title XXVI, Part G of the PHS Act be a standalone Public Law.

CDC response: The requested action is outside the scope of this final notice and Delegation of Authority.

Comment: One commenter recommended that CDC/NIOSH facilitate a structured process to engage key stakeholders in development of any regulation and guidance materials related to the Ryan White HIV/AIDS Treatment Extension Act.

CDC response: CDC appreciates this comment and agrees that transparency and stakeholder involvement are extremely important. This is why CDC published its draft guidance in the **Federal Register** and requested public comments to assist in development of the final guidance. Even after this final notice is issued, CDC will encourage stakeholders to continue to provide comments and intends to establish a Web site to facilitate ongoing communication.

Comment: One commenter stated that he or she supports and would be willing to participate in pre-rabies vaccination for wildlife rehabilitators and others who volunteer or are employed working with animals.

CDC response: Although CDC appreciates this response, this topic is outside the scope of this notice and the Delegation of Authority.

Final Notice

For the reasons discussed in the preamble, CDC amends Implementation of Section 2695 (42 U.S.C. 300ff–131) Public Law 111–87: Infectious Diseases and Circumstances Relevant to Notification Requirements as follows:

Implementation of Section 2695 (42 U.S.C. 300ff–131) Public Law 111–87: Infectious Diseases and Circumstances Relevant to Notification Requirements

The Ryan White HIV/AIDS Treatment Extension Act of 2009 [11] (Pub. L. 111–87) amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii) and addresses notification procedures and requirements for medical facilities and state public health officers and their designated officers regarding exposure of emergency response employees (EREs) to potentially life-threatening infectious diseases.[12] (See Title XXVI, Part G of the PHS Act, codified as amended at 42 U.S.C. 300ff–131 to 300ff–140). This document sets forth the final list of diseases to which these provisions apply; final guidelines describing circumstances under which exposure to listed diseases may occur, and final guidelines for determining whether an exposure to the listed diseases has occurred, as required by the Act. The final list of diseases and guidelines incorporate comments received by CDC on a draft list and guidelines (75 FR 77642, December 13, 2010).

Contents

- Definitions
- Part I. List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed.
- Part II. Guidelines Describing the Circumstances in Which Emergency Response Employees May Be Exposed to Such Diseases.
- Part III. Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purposes of Section 2695B(d) [42 U.S.C. 300ff–133(d)].

Definitions

The following definitions are used in the list of diseases and guidelines:

Aerosol means tiny particles or droplets suspended in air. These range in diameter from about 0.001 to 100 μm.[13]

Aerosolized transmission means person-to-person transmission of an infectious agent through the air by an aerosol. See ''aerosolized airborne transmission'' and ''aerosolized droplet transmission.''

Aerosolized airborne transmission means person-to-person transmission of an infectious agent by an aerosol of small particles able to remain airborne for long periods of time. These are able to transmit diseases on air currents over long distances, to cause prolonged airspace contamination, and to be inhaled into the trachea and lung.[14]

Aerosolized droplet transmission means person-to-person transmission of an infectious agent by large particles only able to remain airborne for short periods of time. These generally transmit diseases through the air over short distances (approximately 6 feet), do not cause prolonged airspace contamination, and are too large to be inhaled into the trachea and lung.[15]

Contact or body fluid transmission means person-to-person transmission of an infectious agent through direct or indirect contact with an infected person's blood or other body fluids.[16]

Exposed means to be in circumstances in which there is recognized risk for transmission of an infectious agent from a human source to an ERE [17] or, in the case of a Select Agent, from a surface or environment contaminated by the agent to an ERE.

Potentially life-threatening infectious disease means an infectious disease to which EREs may be exposed and that has reasonable potential to cause death or fetal mortality in either healthy EREs or in EREs who are able to work but take medications or are living with conditions that might impair host defense mechanisms.

Part I. List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed

The *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed* is divided into four sections: Diseases routinely transmitted by contact or body fluid exposures, those routinely transmitted through aerosolized airborne means, those routinely transmitted through aerosolized droplet means, and those caused by agents potentially used for bioterrorism or biological warfare. Diseases often have multiple transmission pathways. However, for purposes of this classification, diseases routinely transmitted via the aerosol airborne or aerosol droplet routes are so classified, even if other routes, such as contact transmission, also occur. CDC will continue to monitor the scientific literature on these and other infectious diseases. In the event that CDC determines that a newly emerged infectious disease fits criteria for inclusion in the list of potentially life-threatening infectious diseases required by the Ryan White HIV/AIDS Treatment Extension Act of 2009, CDC will amend the list and add the disease.

A. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted by Contact or Body Fluid Exposures

- Anthrax, cutaneous (*Bacillus anthracis*)
- Hepatitis B (HBV)
- Hepatitis C (HCV)

[11] The Ryan White Act (Pub. L. 111–87) amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii), including the addition of a Part G to Title XXVI.

[12] See Title XXVI, Part G of the PHS Act, codified as amended at 42 U.S.C. 300ff–131 to 300ff–140.

[13] Baron P. Generation and Behavior of Airborne Particles (Aerosols). PowerPoint Presentation. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Applied Technology. *http://www.cdc.gov/niosh/topics/aerosols/pdfs/Aerosol_101.pdf.* Accessed September 22, 2011.

Baron PA, Willeke K, eds. Aerosol measurement: Principles, Techniques, and Applications. Second edition. New York: John Wiley & Sons, Inc. 2001.

[14] Baron P. Generation and Behavior of Airborne Particles (Aerosols). PowerPoint Presentation. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Applied Technology. *http://www.cdc.gov/niosh/topics/aerosols/pdfs/Aerosol_101.pdf.* Accessed September 22, 2011.

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.* Accessed September 22, 2011.

[15] Baron P. Generation and Behavior of Airborne Particles (Aerosols). PowerPoint Presentation. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Division of Applied Technology. *http://www.cdc.gov/niosh/topics/aerosols/pdfs/Aerosol_101.pdf.* Accessed September 22, 2011.

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.* Accessed September 22, 2011.

[16] Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.* Accessed September 22, 2011.

[17] Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. *http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf.* Accessed September 22, 2011.

- Human immunodeficiency virus (HIV)
- Rabies (Rabies virus)
- Vaccinia (Vaccinia virus)
- Viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, and other viruses yet to be identified) [18]

B. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Airborne Means

These diseases are included within ''those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.'' [19]

- Measles (Rubeola virus)
- Tuberculosis (*Mycobacterium tuberculosis*)—infectious pulmonary or laryngeal disease; or extrapulmonary (draining lesion)
- Varicella disease (*Varicella zoster* virus)—chickenpox, disseminated zoster

C. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means

These diseases are included within ''those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.'' [20]

- Diphtheria (*Corynebacterium diphtheriae*)
- Novel influenza A viruses as defined by the Council of State and Territorial Epidemiologists (CSTE) [21]
- Meningococcal disease (*Neisseria meningitidis*)
- Mumps (Mumps virus)
- Pertussis (*Bordetella pertussis*)
- Plague, pneumonic (*Yersinia pestis*)
- Rubella (German measles; Rubella virus)
- SARS-CoV

D. Potentially Life-Threatening Infectious Diseases Caused by Agents Potentially Used for Bioterrorism or Biological Warfare

These diseases include those caused by any transmissible agent included in the HHS Select Agents List.[22] Many are not routinely transmitted human to human but may be transmitted via exposure to contaminated environments. (See the special note in Part II.C for further explanation.) The HHS Select Agents List is updated regularly and can be found on the National Select Agent Registry Web site: *http://www.selectagent.gov/.*

Part II. Guidelines Describing the Circumstances in Which Emergency Response Employees May Be Exposed to Such Diseases

A. Exposure to Diseases Routinely Transmitted Through Contact or Body Fluid Exposures

Contact transmission is divided into two subgroups: Direct and indirect. Direct transmission occurs when microorganisms are transferred from an infected person to another person without a contaminated intermediate object or person. Indirect transmission involves the transfer of an infectious agent through a contaminated intermediate object or person.

Contact with blood and other body fluids may transmit the bloodborne pathogens HIV, HBV, and HCV. When EREs have contact circumstances in which differentiation between fluid types is difficult, if not impossible, all body fluids are considered potentially hazardous. In the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, an exposure incident is defined as a ''specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.'' [23]

Occupational exposure to cutaneous anthrax would include exposure of an ERE's nonintact skin or mucous membrane to drainage from a cutaneous anthrax lesion; percutaneous injuries with sharp instruments potentially contaminated with lesion drainage should also be considered exposures. Contact with blood or other bodily fluids is not thought to pose a significant risk for anthrax transmission. Occupational exposure to rabies would include exposure of an ERE's wound, nonintact skin, or mucous membrane to saliva, nerve tissue, or cerebral spinal fluid from an infected individual. Percutaneous injuries with contaminated sharp instruments should be considered exposures because of potential contact with infected nervous tissue. Intact skin contact with infectious materials or contact only with blood, urine, or feces is not thought to pose a significant risk for rabies transmission. Occupational exposures of concern to vaccinia would include contact of mucous membranes (eyes, nose, mouth, *etc.*) or non-intact skin with drainage from a vaccinia vaccination site or other mucopurulent lesion caused by vaccinia infection.

B. Exposure to Diseases Routinely Transmitted Through Airborne or Aerosolized Means

Occupational exposure to pathogens routinely transmitted through aerosolized airborne transmission may occur when an ERE shares air space with a contagious individual who has an infectious disease caused by these pathogens. Such an individual can expel small droplets into the air through activities such as coughing, sneezing and talking. After water evaporates from the airborne droplets, the dried out remnants can remain airborne as droplet nuclei. Occupational exposure to pathogens routinely transmitted through aerosolized droplet transmission may occur when an ERE comes within about 6 feet of a contagious individual who has an infectious disease caused by these pathogens and who creates large respiratory droplets through activities such as sneezing, coughing, and talking.

C. Special Note on Exposure to Diseases Transmitted by Agents Potentially Used for Bioterrorism or Biological Warfare

The Select Agents list [24] maintained by HHS, lists biological agents and

[18] For most viral hemorrhagic fevers (VHFs), routine transmission is limited to transmission from a zoonotic reservoir or direct contact with an infected person (*e.g.* Ebola virus, Marburg virus) or through arthropod-borne transmission (Rift Valley fever, Crimean-Congo hemorrhagic fever). For a small number of VHF viruses, transmission may occur through droplet transmission (*e.g.* Nipah virus), however prolonged close contact is likely necessary. Aerosol transmission does not occur in natural (non-laboratory) settings.

[19] Section 2695(b) [42 U.S.C. 300ff–131(b)].

[20] Section 2695(b) [42 U.S.C. 300ff–131(b)].

[21] Council of State and Territorial Epidemiologists, Position Statement Number: 09–ID–43. Available at *http://www.cdc.gov/osels/ph_surveillance/nndss/casedef/novel_influenzaA.htm* (Accessed July 18, 2011).

[22] 42 CFR 73.3, 73.4.

[23] 29 CFR 1910.1030.

[24] Notwithstanding any notification procedures specified here, all reporting requirements that are required under 42 CFR part 73 remain applicable. The HHS Select Agents list is updated regularly and can be found on the National Select Agent Registry Web site: *http://www.selectagent.gov/.* Agents on the HHS select agents list at the time of publication of this notice include the following:

42 CFR 73.3:

Botulinum neurotoxin producing species of Clostridium; Cercopithecine herpesvirus 1 (Herpes B virus); *Coccidioides posadasii/Coccidioides immitis; Coxiella burnetii;* Crimean-Congo haemorrhagic fever virus; Eastern Equine Encephalitis virus; Ebola viruses; *Francisella tularensis;* Lassa fever virus; Marburg virus; Monkeypox virus; Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus); *Rickettsia prowazekii; Rickettsia rickettsii;* South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito); Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever]); Variola major virus (Smallpox virus) and Variola minor virus (Alastrim); *Yersinia pestis.*

42 CFR 73.4:

Bacillus anthracis; Brucella abortus; Brucella melitensis; Brucella suis; Burkholderia mallei (formerly *Pseudomonas mallei*); *Burkholderia*

toxins that have the potential to pose a severe threat to human health and that may be used for or adapted for bioterrorist attacks. There are special reporting requirements for Select Agents, as detailed in 42 CFR part 73. Those agents included on the HHS Select Agents List that are routinely transmitted person to person and for which natural transmission remains a significant concern are categorized in the ''List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May be Exposed,'' Part I above, according to their modes of transmission. The remaining agents on the Select Agent List would not typically exhibit human-to-human transmission or be considered contemporary contagious threats. However, in the setting of potential intentional modification to artificially increase transmissibility and/or lethality (''weaponization'') and deployment as bio-weapons (potentially in quantities far greater than would naturally be encountered), atypical pathways of transmission may occur. In this case, EREs may be exposed by entering contaminated environments to care for victims and by exposure to contaminated individuals from those environments.

Part III. Guidelines Describing the Manner in Which Medical Facilities Should Make Determinations for Purposes of Section 2695B(d) [42 U.S.C. 300ff–133(d)]

Section 2695B(d) [42 U.S.C. 300ff–133(d)] specifies that medical facilities must respond to appropriate requests by making determinations about whether EREs have been exposed to infectious diseases included on the list issued pursuant to sec. 2695(a)(1) [42 U.S.C. 300ff–131(a)(1)]. A medical facility has access to two types of information related to a potential exposure incident to use in making a determination. First, the request submitted to the medical facility contains a ''statement of the facts collected'' about the ERE's potential exposure incident.[25] Information about infectious disease transmission provided in relevant CDC guidance documents [26] or in current medical literature should be considered in assessing whether there is a realistic possibility that the exposure incident described in the statement of the facts could potentially transmit an infectious disease included on the list issued pursuant to sec. 2695(a)(1) [42 U.S.C. 300ff–131(a)(1)].

Second, the medical facility possesses medical information about the victim of an emergency transported and/or treated by the ERE. This is the medical information that the medical facility would normally obtain according to its usual standards of care to diagnose or treat the victim, since the Act does not require special testing in response to a request for a determination. As stated in sec. 2695G(b) [42 U.S.C. 300ff–138(b)], ''this part may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for any infectious disease.''

Information about the potential exposure incident and medical information about the victim should be used in the following manner to make one of the four possible determinations as required by sec. 2695B(d) [42 U.S.C. 300ff–133(d)]:

(1) The ERE involved has been exposed to an infectious disease included on the list:

—Facts provided in the request document a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved ERE; and

—The medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE had a listed infectious disease that was possibly contagious at the time of the potential exposure incident.

(2) The ERE involved has not been exposed to an infectious disease included on the list:

—Facts provided in the request rule out a realistic possibility that an exposure incident occurred with potential for transmitting a listed infectious disease from the victim of an emergency to the involved ERE; or

—The medical facility possesses sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE did not have a listed infectious disease that was possibly contagious at the time of the potential exposure incident.

(3) The medical facility possesses no information on whether the victim involved has an infectious disease included on the list:

—The medical facility lacks sufficient medical information allowing it to determine whether the victim of an emergency treated and/or transported by the involved ERE had, or did not have, a listed infectious disease at the time of the potential exposure incident.

—If the medical facility subsequently acquires sufficient medical information allowing it to determine that the victim of an emergency treated and/or transported by the involved ERE had a listed infectious disease that was possibly contagious at the time of the potential exposure incident, then it should revise its determination to reflect the new information.

(4) The facts submitted in the request are insufficient to make the determination about whether the ERE was exposed to an infectious disease included on the list:

—Facts provided in the request insufficiently document the exposure incident, making it impossible to determine if there was a realistic possibility that an exposure incident occurred with potential for transmitting an infectious disease included on the list issued pursuant to Section 2695(a)(1) [42 U.S.C. 300ff–131(a)(1)] from the victim of an emergency to the involved ERE.

Dated: October 26, 2011.

James W. Stephens,

Director, Office of Science Quality, Office of the Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2011–28234 Filed 11–1–11; 8:45 am]

BILLING CODE P

pseudomallei (formerly *Pseudomonas pseudomallei*); Hendra virus; Nipah virus; Rift Valley fever virus; Venezuelan Equine Encephalitis virus.

[25] Section 2695B [42 U.S.C. 300ff–133].

[26] For example:

Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

CDC. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis. MMWR 2005;54 (No. RR–9):1–17.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6049–N]

Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2012

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the $523 calendar year (CY) 2012

application fee for institutional providers that are initially enrolling in the Medicare or Medicaid programs or Children's Health Insurance Program (CHIP); revalidating their Medicare, Medicaid or CHIP enrollment; or adding a new Medicare practice location. This fee is required with any enrollment application submitted on or after January 1, 2012 and on or before December 31, 2012.

DATES: *Effective Date:* This notice is effective on December 2, 2011.

FOR FURTHER INFORMATION CONTACT: Frank Whelan, (410) 786–1302 for Medicare enrollment issues. Claudia Simonson, (312) 353–2115 for Medicaid and CHIP enrollment issues.

SUPPLEMENTARY INFORMATION:

I. Background

In the February 2, 2011 **Federal Register** (76 FR 5862), we published a final rule with comment period entitled: ''Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.'' This rule finalized, among other things, provisions related to the submission of application fees as part of the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) provider enrollment processes. Specifically, and as indicated in 42 CFR 424.514, ''institutional providers'' that are initially enrolling in the Medicare, Medicaid or CHIP program, revalidating their enrollment or adding a new Medicare practice location, are required to submit a fee with an enrollment application submitted on or after March 25, 2011. An ''institutional provider'' is defined at 42 CFR 424.502 as—

> Any provider or supplier that submits a paper Medicare enrollment application using the CMS–855A, CMS–855B (not including physician and non-physician practitioner organizations), CMS–855S or associated Internet-based PECOS enrollment application.

As indicated in 42 CFR 424.514 and 455.460, the application fee is not required for either of the following:

- A Medicare physician or non-physician practitioner submitting a CMS–855I.
- A prospective or re-enrolling Medicaid or CHIP provider—

++ Who is an individual physician or non-physician practitioner; or

++ That is enrolled in Title XVIII of the Act or another State's title XIX or XXI plan and has paid the application fee to a Medicare contractor or another State.

In the March 23, 2011 **Federal Register** (76 FR 16422), we published a notice announcing—

- A $505 calendar year (CY) 2011 application fee for institutional providers that are initially enrolling in the Medicare, Medicaid, or CHIP program; revalidating their enrollment; or adding a new Medicare practice location;
- That institutional providers are required to submit the $505 fee with enrollment applications submitted on or after March 25, 2011 and on or before December 31, 2011; and
- That prospective or re-enrolling Medicaid or CHIP providers must submit the application fee unless: (1) The provider is an individual physician or non-physician practitioner; or (2) the provider is enrolled in Title XVIII of the Act or another State's title XIX or XXI plan and has paid the application fee to a Medicare contractor or another State.

II. Provisions of the Notice

A. Current Fee Amount

As noted in section I. of this notice, the fee amount for the period of March 25, 2011 through December 31, 2011 is $505. This figure was calculated as follows:

- Section 1866(j)(2)(C)(i)(I) of the Social Security Act (the Act) established a $500 application fee for institutional providers in CY 2010.
- Consistent with section 1866(j)(2)(C)(i)(II) of the Act, 42 CFR 424.514(d)(2) states that for CY 2011 and subsequent years, the fee will be adjusted by the percentage change in the consumer price index (CPI) for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.
- The CPI increase for CY 2011, which was calculated to be 1.0 percent, was based on data obtained from the Bureau of Labor Statistics. This resulted in an application fee for CY 2011 of $505 (or $500 × 1.01). For more detailed information on the CPI and the calculation of the application fee, see the February 2, 2011 final rule with comment period (76 FR 5955) and the March 23, 2011 notice (76 FR 16423).

B. Fee Amount for Calendar Year 2012

The CPI increase for the period of July 2010 through June 2011 was 3.54 percent, based on data obtained from the Bureau of Labor Statistics. (This percentage is higher than the 2.0 percent CPI increase that we estimated for CY 2012 in the February 2, 2011 final rule with comment period (76 FR 5955).) This results in a projected application fee amount for the period of January 1, 2012 through December 31, 2012 of $522.87 (or $505 × 1.0354). However, in the preamble to the February 2, 2011 final rule with comment period (76 FR 5907), we stated that ''(t)o ease the administration of the fee, if the adjustment sets the fee at an uneven dollar amount, we will round the fee to the nearest whole dollar amount.'' Therefore, the projected application fee amount for CY 2012 will be rounded to the ''nearest whole dollar amount,'' which is $523.00. This represents an $8.00 difference from the $515 fee that we had originally projected for CY 2012.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). However, it does reference previously approved information collections. As stated in section I. of this notice, the forms CMS–855A, CMS–855B, and CMS–855I are approved under OMB control number 0938–0685; the CMS–855S is approved under OMB control number 0938–1056.

IV. Regulatory Impact Statement

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)). 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. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As explained in this section of the notice (section IV), we estimate that the total cost of the increase in the application fee will not exceed $100 million. This notice therefore does not reach the $100 million economic threshold and is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. As we stated in the RIA for the February 2, 2011 final rule with comment period (76 FR 5952) and the regulatory impact statement of the March 23, 2011 notice (76 FR 16423), we do not believe that the application fee will have a significant impact on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This notice does not mandate such expenditures by States and local governments.

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. Since this notice does not impose substantial direct costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

The costs associated with this notice involve the increase in the application fee that certain providers and suppliers must pay in CY 2012. In the RIA for the February 2, 2011 final rule with comment period (76 FR 5955 through 5958), we estimated the total amount of application fees for CYs 2011 through 2015. For 2012, and based on a $515 application fee, we projected in Tables 11 and 12 (76 FR 5955 and 5956) a total cost in fees of $71,803,875 for Medicare institutional providers (or 139,425 providers × $515). In the February 2, 2011 final rule with comment period (76 FR 5957 and 5958), we estimated the total cost in CY 2012 for Medicaid providers to be $12,944,010 (or 25,134 providers × $515), as indicated in Tables 13 and 14.

We are retaining the figure of 25,134 Medicaid providers for purposes of this notice. However, we are changing the Medicare provider estimate based on our plan to revalidate all Medicare providers and suppliers– even if the revalidation is considered ''off-cycle'' per 42 CFR 424.515(e).

1. Medicare

For purposes of this notice only, we estimate that approximately 840,000 Medicare providers and suppliers will be subject to revalidation in CY 2012. Of this total, we believe that roughly 80 percent will be exempt from the application fee requirement because the provider or supplier: (1) Is of a type (for example, a physician) that is exempt from the requirement, or (2) qualifies for a hardship exception under 42 CFR 424.514(c). This leaves 168,000 revalidating providers and suppliers that will have to pay the fee.

In the February 2, 2011 final rule with comment period (76 FR 5955), we estimated that 31,200 newly-enrolling institutional providers would be subject to the application fee in CY 2012. We stand by this projection for purposes of this notice. Using a figure of 199,200 providers and suppliers (168,000 + 31,200), we estimate an increase in the cost of the Medicare application fee requirement in CY 2012 of $1,593,600 (or 199,200 × $8.00).

2. Medicaid and CHIP

In the February 2, 2011 final rule with comment period (76 FR 5957 and 5958), we estimated that 25,134 (8,438 newly enrolling + 16,696 re-enrolling) Medicaid and CHIP providers would be subject to an application fee in CY 2012. This results in an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2012 of $201,072 (or 25,134 × $8.00).

3. Total

Based on the foregoing, we estimate the total increase in the cost of the application fee requirement for Medicare, Medicaid, and CHIP providers and suppliers in CY 2012 to be $1,794,672.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 30, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–28424 Filed 11–1–11; 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

Title: Descriptive Study of Tribal Temporary Assistance for Needy Families (TANF) Programs.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) is proposing an information collection activity as part of the Descriptive Study of Tribal TANF Programs. The proposed information collection consists of semi-structured interviews and focus groups with key Tribal TANF respondents on questions of Tribal TANF administration, policies, service delivery, and program context. Through this information collection, ACF seeks to gain an in-depth, systematic understanding of program implementation, operations, outputs and outcomes in selected sites, and identify promising practices and other areas for further study.

Respondents: Tribal TANF administrators, staff and participants, and staff of related programs.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Discussion Guide for Use with Tribal TANF administrators	13	1	2	26
Discussion Guide for Use with Tribal TANF staff	12	1	1	12
Discussion Guide for Focus Groups with Tribal TANF clients	20	1	2	40
Discussion Guide for Use with staff of related programs	20	1	1	20
All Instruments	65			98

Estimated Total Annual Burden Hours: 98.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. 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: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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.

Dated: October 26, 2011.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2011–28273 Filed 11–1–11; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities Meeting, Via Conference Call, Cancellation

AGENCY: President's Committee for People with Intellectual Disabilities (PCPID).

ACTION: Notice of PCPID Conference Call Cancellation.

DATES: The conference call was scheduled for October 28, 2011, 1 p.m. to 2:30 p.m.

FOR FURTHER INFORMATION CONTACT: Laverdia Taylor Roach, Senior Advisor, President's Committee for People with Intellectual Disabilities, The Aerospace Center, Second Floor West, 370 L'Enfant Promenade SW., Washington, DC 20447. Telephone: (202) 619–0634. Fax: (202) 205–9519. Email: *LRoach@acf.hhs.gov.*

Further meetings will be announced through a separate **Federal Register** notice.

Dated: October 26, 2011.

Jamie Kendall,

Deputy Commissioner, Administration on Developmental Disabilities.

[FR Doc. 2011–28292 Filed 11–1–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–2955]

Revised Guidance for Industry on Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision), VICH GL18(R); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry (#100) entitled ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision)'' VICH GL18(R). This revised guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guidance is intended to recommend acceptable amounts of residual solvents in new animal drugs (referred to as pharmaceuticals or veterinary medicinal products in this guidance) for the safety of the target animal as well as for the safety of human consumers of products derived from treated food producing animals. It is intended to assist in developing new animal drug applications (referred to as marketing applications in this guidance) submitted to the European Union, Japan, and the United States.

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

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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: Mai Huynh, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8273, *mai.huynh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Revised Guidance on Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients

In the **Federal Register** of August 17, 2010 (75 FR 50771), FDA published a notice of availability for a draft revised guidance entitled ''Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision) VICH GL18(R)'' giving interested persons until October 18, 2010, to comment on the draft revised guidance. This draft incorporated a lower permissible daily exposure limit for *N*-Methypyrrolidone, which is still being kept in Class 2, and placed tetrahydrofuran into Class 2 from Class 3. Based on comments received from the draft revised guidance, additional information was added in section 3.2 of this guidance to include reference to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guideline entitled ''Impurities: Guideline for Residual Solvents (Q3C(R4)).'' The revised guidance announced in this notice finalizes the draft revised guidance announced on August 17, 2010. The revised guidance is a product of the Quality Expert Working Group of the VICH.

III. Paperwork Reduction Act of 1995

This revised 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 this document have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This revised document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline''. In addition, guidance documents must not include mandatory language such as ''shall'', ''must'', ''require'', or ''requirement'', unless FDA is using these words to describe a statutory or regulatory requirement.

The revised VICH guidance (GFI #100) is consistent with the Agency's current thinking on this topic. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

V. Comments

Interested persons may, at any time, submit either electronic or written comments regarding this revised guidance document to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: October 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28371 Filed 11–1–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Autism Coordinating Committee; Call for Nominations

In accordance with Public Law 112–32, The Combating Autism Reauthorization Act the Department of Health and Human Services has been authorized to continue to support the Interagency Autism Coordinating Committee (IACC) until September 30, 2014 and is seeking nominations for public membership on this committee. The Secretary of the Department of Health and Human Services, who will make the final selections and appointments of public members, has directed the Office of Autism Research Coordination (OARC) to assist the Department in conducting an open and transparent nomination process. Nominations of new public members are encouraged, but current members may also be re-nominated to continue to serve. Self-nominations and nominations of other individuals are both permitted. Only one nomination per individual is required. Multiple nominations for the same individual will not increase likelihood of selection. The Secretary may select public members from the pool of submitted

nominations and other sources as needed to meet statutory requirements and to form a balanced committee that represents the diversity within the community (details below). Those eligible for nomination include leaders or representatives of major autism spectrum disorder (ASD) research, advocacy and service organizations, parents or guardians of individuals with ASD, individuals on the autism spectrum, providers, educators, researchers and other individuals with professional or personal experience with ASD. In accordance with White House Office of Management and Budget guidelines (FR Doc. 2011–25736), federally-registered lobbyists are not eligible. As specified in Public Law 109–416, which has been extended by Public Law 112–32, the Committee will carry out the following responsibilities: (a) Develop a summary of advances in autism spectrum disorder research supported or conducted by the Federal agencies relevant to causes, prevention, treatment, early screening, diagnosis or rule out, intervention, and access to services and supports for individuals with autism spectrum disorder; (b) monitor Federal activities with respect to autism spectrum disorder; (c) make recommendations to the Secretary regarding any appropriate changes to such activities, including recommendations to the Director of NIH with respect to the strategic plan; (d) make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder; (e) develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research, including proposed budgetary requirements.

In accordance with Public Law 109–416, which has been extended by Public Law 112–32, ''Not fewer than 6 members of the Committee, or 1/3 of the total membership of the Committee, whichever is greater, shall be composed of non-Federal public members appointed by the Secretary, of which—(a) at least one such member shall be an individual with a diagnosis of autism spectrum disorder; (b) at least one such member shall be a parent or legal guardian of an individual with an autism spectrum disorder; and (c) at least one such member shall be a representative of leading research, advocacy, and service organizations for individuals with autism spectrum disorder.''

Public members of the Committee shall serve for a term of 4 years, and may be reappointed for one or more additional 4 year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. Public members will serve as Special Government Employees. The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.

In 2008–2011, the Committee held an average of 15 meetings, workshops and phone conferences per year. Travel expenses are provided for Committee members to facilitate attendance at in-person meetings.

The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Requests for reasonable accommodation to enable participation on the Committee should be indicated in the nomination submission. Nominations are due by COB November 30, 2011 and may be sent to Dr. Susan Daniels, Acting Director, Office of Autism Research Coordination/NIMH/NIH, 6001 Executive Boulevard, Room 8185, Bethesda MD 20892–2190 by standard or express mail, or via email to *IACCPublicInquiries@mail.nih.gov.* Nominations should include a cover letter of no longer than 3 pages describing the candidate's interest in seeking appointment to the IACC, including relevant personal and professional experience with ASD, as well as contact information and a current curriculum vitae or resume. Please do not include additional materials unless requested. More information about the IACC is available at *http://www.iacc.hhs.gov.*

Dated: October 27, 2011.

Susan A. Daniels,

Acting Director, Office of Autism Research Coordination, National Institute of Mental Health.

[FR Doc. 2011–28375 Filed 11–1–11; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Pilot and Feasibility Clinical Research Studies in Digestive. Diseases and Nutrition.

Date: November 14, 2011.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road. Bethesda, MD 20852.

Contact Person: Peter J Perrin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health,6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, (301) 435–0682, *perrinp@csr.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.

(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: October 27, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–28370 Filed 11–1–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is

hereby given of a meeting of the Interagency Breast Cancer and Environmental Research Coordinating Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Interagency Breast Cancer and Environmental Research Coordinating, Committee (IBCERC), Research Process Subcommittee.

Date: December 12, 2011.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: The purpose of the meeting is to continue the work of the Research Process Subcommittee as it addresses a broad set of objectives related to the overall mandate of the IBCERC including: setting research priorities, decreasing redundancies across federal and non-governmental organizations, developing a process for soliciting research, fostering collaborations, highlighting peer review issues, and identifying the most appropriate models for agencies to work together. The meeting agenda will be available on the Web at *http://www.niehs.nih.gov/about/orgstructure/boards/ibcercc/.*

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709 (Telephone Conference Call).

Contact Person: Gwen W. Collman, Ph.D., Director, Division of Extramural Research and Training, Nat. Inst. of Environmental Health Sciences, National Institutes of Health, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 27, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–28379 Filed 11–1–11; 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; PAR11–107 Ancillary Studies to the NIDDK Intestinal Stem Cell Consortium (ISCC).

Date: December 1, 2011.

Time: 1 p.m. to 2:30 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: 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: October 27, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–28378 Filed 11–1–11; 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 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 Allergy and Infectious Diseases Special Emphasis Panel; NIH/PEPFAR Collaboration for Implementation Science and Impact Evaluation.

Date: December 2, 2011.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Betty Poon, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 402–6891, *poonb@mail.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH/PEPFAR Collaboration for Implementation Science and Impact Evaluation.

Date: December 16, 2011.

Time: 11 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Betty Poon, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, (301) 402–6891, *poonb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: October 27, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–28377 Filed 11–1–11; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS/HIV Immunology.

Date: November 28–29, 2011.

Time: 7 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5106, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@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: October 26, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–28374 Filed 11–1–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2011–0107]

Homeland Security Information Network Advisory Committee

AGENCY: Department of Homeland Security.

ACTION: Committee Management; Notice of Federal Advisory Committee Charter Renewal and Request for Applicants for Appointment to Homeland Security Information Network Advisory Committee.

SUMMARY: The Secretary of Homeland Security has determined that the renewal of the Homeland Security Information Network Advisory Committee (HSINAC) is necessary and in the public interest in connection with the performance of duties of the Department of Homeland Security. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Qualified individuals interested in serving on this committee are invited to apply for appointment.

DATES: Applications for membership should be mailed to the individual listed under **FOR FURTHER INFORMATION CONTACT** and should reach the Designated Federal Officer, HSINAC on or before November 18, 2011. If you desire to submit comments on the establishment of this committee, they must be received within 60 days of the publication of this notice.

ADDRESSES: Applications for appointment to the HSINAC should include a resume of no more than two pages and a letter stating their interest in joining the committee. Applications must be mailed or Emailed to:

- *Email: david.steigman@dhs.gov.*
- *Fax:* (202) 357–7678
- *Mail:* David Steigman, Designated Federal Officer, Homeland Security Information Network Advisory Committee, 245 Murray Lane, SW., BLDG 410, Washington, DC 20528–0426.

If you desire to submit comments on this action, they must be submitted within 60 days of the publication of this notice. Comments must be identified by docket number DHS–2011–0107 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: David.Steigman@dhs.gov.* Include the docket number, DHS–2011–0107, in the subject line of the message.
- *Fax:* (202) 357–7678
- *Mail:* David Steigman, Department of Homeland Security, 245 Murray Lane, SW., BLDG 410, Washington, DC 20528–0426.
- *Instructions:* All comments received must include the words ''Department of Homeland Security'' and DHS–2011–0107, the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov.* including any personal information provided. Do not submit applications for appointment to this Web site.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: David Steigman, 245 Murray Lane, SW., BLDG 410, Washington, DC 20528–0426; *david.steigman@dhs.gov;* telephone: (202) 357–7809; fax: (202) 357–7678.

Name of Committee: Homeland Security Information Network Advisory Committee (HSINAC)

SUPPLEMENTARY INFORMATION: For the reasons set forth below, the Secretary of Homeland Security has determined that the renewal of the HSINAC is necessary and in the public interest. This determination follows consultation with the Committee Management Secretariat, General Services Administration.

The HSINAC is being renewed in accordance with the provisions of the Federal Advisory Committee Act (FACA) 5 U.S.C. App. This Committee advises and makes recommendations to the Secretary of Homeland Security on matters relating to the Homeland Security Information Network (HSIN), including system requirements, operating policies, community organization, knowledge management, interoperability, federation with other systems, and any other aspect of HSIN that supports the operations of DHS and its federal, state, territorial, local, tribal, international and private sector mission partners. The committee will meet approximately three times each year, usually in the Washington, DC metropolitan area, but may meet more often as the need arises.

Balanced Membership Plans: The HSINAC will be composed of individual members possessing expertise, knowledge, and experience regarding the business processes and information sharing needs of one or more of the homeland security mission areas. Members shall be appointed based on their expertise in professions and disciplines engaged in homeland security operations and in support of homeland security mission requirements.

Because a balance of perspectives is essential to ensure that the HSINAC truly represents the broad spectrum of HSIN users, HSINAC membership shall expressly include individuals from federal, state, local, tribal, and territorial governments and the private sector, including:

1. Three members drawn from currently serving state, tribal, or local law enforcement;

2. One member drawn from currently serving federal law enforcement;

3. Two members drawn from currently serving State Homeland Security Advisors;
4. Two members drawn from currently serving emergency managers;
5. Two members drawn from currently serving fire services;
6. Two members drawn from currently serving public health or agriculture sectors;
7. Three members drawn from currently serving senior managers in private sector industries deemed critical infrastructure or key resources in the National Infrastructure Protection Plan;
8. One member drawn from currently serving in an Office of the Adjutant General of the National Guard;
9. One member drawn from currently serving State or local Chief Information Security Officer or cyber-related position within State or local government;
10. One member drawn from currently serving local, county/parish, or city government;
11. One member drawn from currently serving tribal government;
12. One member drawn from currently serving in any discipline with relevant expertise in state, local, tribal, or territorial homeland security.

Of the above-described members, two shall serve in, or have direct oversight of, different state or major urban area fusion centers.

Duration: The HSINAC Charter was filed with Congress July 14, 2011 and remains in effect through July 14, 2013.

Responsible DHS Officials: David Steigman, HSINAC Designated Federal Officer; Department of Homeland Security, 245 Murray Lane, SW., BLDG 410, Washington, DC 20528–0426; *David.Steigman@dhs.gov,* (202) 357–7809.

Applying for Appointment: The committee will fill all the positions listed above. The HSINAC will be composed of individual members possessing expertise, knowledge, and experience regarding the business processes and information sharing needs of one or more of the homeland security mission areas. Members are appointed based on their expertise in professions and disciplines engaged in homeland security operations and in support of homeland security mission requirements. Members will serve a term of two years. Members are appointed by the Secretary of Homeland Security at the recommendation of the HSIN Program Director.

Members of the HSINAC will be appointed and serve as Special Government Employees (SGE), as defined in section 202(a) of title 18 United States Code, except for those members who currently are serving employees of the federal government. As a candidate for appointment as a SGE, applicants are required to complete a Confidential Financial Disclosure Report (OGE Form 450). DHS may not release the forms or the information in them to the public except under an order issued by a Federal court or as otherwise provided under the Privacy Act (5 U.S.C. 552a). Applicants can obtain this form by going to the Web site of the Office of Government Ethics (*http://www.oge.gov*), or by contacting the individual listed above. Applications which are not accompanied by a completed OGE Form 450 will not be considered.

Members serve at their own expense and receive no salary from the Federal government, although they may be reimbursed for per diem and travel expenses.

In support of the policy of the Department of Homeland Security on gender and ethnic diversity, qualified women and minorities are encouraged to apply for membership.

Dated: October 18, 2011.

Deborah Kent,

Program Director, Homeland Security Information Network Program.

[FR Doc. 2011–28399 Filed 11–1–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2011–0104]

Privacy Act of 1974; Department of Homeland Security, U.S. Customs and Border Protection, DHS/CBP–009—Electronic System for Travel Authorization (ESTA) System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security proposes to update an existing Department of Homeland Security system of records notice titled ''Department of Homeland Security/U.S. Customs and Border Protection–009 Electronic System for Travel Authorization System of Records.'' This system collects and maintains a record of nonimmigrant aliens who want to travel to the United States under the Visa Waiver Program, and is used to determine whether the applicant is eligible to travel to the United States under the Visa Waiver Program by screening his or her information against various security and law enforcement databases. DHS/CBP is updating this system of records notice to reflect: (1) Updated categories of records to include payment information, including credit card number, Pay.gov tracking number, billing name, billing address, and the applicant's country of birth (to reduce the number of false matches); (2) updated routine uses to allow DHS/CBP to share payment information with Department of Treasury's Pay.gov for processing; and (3) updated routine uses to allow sharing of the ESTA application data (which excludes payment information) with federal, state, local, tribal, foreign, or international government agencies (including intelligence agencies) once they have established that they will use the information for a purpose which is compatible with the purpose of the original collection. This newly updated system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before December 2, 2011. This new system will be effective December 2, 2011.

ADDRESSES: You may submit comments, identified by docket number DHS–2011–0104 by one of the following methods:

- *Federal e-Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (703) 483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Laurence E. Castelli (202) 325–0280), CBP Privacy Officer, Office of International Trade, U.S. Customs and Border Protection, Mint Annex, 799 Ninth Street NW., Washington, DC 20229. For privacy issues please contact: Mary Ellen Callahan (703) 235–0780), Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security proposes to update an existing Department of Homeland Security system of records notice titled, DHS/CBP–009—Electronic System for Travel Authorization (ESTA) June 10, 2008, 73 FR 32720. This system collects and maintains records of nonimmigrant aliens who want to travel to the United States under VWP and is used to determine whether the applicant is eligible to travel to the United States by screening his or her information against various security and law enforcement databases.

In 2008, a web-based system called the Electronic System for Travel Authorization (ESTA) was developed to determine the eligibility of visitors to travel to the United States by air or sea under the Visa Waiver Program (VWP), prior to boarding a carrier en route to the United States, and whether such travel poses a law enforcement or security risk by screening the information provided against selected security and law enforcement databases.

Pursuant to Section 711(d)(1)(E) of the *Implementing the Recommendations of the 9/11 Commission Act,* CBP amended its regulations to include the collection of an application fee for each application submitted as required by the Travel Promotion Act (TPA), which was signed into law on March 4, 2010.

In addition to the application fee, TPA also mandates that CBP collect $10 from each approved applicant, effective six months from the date the legislation was signed. CBP must transfer these funds quarterly to the Travel Promotion Fund for use by the Corporation for Travel Promotion. CBP published regulations instituting the fee on August, 9, 2010 (75 FR 47701).

Through the ESTA web-based interface, the user will be prompted through several screens to capture the required application information. Once the applicant has entered all required application information, ESTA will take the applicant through a series of screens where he/she enters his/her billing name, billing address, and credit card information. ESTA forwards all of this payment information to Pay.gov for payment processing and the applicant name and an ESTA tracking number to the DHS/CBP–018 Credit/Debit Card Data System (CDCDS) System of Records for payment reconciliation. Pay.gov sends a nightly activity file, including the last four digits of the credit card, authorization number, billing name, billing address, ESTA tracking number, and Pay.gov tracking numbers, to CDCDS. Pay.gov also sends a daily batch file with the necessary payment information to Fifth Third Bank for settlement processing. After processing, Fifth Third Bank sends a settlement file, including the full credit card number, authorization number, card type, transaction date, amount, and ESTA tracking number to CDCDS. Once ESTA receives confirmation from Pay.gov that the payment has been processed successfully, ESTA will retain the Pay.gov tracking number for payment reconciliation purposes.

As CBP enhances and updates ESTA, CBP anticipates amending its application to include the applicant's country of birth, which will assist in reducing false matches during the vetting process.

DHS is updating the categories of records and routine uses for this system of records notice to permit the collection and use of a Pay.gov tracking number associated with the applicant's payment information, including billing name, billing address, and credit card information for the newly-required application fee, and the applicant's country of birth, which will assist in reducing false matches during the vetting process. Additionally, this update includes a routine use permitting the sharing of payment information with the Department of the Treasury's Pay.gov Web site.

DHS changed the order of routine uses to be consistent across all DHS SORNs and for ease of use by DHS personnel. This change impacts the following uses, which were not substantially changed. Former routine use G, which addressed certain governmental agencies' responsibility for, in part, investigating and enforcing civil or criminal laws, was eliminated because of redundancy. Former routine use L is now routine use K, which clarifies the sharing that takes place with the intelligence community. The TPA requires CBP to include the collection of an application fee for each application submitted. Accordingly, routine use P was added to explicitly allow for payment processing and reconciliation activities. Routine use Q was also added.

The Department of Homeland Security issued a Final Rule for this system of records in the **Federal Register** (74 FR 45069) on August 31, 2009. This SORN update does not change the nature of reasons for this system of records or the need for the exemptions to certain aspects of the Privacy Act. This newly-updated system will be included in the Department of Homeland Security's inventory of record systems.

The purpose of this system of records is to determine the eligibility of aliens to travel to the U.S. by air or sea under the VWP. DHS/CBP has authority to operate this system under the Homeland Security Act of 2002, Public Law 107–296; 5 U.S.C. 301 and Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act) (Pub. L. 110–53); and the Travel Promotion Act (Pub. L. 111–145). Updates to this system include the collection of additional information, and DHS/CBP has set in place processes and agreements to safeguard the additional data collected. New routine uses included in this update primarily relate to the addition of payment information and allow for processing of such information, which is directly compatible with the purpose for which the information was collected. Additional routine uses were edited to align with standards across DHS SORNs for ease of use and understanding by DHS personnel.

Consistent with DHS's information sharing mission, information stored in ESTA may be shared with other DHS components, as well as appropriate Federal, state, local, tribal, foreign, or international government agencies. This sharing will only take place after DHS determines that the receiving component or agency has a need to know the information to carry out national security, law enforcement, immigration, intelligence, or other functions consistent with the routine uses set forth in this system of records notice.

II. Privacy Act

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. Individuals may request access to their own records that are maintained in a system of records in the possession

or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR part 5.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to which their records are put, and to assist individuals to more easily find such files within the agency. Below is the description of the Department of Homeland Security, U.S. Customs and Border Protection, DHS/CBP–009—Electronic System for Travel Authorization (ESTA) system of records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/Customs and Border Protection (CBP)–009

SYSTEM NAME:

DHS/CBP–009 Electronic System for Travel Authorization (ESTA).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained in the ESTA system at the U.S. Customs and Border Protection (CBP) Headquarters in Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include foreign nationals from VWP countries who are seeking to enter the United States by air or sea under the VWP. Under the Immigration and Nationality Act (INA), title 8 of the United States Code, these persons are required to report their arrival and departure to and from the United States. This system only collects information pertaining to persons in nonimmigrant status, that is, persons who are not covered by the protections of the Privacy Act at the time they provide their information. However, given the importance of providing privacy protections to international travelers, DHS has decided to apply the privacy protections and safeguards outlined in this notice to all international travelers subject to ESTA.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

- Full Name (First, Middle, and Last)
- Date of birth
- Gender
- Email Address
- Phone Number
- Travel document type (*e.g.,* passport), number, issuance date, expiration date and issuing country
- Country of Citizenship
- ESTA Application Number
- Pay.gov Payment Tracking Number (*i.e.,* confirmation of payment; absence of payment confirmation will result in a ''not cleared'' determination)
- Country of Birth
- Date of Anticipated Crossing
- Airline and Flight Number
- City of Embarkation
- Address while visiting the United States (Number, Street, City, State)
- Whether the individual has a communicable disease, physical or mental disorder, or is a drug abuser or addict
- Whether the individual has been arrested or convicted for a moral turpitude crime, drug possession or use, or has been sentenced for a period longer than five years
- Whether the individual has engaged in espionage, sabotage, terrorism or Nazi activity between 1933 and 1945
- Whether the individual is seeking work in the U.S.
- Whether the individual has been excluded or deported, or attempted to obtain a visa or enter U.S. by fraud or misrepresentation
- Whether the individual has ever detained, retained, or withheld custody of a child from a U.S. citizen granted custody of the child
- Whether the individual has ever been denied a U.S. visa or entry into the U.S., or had a visa cancelled. (If yes, when and where)
- Whether the individual has ever asserted immunity from prosecution
- Any change of address while in the U.S.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Homeland Security Act of 2002, Public Law 107–296; 5 U.S.C. 301 and Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act), (Pub. L. 110–53); and the Travel Promotion Act (Pub. L. 111–145).

PURPOSE(S):

The purpose of this system is to collect and maintain a record of nonimmigrant aliens who want to travel to the United States under the Visa Waiver Program, and to determine whether applicants are eligible to travel to the United States under the VWP by screening their information against various security and law enforcement databases.

The Pay.gov tracking number (associated with the payment information provided to Pay.gov and stored in CDCDS) will be used to process ESTA and TPA fees and to reconcile issues regarding payment between ESTA, CDCDS, and Pay.gov. Payment information will not be used for vetting purposes and is stored in a separate system (CDCDS) from the ESTA application data.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (including United States Attorney Offices) or other Federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. Any employee of DHS in his/her official capacity;

3. Any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or

4. The United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other Federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of

information in the system of records has been compromised;

2. The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individual that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate Federal, state, tribal, local, international, or foreign law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To appropriate Federal, state, local, tribal, or foreign governmental agencies or multilateral governmental organizations for the purpose of protecting the vital health interests of a data subject or other persons (*e.g.;* to assist such agencies or organizations in preventing exposure to or transmission of a communicable or quarantinable disease or to combat other significant public health threats; appropriate notice will be provided of any identified health threat or risk);

I. To third parties during the course of a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure;

J. To a Federal, state, tribal, local, international, or foreign government agency or entity for the purpose of consulting with that agency or entity: (1) To assist in making a determination regarding redress for an individual in connection with the operations of a DHS component or program; (2) for the purpose of verifying the identity of an individual seeking redress in connection with the operations of a DHS component or program; or (3) for the purpose of verifying the accuracy of information submitted by an individual who has requested such redress on behalf of another individual;

K. To Federal and foreign government intelligence or counterterrorism agencies when DHS reasonably believes such use is to assist in counterterrorism efforts, and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure;

L. To the Department of State in the processing of petitions or applications for benefits under the Immigration and Nationality Act, and all other immigration and nationality laws including treaties and reciprocal agreements;

M. To an organization or individual in either the public or private sector, either foreign or domestic, where there is a reason to believe that the recipient is or could become the target of a particular terrorist activity or conspiracy, to the extent the information is relevant to the protection of life or property and disclosure is appropriate to the proper performance of the official duties of the person making the disclosure;

N. To the carrier transporting an individual to the United States, but only to the extent that CBP provides information that the ESTA status is not applicable to the traveler, or, if applicable, that the individual is authorized to travel, not authorized to travel, pending, or has not applied.

O. To Pay.gov, for payment processing and payment reconciliation purposes.

P. To the news media and the public, with the approval of the Chief Privacy Officer in consultation with counsel, when there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DHS or is necessary to demonstrate the accountability of DHS's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

These records may be retrieved by any of the data elements supplied by the applicant. The payment information and Pay.gov payment tracking number may be used to track the amount of payment associated with an ESTA application and to reconcile payment discrepancies. As CBP updates and enhances ESTA, applicants will be able to access their ESTA information to view and amend their applications by providing their ESTA number and passport number. Once they have provided their ESTA number and passport number, applicants may view their ESTA status (authorized to travel, not authorized to travel, pending) and submit limited updates to their travel itinerary information. If an applicant does not know his/her application number, he/she can provide his or her passport number, date of birth, and passport issuing country to retrieve his/her application number.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

Application information submitted to ESTA generally expires and is deemed ''inactive'' two years after the initial submission of information by the applicant. In the event that a traveler's passport remains valid for less than two years from the date of the ESTA approval, the ESTA will expire concurrently with the passport. Information in ESTA will be retained for one year after the ESTA expires. After

this period, the inactive account information will be purged from online access and archived for 12 years. Data linked at any time during the 15 year retention period (3 years active, 12 years archived), to active law enforcement lookout records, CBP matches to enforcement activities, and/or investigations or cases, including applications for ESTA that are denied, will remain accessible for the life of the law enforcement activities to which they may become related. NARA guidelines for retention and archiving of data will apply to ESTA and CBP is in negotiation with NARA for approval of the ESTA data retention and archiving plan.

Payment information is not stored in ESTA, but is forwarded to Pay.gov and stored in CBP's financial processing system, CDCDS, pursuant to the DHS/CBP–018, CDCDS system of records notice.

The ESTA has allowed for the automation of the paper I–94W form in the air and sea environment. In those instances where a VWP traveler is admitted using the automated process, the corresponding admission record will be maintained in accordance with the retention schedule for I–94W, which is 75 years. I–94W and I–94 data are maintained for this period of time in order to ensure that the information related to a particular admission to the United States is available for providing any applicable benefits related to immigration or other enforcement purposes.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Automated Systems, U.S. Customs and Border Protection Headquarters, 1300 Pennsylvania Avenue NW., Washington, DC 20229.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted portions of this system from the notification, access, and amendment procedures of the Privacy Act because it is a law enforcement system. However, CBP will consider individual requests to determine whether or not information may be released. Thus, individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or component's FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Director, Disclosure and FOIA, *http://www.dhs.gov* or 1 (866) 431–0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you,
- Identify which component(s) of the Department you believe may have the information about you,
- Specify when you believe the records would have been created,
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records,
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information, the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

The system obtains information from the online ESTA application submitted by the applicant. This information is processed by the Automated Targeting System (ATS) to screen for terrorists or threats to aviation and border security and TECS (for matches to persons identified to be of law enforcement interest), and result of ''authorized to travel,'' ''not authorized to travel,'' or ''pending'' is maintained in ESTA. ''Pending'' will be resolved to ''authorized to travel'' or ''not authorized to travel'' based on further research by CBP. Pay.gov provides the Pay.gov tracking number once payment information has been forwarded to it and processed. It is used to reconcile payments between ESTA, CDCDS, and Pay.gov.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

No exemption shall be asserted with respect to information maintained in the system as it relates to data submitted by or on behalf of a person who travels to visit the United States and crosses the border, nor shall an exemption be asserted with respect to the resulting determination (authorized to travel, pending, or not authorized to travel). Information in the system may be shared with law enforcement and/or intelligence agencies pursuant to the above routine uses. The Privacy Act requires DHS to maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agencies has sought particular records may affect ongoing law enforcement or intelligence activity. As such, pursuant to 5 U.S.C. 552a(j)(2) and (k)(2), DHS will claim exemption from (c)(3), (e)(8), and (g) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information.

Dated: October 3, 2011.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–28405 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2011–0102]

Privacy Act of 1974; Department of Homeland Security U.S. Customs and Border Protection DHS/CBP–003 Credit/Debit Card Data System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice of Privacy Act system of records.

SUMMARY: In accordance with the Privacy Act of 1974 the Department of Homeland Security proposes to establish a new Department of Homeland Security system of records notice titled ''Department of Homeland Security/U.S Customs and Border Protection—003 Credit/Debit Card Data System of Records.'' This system allows U.S. Customs and Border Protection to collect, use, and maintain records

related to any credit and debit card transactions with it has with individuals. Additionally, the Department of Homeland Security is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act, concurrent with this system of records elsewhere in the **Federal Register**. This newly established system will be included in the Department of Homeland Security's inventory of record systems.

DATES: Submit comments on or before December 2, 2011. This new system will be effective December 2, 2011.

ADDRESSES: You may submit comments, identified by docket number DHS–2011–0102 by one of the following methods:

- *Federal e-Rulemaking Portal: http://;www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (703) 483–2999.
- *Mail:* Mary Ellen Callahan, Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.
- *Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For general questions please contact: Laurence E. Castelli (202) 325–0280) Privacy Officer, Office of International Trade, U.S. Customs and Border Protection, Mint Annex, 799 Ninth Street NW., Washington, DC 20229. For privacy issues please contact: Mary Ellen Callahan (703) 235–0780, Chief Privacy Officer, Privacy Office, U.S. Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS) U.S. Customs and Border Protection (CBP) proposes to establish a new DHS system of records notice titled, ''DHS/CBP–003 Credit/Debit Card Data System of Records.''

This system collects, uses, and maintains records related to any credit and debit card transactions with CBP. CBP is providing notice to the public regarding the collection, use, and dissemination of any credit and debit card transaction information provided to CBP. Many programs administered by CBP require an individual or business to provide payment for various purposes, including services, applications, fees, and duties, among others. As CBP expands methods of payment, many of these transactions will permit use of credit and debit cards, which will require the collection of the card data, disseminating that data to process the transaction, and maintaining the data for recordkeeping purposes. Information from this system will be shared with the Department of Treasury, banks, and credit and debit card processors as necessary. The data will not be used for law enforcement or intelligence purposes unless the individual's underlying transaction becomes associated with a law enforcement or intelligence action.

The purpose of this system is to provide payment processing and recordkeeping of credit and debit card transactions with CBP. Authority for maintenance of this system is given by The Homeland Security Act of 2002, Public Law 107–296; 5 U.S.C. 301; 8 U.S.C. 1101, *et seq.;* 19 U.S.C. 1, *et seq.*; Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act), (Pub. L. 110–53); and the Travel Promotion Act (Pub. L. 111–145).

This newly established system will allow CBP to collect credit and/or debit card payment information from individuals providing payment to CBP for services, applications, fees, duties, and other official activities. Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions. All routine uses proposed are compatible with the purpose for which the information was collected and CBP's mission.

Consistent with DHS's information sharing mission, information stored in the Credit/Debit Card Data system of records may be shared with other DHS components, as well as appropriate federal, state, local, foreign, or international or tribal government agencies. This sharing will only take place after DHS determines that the receiving component or agency has a need to know the information to carry out national security, law enforcement, immigration, intelligence, or other functions consistent with the routine uses set forth in this system of records notice.

Additionally, the Department of Homeland Security is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act, concurrent with this system of records elsewhere in the **Federal Register.** DHS is not exempting any data in the system regarding an individual's credit or debit card transaction. This system, however, may contain records or information pertaining to the accounting of disclosures made from this system to other law enforcement or intelligence agencies (federal, state, local, foreign, international or tribal) in accordance with the published routine uses or statutory basis for disclosure under 5 U.S.C. 552a(b). For the accounting of these disclosures only, in accordance with 5 U.S.C. 552a (j)(2), and (k)(2), DHS will claim exemptions for these records or information.

II. Privacy Act

The Privacy Act embodies fair information principles in a statutory framework governing the means by which the United States Government collects, maintains, uses, and disseminates individuals' records. The Privacy Act applies to information that is maintained in a ''system of records.'' A ''system of records'' is a group of any records under the control of an agency for which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined to encompass United States citizens and lawful permanent residents. As a matter of policy, DHS extends administrative Privacy Act protections to all individuals where systems of records maintain information on U.S. citizens, lawful permanent residents, and visitors. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DHS by complying with DHS Privacy Act regulations, 6 CFR part 5.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the type and character of each system of records that the agency maintains, and the routine uses that are contained in each system in order to make agency record keeping practices transparent, to notify individuals regarding the uses to their records are put, and to assist individuals to more easily find such files within the

agency. Below is the description of the U.S. Customs and Border Protection DHS/CBP–003 Credit/Debit Card Data system of records.

In accordance with 5 U.S.C. 552a(r), DHS has provided a report of this system of records to the Office of Management and Budget and to Congress.

System of Records

Department of Homeland Security (DHS)/U.S. Customs and Border Protection (CBP)—003

SYSTEM NAME:

DHS/CBP—003 Credit/Debit Card Data System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Records are maintained in the Automated Commercial System at the CBP Headquarters in Washington, DC and field offices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Categories of individuals covered by this system include any individuals that provide credit or debit card information as a means of payment to CBP.

CATEGORIES OF RECORDS IN THE SYSTEM:

Categories of records in this system include:

- Individual's Name;
- Address;
- Billing Name;
- Billing Address;
- Credit or Debit Card Number;
- Card Expiration Date;
- Charge Amount;
- Authorization Number; and
- Tracking numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Homeland Security Act of 2002, Public Law 107–296; 5 U.S.C. 301; 8 U.S.C. 1101, *et seq.;* 19 U.S.C. 1, *et seq.;* Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act), (Pub. L. 110–53); and the Travel Promotion Act (Pub. L. 111–145).

PURPOSE(S):

The purpose of this system is to provide payment processing and recordkeeping of credit and debit card transactions with CBP.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (including United States Attorney Offices) or other federal agency conducting litigation or in proceedings before any court, adjudicative or administrative body, when it is relevant and necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

1. DHS or any component thereof;

2. any employee of DHS in his/her official capacity;

3. any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee; or

4. the United States or any agency thereof, is a party to the litigation or has an interest in such litigation, and DHS determines that the records are both relevant and necessary to the litigation and the use of such records is compatible with the purpose for which DHS collected the records.

B. To a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of the individual to whom the record pertains.

C. To the National Archives and Records Administration or other Federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

D. To an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

E. To appropriate agencies, entities, and persons when:

1. DHS suspects or has confirmed that the security or confidentiality of information in the system of records has been compromised;

2. The Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by DHS or another agency or entity) or harm to the individual that rely upon the compromised information; and

3. The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DHS's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

F. To contractors and their agents, grantees, experts, consultants, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for DHS, when necessary to accomplish an agency function related to this system of records. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as are applicable to DHS officers and employees.

G. To an appropriate federal, state, local, foreign, international or tribal law enforcement agency or other appropriate authority charged with investigating or prosecuting a violation or enforcing or implementing a law, rule, regulation, or order, where a record, either on its face or in conjunction with other information, indicates a violation or potential violation of law, which includes criminal, civil, or regulatory violations and such disclosure is proper and consistent with the official duties of the person making the disclosure.

H. To the Department of Treasury's Pay.gov, banks, and credit and debit card processors, for payment processing and payment reconciliation purposes.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records are stored on magnetic disc, tape, digital media, and CD–ROM.

RETRIEVABILITY:

Records may be retrieved by any of the data elements listed in categories of records, above.

SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DHS automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to those individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RETENTION AND DISPOSAL:

Payment information will be maintained in this system for nine months in an active state to reconcile accounts and six years and three months in an archived state in conformance with NARA General Schedule 6 Item 1 Financial Records management requirements. The nine month active status is necessary to handle reconciliation issues (including chargeback requests and retrievals). CBP must respond to these issues within 10 to 15 days or lose the payment.

SYSTEM MANAGER AND ADDRESS:

Director, Office of Automated Systems, U.S. Customs and Border Protection Headquarters, 1300 Pennsylvania Avenue NW., Washington, DC 20229.

NOTIFICATION PROCEDURE:

The Secretary of Homeland Security has exempted portions of this system from the notification, access, and amendment procedures of the Privacy Act because it is a law enforcement system. However, CBP will consider individual requests to determine whether or not information may be released. Thus, Individuals seeking notification of and access to any record contained in this system of records, or seeking to contest its content, may submit a request in writing to the Headquarters or component's FOIA Officer, whose contact information can be found at *http://www.dhs.gov/foia* under ''contacts.'' If an individual believes more than one component maintains Privacy Act records concerning him or her the individual may submit the request to the Chief Privacy Officer, Department of Homeland Security, 245 Murray Drive SW., Building 410, STOP–0655, Washington, DC 20528.

When seeking records about yourself from this system of records or any other Departmental system of records your request must conform with the Privacy Act regulations set forth in 6 CFR Part 5. You must first verify your identity, meaning that you must provide your full name, current address and date and place of birth. You must sign your request, and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. While no specific form is required, you may obtain forms for this purpose from the Director, Disclosure and FOIA, *http://www.dhs.gov* or 1–(866) 431–0486. In addition you should provide the following:

- An explanation of why you believe the Department would have information on you,
- Identify which component(s) of the Department you believe may have the information about you,
- Specify when you believe the records would have been created,
- Provide any other information that will help the FOIA staff determine which DHS component agency may have responsive records,
- If your request is seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

Without this bulleted information the component(s) may not be able to conduct an effective search, and your request may be denied due to lack of specificity or lack of compliance with applicable regulations.

RECORD ACCESS PROCEDURES:

See ''Notification procedure'' above.

CONTESTING RECORD PROCEDURES:

See ''Notification procedure'' above.

RECORD SOURCE CATEGORIES:

Records are obtained from individuals directly in the course of collecting payment for various purposes, including services, applications, fees, and duties, among others.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

No exemption shall be asserted with respect to information maintained in the system as it relates to data submitted by or on behalf of a person who provided payment information. Information in the system may be shared with law enforcement and/or intelligence agencies pursuant to the above routine uses. The Privacy Act requires DHS maintain an accounting of the disclosures made pursuant to all routines uses. Disclosing the fact that a law enforcement or intelligence agencies has sought particular records may affect ongoing law enforcement or intelligence activity. As such, pursuant to 5 U.S.C. 552 a (j)(2) and (k)(2), DHS will claim exemption from (c)(3), (d), (e)(8), and (g) of the Privacy Act of 1974, as amended, as is necessary and appropriate to protect this information.

Dated: October 3, 2011.

Mary Ellen Callahan,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2011–28406 Filed 11–1–11; 8:45 am]

BILLING CODE 9110–06–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2001–11120]

Extension of Agency Information Collection Activity Under OMB Review: Imposition and Collection of Passenger Civil Aviation Security Service Fees

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0001, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on May 12, 2011, 76 FR 27655. The collection involves air carriers and foreign air carriers maintaining an accounting system to account for the passenger civil aviation security service fees collected and reporting this information to TSA on a quarterly basis, as well as retaining the data used for these reports for a three-year rolling period.

DATES: Send your comments by December 2, 2011. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Joanna Johnson, TSA PRA Officer, Office of Information Technology (OIT), TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–3651; email *TSAPRA@dhs.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection

Title: Imposition and Collection of Passenger Civil Aviation Security Service Fees.

Type of Request: Extension of a currently approved collection.

OMB Control Number: 1652–0001.

Forms(s): TSA–Form–2502.

Affected Public: Air carriers.

Abstract: TSA regulations, 49 CFR part 1510, require air carriers and foreign air carriers to collect the ''September 11th Security Service Fee'' from passengers and to submit the fee to TSA by a certain date. These carriers are further required to submit quarterly reports to TSA that provide an accounting of the fees imposed, collected, refunded to passengers, and remitted to TSA and to retain this data for a rolling three-year period. TSA has temporarily suspended an additional requirement for air carriers with over 50,000 passengers to submit annual audits of its fee collections and remittance; this requirement may be reinstated in the future. This information collection request covers both the quarterly reports and the annual audits.

Number of Respondents: 196.

Estimated Annual Burden Hours: An estimated 2,884 hours annually.

Issued in Arlington, Virginia, on October 27, 2011.

Joanna Johnson,

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2011–28380 Filed 11–1–11; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5500–FA–11]

Announcement of Funding Awards for the Self-Help Homeownership Opportunity Program (SHOP) for Fiscal Year 2011

AGENCY: Office of Community Planning and Development, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department in a competition for funding under the Fiscal Year 2011 (FY 2011) Notice of Funding Availability (NOFA) for the Self-Help Homeownership Opportunity Program (SHOP). This announcement contains the consolidated names and addresses of this year's award recipients under SHOP.

FOR FURTHER INFORMATION CONTACT: For questions concerning SHOP Program awards, contact Ginger Macomber, SHOP Program Manager, Office of Affordable Housing Programs, U.S. Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–4500, telephone (202) 402–4605. Hearing or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The SHOP program provides grants to national and regional nonprofit organizations and consortia that have experience in providing self-help housing. Grant funds are used to purchase land and install or improve infrastructure, which together may not exceed an average investment of $15,000 per dwelling unit. Low-income homebuyers contribute a minimum of 100 hours of sweat equity on the construction of their homes and/or the homes of other homebuyers participating in the local self-help housing program. Sweat equity can include, but is not limited to, assisting in the painting, carpentry, trim work, drywall, roofing and siding for the housing. Persons with disabilities can substitute administrative tasks. Donated volunteer labor is also required.

The SHOP funds together with the sweat equity and volunteer labor contributions significantly reduce the cost of the housing for the low-income homebuyers. The FY 2011 awards announced in this Notice were selected for funding in the competition posted on the grants.gov Web site. Applications were scored and selected for funding based on the selection criteria in the General Section and the SHOP program section.

The amount appropriated in FY 2011 to fund the SHOP grants was $26,676,540. The allocations for SHOP grantees are as follows:

Community Frameworks, 409 Pacific Avenue Suite 105, Bremerton, WA 98337	$2,978,716
Habitat for Humanity International, 121 Habitat Street, Americus, GA 31709	14,664,239
Housing Assistance Council, 1025 Vermont Avenue Suite 606, Washington, DC 20005	8,333,535
Tierra del Sol Housing Corporation, Western States Housing Consortium, P.O. Box 2626, 880 Anthony Drive, Anthony, NM 88021	700,050
Total	26,676,540

These non-profit organizations propose to distribute SHOP funds to several hundred local affiliates and consortium members that will acquire and prepare the land for construction, select homebuyers, coordinate the homebuyer sweat equity and volunteer efforts, and assist in the arrangement of interim and permanent financing for the homebuyers.

Dated: October 24, 2011.

Mercedes Márquez,

Assistant Secretary for Community Planning and Development.

[FR Doc. 2011–28434 Filed 11–1–11; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

Notice on Outer Continental Shelf Oil and Gas Lease Sales

AGENCY: Bureau of Ocean Energy Management (BOEM), Interior.

ACTION: List of Restricted Joint Bidders.

SUMMARY: Pursuant to the authority vested in the Director of the Bureau of Ocean Energy Management by the joint bidding provisions of 30 CFR 256.41, each entity within one of the following groups shall be restricted from bidding with any entity in any other of the following groups at Outer Continental Shelf oil and gas lease sales to be held during the bidding period November 1, 2011, through April 30, 2012. The List of Restricted Joint Bidders published in the **Federal Register** on May 17, 2011, covered the period May 1, 2011, through October 31, 2011.

Group I
- Exxon Mobil Corporation
- ExxonMobil Exploration Company

Group II
- Shell Oil Company
- Shell Offshore Inc.
- SWEPI LP
- Shell Frontier Oil & Gas Inc.
- SOI Finance Inc.
- Shell Gulf of Mexico Inc.

Group III
- BP America Production Company
- BP Exploration & Production Inc.
- BP Exploration (Alaska) Inc.

Group IV
- Chevron Corporation
- Chevron U.S.A. Inc.
- Chevron Midcontinent, L.P.
- Unocal Corporation
- Union Oil Company of California
- Pure Partners, L.P.

Group V
- ConocoPhillips Company
- ConocoPhillips Alaska, Inc.
- Phillips Pt. Arguello Production Company
- Burlington Resources Oil & Gas Company LP
- Burlington Resources Offshore Inc.
- The Louisiana Land and Exploration Company
- Inexeco Oil Company

Group VI
- Eni Petroleum Co. Inc.
- Eni Petroleum US LLC
- Eni Oil US LLC
- Eni Marketing Inc
- Eni BB Petroleum Inc.
- Eni US Operating Co. Inc.
- Eni BB Pipeline LLC

Group VII
- Statoil ASA
- Statoil Gulf of Mexico LLC
- Statoil USA E&P Inc.
- Statoil Gulf Properties Inc.

Group VIII
- Petrobras America Inc.
- Petroleo Brasileiro S.A.

Group IX
- Total E&P USA, Inc.

Dated: October 19, 2011.

Tommy P. Beaudreau,

Director, Bureau of Ocean Energy Management.

[FR Doc. 2011–28314 Filed 11–1–11; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–1011–8743; 2200–3200–665]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before October 15, 2011. Pursuant to § 60.13 of 36 CFR Part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation. Comments may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service,1201 Eye St. NW., 8th floor, Washington DC 20005; or by fax, (202) 371–6447. Written or faxed comments should be submitted by November 17, 2011. 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.

J. Paul Loether,

Chief, National Register of Historic Places, National Historic Landmarks Program.

ARIZONA

Maricopa County

Palo Verde Ruin, Address Restricted, Peoria, 11000842

DELAWARE

New Castle County

Carswell, Stuart Randall & Pricilla Kellogg, House, 102 Briar Ln., Newark, 11000844

DISTRICT OF COLUMBIA

District of Columbia

Washington, Margaret Murray, School, (Public School Buildings of Washington, DC MPS) 27 O St., NW., Washington, 11000843

ILLINOIS

Champaign County

Ahrens, Henry, House, 212 E. University Ave., Champaign, 11000845

Squires, Frederick, House, 1003 W. Church St., Champaign, 11000846

Cook County

Building at 2440 N. Lakeshore Avenue, 2440 N. Lakeshore Ave., Chicago, 11000847

Parkway Garden Homes, 6330–6546 S. Martin Luther King Dr., Chicago, 11000848

Wholesale Florists Exchange, 1313 W. Randolph St., Chicago, 11000849

La Salle County

Ottawa Commercial Historic District, Roughly 600–1129 Columbus St., 601–1215 LaSalle St., Ottawa, 11000850

Winnebago County

Peacock Brewery, 200 Prairie & 500 N. Madison Sts., Rockford, 11000851

MARYLAND

Baltimore County

Bare Hills Historic District, Falls Rd. between Light Rail and N. of Coppermine Terr., Bare Hills, 11000852

MASSACHUSETTS

Essex County

Sacred Heart Parish Complex, 321 S. Broadway, Lawrence, 11000853

Middlesex County

Acton High School, 3 Charter Rd., Acton, 11000854

OHIO

Montgomery County

Woodland Cemetery Association of Dayton Historic District, 118 Woodland Ave., Dayton, 11000855

Stark County

Louisville Historic District, Roughly bounded by Chapel, Lincoln, St. Louis Ct., Nickelplate, E. Gorgas, & Center Ct., Louisville, 11000856

VIRGINIA

Lancaster County

Village of Morattico Historic District, Portions of Morattico Rd., Riverside, & Saltwater Drs., Church, & Sea Shell Lns., Mulberry Creek, & Water View Rds., Morattico, 11000857

[FR Doc. 2011–28331 Filed 11–1–11; 8:45 am]

BILLING CODE 4312–51–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–802]

Certain Light-Emitting Diodes and Products Containing Same Determination Not To Review an Initial Determination

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 5) granting complainants' unopposed motion to amend the complaint and notice of investigation.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, *telephone:* (202) 205–3065. 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 (*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: This investigation was instituted on August 31, 2011, based on a complaint filed with the U.S. International Trade Commission on July 27, 2011, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of LG Electronics, Inc. of Seoul, Korea and LG Innotek Co., Ltd. of Seoul, Korea (collectively, ''LG''). 76 FR 54254 (August 31, 2011). The complaint alleged 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 light emitting diodes and products containing same by reason of infringement of certain claims of U.S. Patent Nos. 7,928,465; 7,956,364; 6,841,802; 7,649,210; 7,884,388; 7,821,024; 7,868,348; and 7,768,025. The complaint named as respondents OSRAM GmbH of Munich, Germany; OSRAM Sylvania Inc. of Danvers, Massachusetts; and OSRAM Opto Semiconductors GmbH of Regensburg, Germany (collectively, ''OSRAM'').

On September 9, 2011, LG filed an unopposed motion for leave to amend the complaint and notice of investigation and LG and OSRAM filed a joint motion for an extension of time to respond to the complaint and notice of investigation. Specifically, LG requested leave (a) To correct the name of OSRAM GmbH, which recently changed its name to OSRAM AG; (b) to add as respondents Hella KgaA Hueck & Co. of Lippstadt, Germany, Hella Electronics Corp. of Plymouth Township, Michigan, Hella Corporate Center USA of Plymouth Township, Michigan, Hella, Inc. of Peachtree City, Georgia, (collectively, ''Hella''), Automotive Lighting Reutlingen GmbH of Baden-Württemberg, Germany, Automotive Lighting LLC of Auburn Hills, Michigan, Tecnologia de Iluminacion Automotriz S.A. de C.V. of Chihuahua, Mexico (collectively, ''Automotive Lighting''), and OSRAM Opto Semiconductors Inc. of Sunnyvale, California; and (c) to correct a typographical error and update the Harmonized Tariff Schedule section of the complaint. On September 28, 2011, the ALJ granted LG's motion for leave, which constituted the ID. No petitions for review were filed.

The Commission has determined not to review the subject ID.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of section 210.42(h) of the Commission's Rules of Practice and Procedure (19 CFR 210.42(h)).

Issued: October 27, 2011.

By order of the Commission.

James R. Holbein,

Secretary to the Commission.

[FR Doc. 2011–28287 Filed 11–1–11; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1574]

Establishment of the Attorney General's National Task Force on Children Exposed to Violence

AGENCY: Office of Juvenile Justice and Delinquency Prevention (OJJDP)

ACTION: Notice of establishment of federal advisory committee.

SUMMARY: The Attorney General's National Task Force on Children Exposed to Violence (the Task Force) is established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. 2. The Task Force will provide the Attorney General with valuable advice on a broad array of issues to address the national problem of children's exposure to violence. The Task Force will conduct 4 public hearings at various locations around the nation to gather information from key professionals, academics, policy makers, and the public about the extent of the problem of childhood exposure to violence and promising practices for preventing and mitigating the effects of childhood exposure to violence. Based on information gathered at these hearings, the Task Force will develop and provide to the Attorney General a report, which will include high-level policy advice and recommendations regarding preventing children's exposure to violence and mitigating the negative effects experienced by children who are exposed to violence. The Task Force is necessary and in the public interest. The Task Force Charter will terminate on December 31, 2012.

FOR FURTHER INFORMATION CONTACT: Will Bronson, Designated Federal Officer (DFO), Office of Juvenile Justice and Delinquency Prevention, 810 Seventh Street Northwest, Washington, DC 20531; Phone: (202) 305–2427 [**Note:** this is not a toll-free number]; Email: *willie.bronson@usdoj.gov.*

Will Bronson,

Deputy Associate Administrator, Child Protection Division, OJJDP and Task Force DFO, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs.

[FR Doc. 2011–28319 Filed 11–1–11; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1575]

Hearing of the Attorney General's National Task Force on Children Exposed to Violence

AGENCY: Office of Juvenile Justice and Delinquency Prevention (OJJDP).

ACTION: Notice of hearing.

SUMMARY: This is an announcement of the first hearing of the Attorney General's National Task Force on Children Exposed to Violence (hereafter refered to as the Task Force). The Task Force is chartered to provide the Attorney General with valuable advice in the areas of children's exposure to

violence for the purpose of addressing the epidemic levels of exposure to violence faced by our nation's children. Based on the testimony at four public hearings, on comprehensive research, and on extensive input from experts, advocates, and impacted families and communities nationwide, the Task Force will issue a final report to the Attorney General presenting its findings and comprehensive policy recommendations in the fall of 2012.

DATES: The hearing will take place on Tuesday, November 29, and Wednesday, November 30, 2011.

ADDRESSES: The hearing will take place at the University of Maryland Francis King Carey School of Law, 500 W. Baltimore Street, Baltimore, MD.

FOR FURTHER INFORMATION CONTACT: Will Bronson, Task Force Designated Federal Officer (DFO) and Deputy Associate Administrator, Child Protection Division, Office of Juvenile Justice & Delinquency Prevention, Office of Justice Programs, 810 7th Street NW., Washington, DC 20531. Phone: (202) 305–2427 [**Note**: this is not a toll-free number]; email: *willie.bronson@usdoj.gov.*

SUPPLEMENTARY INFORMATION: This hearing is being convened to provide information to the Task Force members about the issue of children's exposure to violence. The final agenda is subject to adjustment, but it is anticipated that on November 29, 2011, there will be a morning and afternoon session, with a break for lunch. The morning session will likely include welcoming remarks and introductions, and panel presentations from invited guests on the impact of children's exposure to violence. The afternoon session will likely include presentations from experts invited to brief the Task Force on measuring and describing children's exposure to violence, and several existing programs that attempt to address this epidemic. Opportunities for public comment will occur in the afternoon on November 29th. On November 30th, there will be a morning and afternoon session, with a brief break for lunch. The morning session will include a review of material presented during the previous day and planning for subsequent hearings. The afternoon session will include a discussion on the structure of the final report.

This meeting is open to the public. Members of the public who wish to attend this meeting must provide photo identification upon entering the hearing facility. Those wishing to provide public testimony during the hearings should register with Will Bronson at the above address at least seven (7) days in advance of the meeting. Registrations will be accepted on a space available basis. Testimony will not be allowed without prior registration. Please bring photo identification and allow extra time prior to the meeting for your arrival. Persons interested in providing written testimony to the Task Force should submit their written comments to the DFO at least seven (7) days prior to the hearing.

Anyone requiring special accommodations should notify Mr. Bronson at least seven (7) days in advance of the meeting.

Will Bronson,

Deputy Associate Administrator, Child Protection Division and National Task Force on Children Exposed to Violence Designated Federal Officer, Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs.

[FR Doc. 2011–28322 Filed 11–1–11; 8:45 am]

BILLING CODE 4410–18–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

Notice: (11–112)

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: All comments should be addressed Lori Parker, Office of the Chief Information Officer, Mail Suite 2S65, National Aeronautics and Space Administration, Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Lori Parker, Office of the Chief Information Officer, NASA Headquarters, 300 E Street, SW., Mail Suite 2S65, Washington, DC 20546, (202) 358–1351, *lori.parker@nasa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The purpose of this ICR is to consolidate, streamline, and update the administration of data collection instruments designed to gather information on change, or growth, made in various domains of STEM awareness, motivation and efficacy, and career pathways, as it relates to NASA's Summer of Innovation. These outcomes are not available unless collected via surveys to students and teachers. The evaluation is an important opportunity to examine the extent to which the SOI-supported activities meet their intended objectives.

II. Method of Collection

Electronic Survey.

III. Data

Title: NASA Summer of Innovation (SOI).

OMB Number: 2700–0150 and 2700–0151.

Type of Review: New.

Affected Public: Individuals or households.

Estimated Number of Respondents: 51640.

Estimated Time per Response: Voluntary.

Estimated Total Annual Burden Hours: 10023.

Estimated Total Annual Cost: $147,856.

IV. Requests for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including automated collection techniques or the use of other forms of information technology.

Lori Parker,

NASA PRA Clearance Officer.

[FR Doc. 2011–28432 Filed 11–1–11; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (11–110)]

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, copyright-only license world-wide to software and its documentation described in NASA Case Nos. ARC–16157–1A, entitled ''OCA Mirroring Systems (OCAMS),'' ARC–15654–1A, entitled ''Brahms: A Multiagent Simulation/Execution Environment For The Brahms Multiagent Language,'' ARC–16160–1B, entitled ''Mobile Agents Architecture,'' ARC–16160–1A, entitled ''Individual Mobile Agents System (iMAS) and the Metabolic Rate Adviso,'' and ARC–16766–1, entitled ''Collaborative Infrastructure,'' to Maarten Sierhuis with his principal place of business at 865 Wisconsin Street, San Francisco, CA 94107. The copyright in the software and documentation 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 Patent Counsel, Office of Chief Counsel, NASA Ames Research Center, Mail Stop 202A–4, Moffett Field, CA 94035–1000. (650) 604–5104; Fax (650) 604–2767.

FOR FURTHER INFORMATION CONTACT: Robert M. Padilla, Chief Patent Counsel, Office of Chief Counsel, NASA Ames Research Center, Mail Stop 202A–4, Moffett Field, CA 94035–1000. (650) 604–5104; Fax (650) 604–2767. Information about other NASA inventions available for licensing can be found online at *http://www.nasa.gov/offices/ipp/centers/arc/home/index.html.*

Dated: October 27, 2011.

Richard W. Sherman,

Deputy General Counsel.

[FR Doc. 2011–28435 Filed 11–1–11; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 11–111]

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 No. 6,972,056 B1; NASA Case No. ARC–14733–1 entitled ''Carbon Nanotube Purification,'' to Ultora, Inc., having its principal place of business at 843 Saint Kitts Court, San Jose CA 95127. The patent rights in this invention have been assigned to the United States of America as represented by the Administrator of the National Aeronautics and Space Administration. The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

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 Patent Counsel, Office of Chief Counsel, NASA Ames Research Center, Mail Stop 202A–4, Moffett Field, CA 94035–1000. (650) 604–5104; Fax (650) 604–2767.

FOR FURTHER INFORMATION CONTACT: Robert M. Padilla, Chief Patent Counsel, Office of Chief Counsel, NASA Ames Research Center, Mail Stop 202A–4, Moffett Field, CA 94035–1000. (650) 604–5104; Fax (650) 604–2767. Information about other NASA inventions available for licensing can be found online at *http://www.nasa.gov/offices/ipp/centers/arc/home/index.html.*

Dated: October 27, 2011.

Richard W. Sherman,

Deputy General Counsel.

[FR Doc. 2011–28437 Filed 11–1–11; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (11–109)]

Privacy Act of 1974; Privacy Act System of Records

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of proposed revisions to an existing Privacy Act system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), the National Aeronautics and Space Administration is issuing public notice of its proposal to modify its existing system of records entitled ''NASA Freedom of Information Act System.'' System modifications are set forth below under the caption **SUPPLEMENTARY INFORMATION.**

DATES: Submit comments within 30 calendar days from the date of this publication. This system will be effective as proposed at the end of the comment period unless comments are received which would require a contrary determination.

ADDRESSES: Patti F. Stockman, Privacy Act Officer, Office of the Chief Information Officer, National Aeronautics and Space Administration Headquarters, Washington, DC 20546–0001, (202) 358–4787, *NASA-PAOfficer@nasa.gov.*

FOR FURTHER INFORMATION CONTACT: NASA Privacy Act Officer, Patti F. Stockman, (202) 358–4787, *NASA-PAOfficer@nasa.gov.*

SUPPLEMENTARY INFORMATION: Modifications to the NASA systems of records include an additional location; clarification of the categories of individuals covered by, records in, and users of, the system; update of how records are retrieved and the locations

of the records; and elaboration of records access procedures.

Linda Y. Cureton,

NASA Chief Information Officer.

NASA 10FOIA

SYSTEM NAME:

NASA Freedom of Information Act System.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Locations 1–11 and 18, as set forth in Appendix A.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals or their representatives who have submitted Freedom of Information Act (FOIA)/Privacy Act (PA) requests for records and/or FOIA administrative appeals with NASA; individuals whose requests for records have been referred to the Agency by other agencies; individuals who are the subject of such requests, appeals; and/or the NASA personnel assigned to handle such requests and appeals.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of records created or compiled in response to FOIA, FOIA/PA or PA requests for records or subsequent administrative appeals and may include: The requester's name, address, telephone number, email address; the original requests and administrative appeals; responses to such requests and appeals; all related memoranda, correspondence, notes, and other related or supporting documentation, and in some instances copies of requested records and records under administrative appeal.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

51 U.S.C. 20113; 44 U.S.C. 3101; 5 U.S.C 552; 14 CFR part 1206.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

This system is maintained for the purpose of processing and tracking access requests and administrative appeals under the FOIA; for the purpose of maintaining a FOIA administrative record regarding Agency action on such requests and appeals; and for the Agency in carrying out any other responsibilities under the FOIA and applicable executive orders. Any disclosures of information will be compatible with the purpose for which the Agency collected the information. The records and information in these records may be disclosed in accordance with a NASA standard routine uses as set forth in Appendix B.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records in this system are maintained in paper files; copies may also be maintained in electronic format.

RETRIEVABILITY:

Information is retrieved by FOIA case file numbers.

SAFEGUARDS:

Approved security plans for these systems have been established in accordance with OMB Circular A–130, Management of Federal Information Resources. Individuals will have access to the system only in accordance with approved authentication methods. Only key authorized employees with appropriately configured system roles can access the systems and only from workstations within the NASA's Intranet.

RETENTION AND DISPOSAL:

Records are retained and disposed of in accordance with the guidelines defined in the NASA Procedural Requirements (NPR) 1441.1D, NASA Records Retention Schedules (NRRS), Schedule 1, Item 49.

SYSTEM MANAGER(S) AND ADDRESS:

System Manager: Principal Agency FOIA Officer, Office of Public Affairs, Location 1, as set forth in Appendix A. Subsystem Managers: Center FOIA Officers, located within locations 2–11 and 18, as set forth in Appendix A.

NOTIFICATION PROCEDURE:

Individuals interested in inquiring about their records should notify the system manager or subsystem manager at the appropriate NASA Center, as set forth in Appendix A.

RECORD ACCESS PROCEDURE:

Individuals seeking to access their FOIA case file should submit their request in writing to the system manager or subsystem manager at the appropriate NASA Center, as set forth in Appendix A. The request envelope should be clearly marked, ''FREEDOM OF INFORMATION REQUEST FOR ACCESS.'' The request should include a general description of the records sought, FOIA case file number, and must include your full name, current address and the date. The request must be signed and either notarized or submitted under penalty of perjury. In some cases, the system manager may require a notarized signature. Some information may be exempt from access in accordance with FOIA regulations.

CONTESTING RECORD PROCEDURES:

The NASA regulations governing access to records, procedures for contesting the contents and for appealing initial determinations are set forth in Title14, Code of Federal Regulations, Part 1212.

RECORD SOURCE CATEGORIES:

Information is collected directly from individuals making Freedom of Information Act requests.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2011–28387 Filed 11–1–11; 8:45 am]

BILLING CODE P

NEIGHBORHOOD REINVESTMENT CORPORATION

Finance, Budget & Program Committee Board of Directors Meeting; Sunshine Act

TIME & DATE: 10 a.m., Thursday, November 3, 2011.

PLACE: 1325 G Street, NW., Suite 800, Boardroom, Washington, DC 20005.

STATUS: Open.

CONTACT PERSON FOR MORE INFORMATION: Erica Hall, Assistant Corporate Secretary (202) 220–2376; *ehall@nw.org.*

AGENDA:

I. Call To Order
II. Executive Session
III. Financial Report
III. Budget Report
IV. Lease Update
V. Corporate Scorecard
VI. NFMC & EHLP
VII. Program Updates
VIII. Adjournment

Erica Hall,

Assistant Corporate Secretary.

[FR Doc. 2011–28473 Filed 10–31–11; 11:15 am]

BILLING CODE 7570–02–P

NUCLEAR REGULATORY COMMISSION

[NRC–2011–0254]

Common-Cause Failure Analysis in Event and Condition Assessment: Guidance and Research, Draft Report for Comment

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment a draft NUREG, NUREG–xxxx, Revision 0, ''Common-Cause Failure Analysis in Event and Condition Assessment: Guidance and Research, Draft Report for Comment.''

DATES: Submit comments by January 31, 2011. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID NRC–2011–0254 in the subject line of your comments. For additional instructions on submitting comments and instructions on accessing documents related to this action, see ''Submitting Comments and Accessing Information'' in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for documents filed under Docket ID NRC–2011–0254. Address questions about NRC dockets to Carol Gallagher (301) 492–3668; email *Carol.Gallagher@nrc.gov.*
- *Mail comments to:* Mail comments to: Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB–05–B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by fax to RADB at (301) 492–3446.
- *Fax comments to:* RADB at (301) 492–3446.

FOR FURTHER INFORMATION CONTACT: Song-Hua Shen, Division of Risk Analysis, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; *telephone:* (301) 251–7571, *email: Song-Hua.Shen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Submitting Comments and Accessing Information

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, *http://www.regulations.gov.* Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- *NRC's Public Document Room (PDR):* The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* Publicly available documents created or received at the NRC are available online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1–(800) 397–4209, (301) 415–4737, or by email to *pdr.resource@nrc.gov.* The draft NUREG is available electronically under ADAMS Accession No. ML111890290. The draft NUREG will also be accessible through the NRC's public site under draft NUREGs for comment.
- *Federal Rulemaking Web Site:* Public comments and supporting materials related to this notice can be found at *http://www.regulations.gov* by searching on Docket ID NRC–2011–0254.

Discussion

The draft NUREG offers guidance for assessing common-cause failure (CCF) potential at the level of the observed performance deficiency, provides essential definitions of technical terms, and describes the treatment of CCF for a number of categories of component failures and outages.

Dated at Rockville, Maryland, this 26 day of October, 2011.

For the Nuclear Regulatory Commission.

Gary DeMoss,

Chief, Performance and Reliability Branch, Division of Risk Analysis, Office of Nuclear Regulatory Research.

[FR Doc. 2011–28385 Filed 11–1–11; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 70–3103; NRC–2010–0264]

Notice of Availability of Uranium Enrichment Fuel Cycle Facility's Inspection Reports Regarding Louisiana Energy Services, National Enrichment Facility, Eunice, NM, Prior to the Commencement of Operations

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: Gregory Chapman, Project Manager, Uranium Enrichment Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Rockville, Maryland, 20852. *Telephone:* (301) 492–3106; *email: Gregory.Chapman@nrc.gov*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC or the Commission) staff has conducted inspections of the Louisiana Energy Services (LES), LLC's, National Enrichment Facility in Eunice, New Mexico, and has verified that Cascades 3 and 4 of the facility have been constructed in accordance with the requirements of the approved license. The NRC staff has prepared inspection reports documenting its findings in accordance with the requirements of the NRC Inspection Manual. On August 23, 2011, the Commission authorized the licensee to start operations of Cascades 3 and 4. The publication of this Notice satisfies the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 70.32 (k) and Section 193(c) of the Atomic Energy Act of 1954, as amended.

The introduction of uranium hexafluoride into any module of the National Enrichment Facility is not permitted until the Commission completes an operational readiness and management measures verification review to verify that management measures that ensure compliance with the performance requirements of 10 CFR 70.61 have been implemented and confirms that the facility has been constructed in accordance with the license and will be operated safely. Subsequent operational readiness and management measures verification reviews will continue throughout the various phases of plant construction; and, upon completion of these subsequent phases, additional notices will be posted to verify that the phase in question has been constructed in

accordance with the license and to acknowledge licensee readiness for operations. As additional cascades are made available for inspection, the Commission will determine whether they are authorized for use. Any cascade authorizations will be discussed in the additional notices.

II. Further Information

Documents related to this action are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are:

Inspection report No.	Date	ADAMS accession No.
70–3103/2009–002	06–26–2009	ML091770643
70–3103/2010–007	03–31–2010	ML100900329
70–3103/2010–010	05–28–2010	ML101480080
70–3103/2010–012	07–21–2010	ML102020385
70–3103/2010–013	08–20–2010	ML102320298
70–3103/2010–015	12–22–2010	ML103560272
70–3103/2011–006	03–31–2011	ML11090A037
70–3103/2011–008	06–15–2011	ML111660886
70–3103/2011–011	09–19–2011	ML11263A098

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room Reference staff at 1–(800) 397–4209, (301) 415–4737 or by email to *pdr.resource@nrc.gov.*

These documents may also be viewed electronically on the public computers located at the NRC's Public Document Room (PDR), O1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland this 24th day of October 2011.

For the U.S. Nuclear Regulatory Commission.

Brian W. Smith,

Chief, Uranium Enrichment Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2011–28386 Filed 11–1–11; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–21; Order No. 925]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Saratoga, Arkansas post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: *November 2, 2011:* Administrative record due (from Postal Service); November 15, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 18, 2011, the Commission received a petition for review of the Postal Service's determination to close the Saratoga post office in Saratoga, Arkansas. The petition for review was filed by Dale Gathright, Jr. (Petitioner) and is postmarked October 12, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–21 to consider Petitioner's appeal. If Petitioner would like to further explain their position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 22, 2011.

Issue apparently raised. Petitioner contends that the Postal Service failed to consider the effect of the closing on the community. *See* 39 U.S.C. 404(d)(2)(A)(i).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 2, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 2, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participants' submissions also will be posted on the Commission's Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online)

pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

The Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than Petitioner and respondent, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 15, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by the Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than November 2, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 2, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Katrina R. Martinez is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

October 18, 2011	Filing of Appeal.
November 2, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 2, 2011	Deadline for the Postal Service to file any responsive pleading.
November 15, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 22, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 12, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 27, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 3, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 6, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28328 Filed 11–1–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–25; Order No. 929]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Glenwood, Alabama post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 4, 2011: Administrative record due (from Postal Service); November 21, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 20, 2011, the Commission received a petition for review of the Postal Service's determination to close the Glenwood post office in Glenwood, Alabama. The petition for review was filed by Dan Jackson, Mayor, Town of Glenwood (Petitioner) and is postmarked October 13, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–25 to consider Petitioner's appeal. If Petitioner would like to further explain his position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 25, 2011.

Categories of issues apparently raised. Petitioner contends that (1) the Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to consider whether or not it could continue to provide a maximum degree of effective and regular postal services to the community. (*see* 39 U.S.C. 404(d)(2)(A)(iii)); and (3) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 4, 2011.

See 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 4, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 21, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than November 4, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 4, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Pat Gallagher is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

October 20, 2011	Filing of Appeal.
November 4, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 4, 2011	Deadline for the Postal Service to file any responsive pleading.
November 21, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 25, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 15, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 30, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 6, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 10, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28333 Filed 11–1–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–22; Order No. 926]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Sattley/Calpine, California post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 4, 2011: Administrative record due (from Postal Service); November 21, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 20, 2011, the Commission received two petitions for review of the Postal Service's determination to close the Sattley/Calpine post office in Calpine, California. The petitions for review were

filed by Bill Nunes and Beverly Mitchell (Petitioners) with the earliest postmarked October 6, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–22 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 25, 2011.

Categories of issues apparently raised. Petitioners contend that (1) the Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); (2) the Postal Service failed to consider whether or not it could continue to provide a maximum degree of effective and regular postal services to the community. (*see* 39 U.S.C. 404(d)(2)(A)(iii)); (3) the Postal Service failed to adequately consider the economic savings resulting from the closure (*see* 39 U.S.C. 404(d)(2)(A)(iv)); (4) Petitioners contend that there are factual errors contained in the Final Determination; and (5) Petitioners contend that the Postal Service failed to provide substantial evidence in support of the determination (*see* 39 U.S.C. 404(d)(5)(c)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 4, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 4, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 21, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than November 4, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 4, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Richard Oliver is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

October 20, 2011	Filing of Appeal.
November 4, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 4, 2011	Deadline for the Postal Service to file any responsive pleading.
November 21, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 25, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 15, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 30, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 6, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 3, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28329 Filed 11–1–11; 8:45 am]
BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–23; Order No. 927]

Post Office Closing

AGENCY: Postal Regulatory Commission.
ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Fairfield, Kentucky post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 4, 2011: Administrative record due (from Postal Service); November 21, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 20, 2011, the Commission received a petition for review and application for suspension of the Postal Service's determination to close the Fairfield post office in Fairfield, Kentucky. The petition for review was filed by William T. Trent, Mayor of the City of Fairfield (Petitioner) and is postmarked October 12, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–23 to consider Petitioner's appeal. If Petitioner would like to further explain his position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 25, 2011.

Categories of issues apparently raised. Petitioner contends that the Postal Service: (1) Failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)) and (2) failed to consider whether or not it could continue to provide a maximum degree of effective and regular postal services to the community. (*see* 39 U.S.C. 404(d)(2)(A)(iii)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 4, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 4, 2011.

Application for Suspension of Determination. In addition to his Petition, William T. Trent, Mayor of the City of Fairfield requests an application for suspension of the Postal Service's determination (*see* 39 CFR 3001.114). Commission rules allow for the Postal Service to file an answer to such application within 10 days after the application is filed. The Postal Service shall file an answer to the application no later than October 31, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 21, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than November 4, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 4, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Tracy Ferguson is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Shoshana M. Grove,
Secretary.

PROCEDURAL SCHEDULE

October 20, 2011	Filing of Appeal.
October 31, 2011	Deadline for application for suspension of determination.
November 4, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 4, 2011	Deadline for the Postal Service to file any responsive pleading.
November 21, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 25, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 15, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 30, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 6, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 9, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28330 Filed 11–1–11; 8:45 am]
BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–27; Order No. 932]

Post Office Closing

AGENCY: Postal Regulatory Commission.
ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the St. Olaf, Iowa post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 4, 2011: Administrative record due (from Postal Service); November 21, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 20, 2011, the Commission received a petition for review of the Postal Service's determination to close the St. Olaf post office in St. Olaf, Iowa. The petition for review was filed by Adam Meyer, Mayor, and City Council of St. Olaf (Petitioners) and is postmarked October 13, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–27 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 25, 2011.

Categories of issues apparently raised. Petitioners contend that the Postal Service failed to consider whether or not it will continue to provide a maximum degree of effective and regular postal services to the community (*see* 39 U.S.C. 404(d)(2)(A)(iii)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 4, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 4, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 21, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other

participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than November 4, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 4, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, James Waclawski is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

October 20, 2011	Filing of Appeal
November 4, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 4, 2011	Deadline for the Postal Service to file any responsive pleading.
November 21, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 25, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 15, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 30, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 6, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 10, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28414 Filed 11–1–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–26; Order No. 931]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Lodi, Texas post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: November 4, 2011: Administrative record due (from Postal Service); November 21, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 20, 2011, the Commission received a petition for review of the Postal Service's determination to close the Lodi post office in Lodi, Texas. The petition for review was filed by Tammy Cornett (Petitioner) and is postmarked October 11, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–26 to consider Petitioner's appeal. If Petitioner would like to further explain her position with supplemental information or facts, Petitioner may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 25, 2011.

Categories of issues apparently raised. Petitioner contends that (1) The Postal Service failed to consider the effect of the closing on the community (*see* 39 U.S.C. 404(d)(2)(A)(i)); and (2) failure of the Postal Service to follow procedures required by law regarding closures (*see* 39 U.S.C. 404(d)(5)(B)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 4, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 4, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 21, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

1. The Postal Service shall file the applicable administrative record regarding this appeal no later than November 4, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 4, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Malin Moench is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register.**

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

PROCEDURAL SCHEDULE

October 20, 2011	Filing of Appeal.
November 4, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 4, 2011	Deadline for the Postal Service to file any responsive pleading.
November 21, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 25, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 15, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 30, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 6, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 8, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28373 Filed 11–1–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL REGULATORY COMMISSION

[Docket No. A2012–24; Order No. 928]

Post Office Closing

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: This document informs the public that an appeal of the closing of the Ozan, Arkansas post office has been filed. It identifies preliminary steps and provides a procedural schedule. Publication of this document will allow the Postal Service, petitioners, and others to take appropriate action.

DATES: *November 4, 2011:* Administrative record due (from Postal Service); November 21, 2011, 4:30 p.m., Eastern Time: Deadline for notices to intervene. *See* the Procedural Schedule in the **SUPPLEMENTARY INFORMATION** section for other dates of interest.

ADDRESSES: Submit comments electronically by accessing the ''Filing Online'' link in the banner at the top of the Commission's Web site (*http://www.prc.gov*) or by directly accessing the Commission's Filing Online system at *https://www.prc.gov/prc-pages/filing-online/login.aspx.* Commenters who cannot submit their views electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section as the source for case-related information for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at (202) 789–6820 (case-related information) or *DocketAdmins@prc.gov* (electronic filing assistance).

SUPPLEMENTARY INFORMATION: Notice is hereby given that, pursuant to 39 U.S.C. 404(d), on October 20, 2011, the Commission received a petition for review of the Postal Service's determination to close the Ozan post office in Ozan, Arkansas. The petition for review was filed by the Customers of Ozan, Arkansas post office (Petitioners) and is postmarked October 12, 2011. The Commission hereby institutes a proceeding under 39 U.S.C. 404(d)(5) and establishes Docket No. A2012–24 to consider Petitioners' appeal. If Petitioners would like to further explain their position with supplemental information or facts, Petitioners may either file a Participant Statement on PRC Form 61 or file a brief with the Commission no later than November 25, 2011.

Categories of issues apparently raised. Petitioners contend that the Postal Service failed to consider whether or not it could continue to provide a maximum degree of effective and regular postal services to the community. (*see* 39 U.S.C. 404(d)(2)(A)(iii)).

After the Postal Service files the administrative record and the Commission reviews it, the Commission may find that there are more legal issues than the one set forth above, or that the Postal Service's determination disposes of one or more of those issues. The deadline for the Postal Service to file the applicable administrative record with the Commission is November 4, 2011. *See* 39 CFR 3001.113. In addition, the due date for any responsive pleading by the Postal Service to this notice is November 4, 2011.

Availability; Web site posting. The Commission has posted the appeal and supporting material on its Web site at *http://www.prc.gov.* Additional filings in this case and participant's submissions also will be posted on the Web site, if provided in electronic format or amenable to conversion, and not subject to a valid protective order. Information on how to use the Commission's Web site is available online or by contacting the Commission's webmaster via telephone at (202) 789–6873 or via electronic mail at *prc-webmaster@prc.gov.*

The appeal and all related documents are also available for public inspection in the Commission's docket section. Docket section hours are 8 a.m. to 4:30 p.m., Eastern Time, Monday through Friday, except on Federal government

holidays. Docket section personnel may be contacted via electronic mail at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Filing of documents. All filings of documents in this case shall be made using the Internet (Filing Online) pursuant to Commission rules 9(a) and 10(a) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained. *See* 39 CFR 3001.9(a) and 3001.10(a). Instructions for obtaining an account to file documents online may be found on the Commission's Web site, *http://www.prc.gov,* or by contacting the Commission's docket section at *prc-dockets@prc.gov* or via telephone at (202) 789–6846.

Commission reserves the right to redact personal information which may infringe on an individual's privacy rights from documents filed in this proceeding.

Intervention. Persons, other than the Petitioners and respondents, wishing to be heard in this matter are directed to file a notice of intervention. *See* 39 CFR 3001.111(b). Notices of intervention in this case are to be filed on or before November 21, 2011. A notice of intervention shall be filed using the Internet (Filing Online) at the Commission's Web site, *http://www.prc.gov,* unless a waiver is obtained for hardcopy filing. *See* 39 CFR 3001.9(a) and 3001.10(a).

Further procedures. By statute, the Commission is required to issue its decision within 120 days from the date it receives the appeal. *See* 39 U.S.C. 404(d)(5). A procedural schedule has been developed to accommodate this statutory deadline. In the interest of expedition, in light of the 120-day decision schedule, the Commission may request the Postal Service or other participants to submit information or memoranda of law on any appropriate issue. As required by Commission rules, if any motions are filed, responses are due 7 days after any such motion is filed. *See* 39 CFR 3001.21.

It is ordered:

The Postal Service shall file the applicable administrative record regarding this appeal no later than November 4, 2011.

2. Any responsive pleading by the Postal Service to this notice is due no later than November 4, 2011.

3. The procedural schedule listed below is hereby adopted.

4. Pursuant to 39 U.S.C. 505, Cassandra Hicks is designated officer of the Commission (Public Representative) to represent the interests of the general public.

5. The Secretary shall arrange for publication of this notice and order and Procedural Schedule in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

PROCEDURAL SCHEDULE

October 20, 2011	Filing of Appeal.
November 4, 2011	Deadline for the Postal Service to file the applicable administrative record in this appeal.
November 4, 2011	Deadline for the Postal Service to file any responsive pleading.
November 21, 2011	Deadline for notices to intervene (*see* 39 CFR 3001.111(b)).
November 25, 2011	Deadline for Petitioners' Form 61 or initial brief in support of petition (*see* 39 CFR 3001.115(a) and (b)).
December 15, 2011	Deadline for answering brief in support of the Postal Service (*see* 39 CFR 3001.115(c)).
December 30, 2011	Deadline for reply briefs in response to answering briefs (*see* 39 CFR 3001.115(d)).
January 6, 2011	Deadline for motions by any party requesting oral argument; the Commission will schedule oral argument only when it is a necessary addition to the written filings (*see* 39 CFR 3001.116).
February 9, 2012	Expiration of the Commission's 120-day decisional schedule (*see* 39 U.S.C. 404(d)(5)).

[FR Doc. 2011–28332 Filed 11–1–11; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Board of Governors; Sunshine Act Meeting

DATES AND TIMES: Tuesday, November 15, 2011, at 10 a.m.; and Wednesday, November 16, at 8 a.m.

PLACE: Washington, DC, at U.S. Postal Service Headquarters, 475 L'Enfant Plaza, SW., in the Benjamin Franklin Room.

STATUS: Tuesday, November 15 at 10 a.m.—Closed; Tuesday, November 15, at 1:30 p.m.—Open; November 15 at 4:30 p.m.—Closed; and Wednesday, November 16 at 8 a.m.—Closed

MATTERS TO BE CONSIDERED:

Tuesday, November 15 at 10 a.m. (Closed)

1. Strategic Issues.
2. Financial Matters.

Tuesday, November 15 at 1:30 p.m. (Open)

1. Approval of Minutes of the Previous Meetings.
2. Remarks of the Chairman of the Board Louis J. Giuliano.
3. Remarks of the Postmaster General and CEO Patrick R. Donahoe.
4. Committee Reports.
5. Consideration of FY 2011 10K, Financial Statements and Annual Report.
6. Consideration of Fiscal Year 2011 Comprehensive Statement and Annual Performance Plan.
7. Consideration of Fiscal Year 2012 Integrated Financial Plan.
8. Consideration of Final Fiscal Year 2013 Appropriation Request.
9. Quarterly Report on Service Performance.
10. Tentative Agenda for the December 13, 2011, Meeting.
11. Election of Chairman and Vice Chairman of the Board of Governors.

Tuesday, November 15 at 4:30 p.m. (Closed—Continuation)

3. Executive Session

Wednesday, November 16 at 8 a.m. (Closed—Continuation)

4. Strategic Matters
5. Pricing
6. Administrative Items
7. Executive Session

CONTACT PERSON FOR MORE INFORMATION: Julie S. Moore, Secretary of the Board, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, DC 20260–1000. Telephone (202) 268–4800.

Julie S. Moore,

Secretary.

[FR Doc. 2011–28466 Filed 10–31–11; 11:15 am]

BILLING CODE 7710–12–P

RAILROAD RETIREMENT BOARD

Actuarial Advisory Committee With Respect to the Railroad Retirement Account; Notice of Public Meeting

Notice is hereby given in accordance with Public Law 92–463 that the Actuarial Advisory Committee will hold a meeting on November 14, 2011, at 9:30 a.m. at the office of the Chief Actuary of the U.S. Railroad Retirement

Board, 844 North Rush Street, Chicago, Illinois, on the conduct of the 25th Actuarial Valuation of the Railroad Retirement System. The agenda for this meeting will include a discussion of the assumptions to be used in the 25th Actuarial Valuation. A report containing recommended assumptions and the experience on which the recommendations are based will have been sent by the Chief Actuary to the Committee before the meeting.

The meeting will be open to the public. Persons wishing to submit written statements or make oral presentations should address their communications or notices to the RRB Actuarial Advisory Committee, cio Chief Actuary, U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

Dated: October 17, 2011.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2011–28271 Filed 11–1–11; 8:45 am]

BILLING CODE M

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29851; File No. 813–00377]

Citadel LLC (formerly Citadel Investment Group, L.L.C.) and CEIF LLC; Notice of Application

October 27, 2011.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice of application for an order under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the ''Act'') granting an exemption from all provisions of the Act, except section 9 and sections 36 through 53 and the rules and regulations under those sections. With respect to sections 17 and 30 of the Act, and the rules and regulations thereunder, and rule 38a–1 under the Act, the exemption is limited as set forth in the application.

Summary of Application: Applicants request an order to exempt certain limited liability companies, limited partnerships, companies and other investment vehicles formed for the benefit of eligible employees of Citadel LLC and its affiliates (''ESC Funds'') from certain provisions of the Act. Each ESC Fund will be an ''employees' securities company'' within the meaning of section 2(a)(13) of the Act.

Applicants: Citadel LLC and CEIF LLC (''CEIF'').

DATES: *Filing Dates:* The application was filed on December 10, 2009, and amended on June 29, 2010, February 17, 2011 and October 7, 2011. Applicants have agreed to file an amendment during the notice period, the substance of which is reflected in this notice.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 21, 2011, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090; Applicants, Citadel LLC and CEIF, 131 South Dearborn Street, Chicago, Illinois 60603.

FOR FURTHER INFORMATION CONTACT: Emerson S. Davis, Senior Counsel, at (202) 551–6868, or Daniele Marchesani, Branch Chief, at (202) 551–6821 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company's name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations

1. Citadel is a global financial institution with a diverse business platform which includes alternative asset management, strategic advisory services and capital markets businesses and services. (Citadel LLC, a Delaware limited liability company, and its ''Affiliates,'' as defined in rule 12b–2 under the Securities Exchange Act of 1934 (''Exchange Act''), other than ESC Funds are referred to collectively as ''Citadel.'')

2. Citadel has established CEIF, a Delaware limited liability company and will in the future establish any other ESC Funds (collectively with CEIF, the ''ESC Funds'' and each, an ''ESC Fund'') for the benefit of Eligible Employees (defined below) as part of a program to create capital building opportunities that are competitive with those at other financial services firms and to facilitate the recruitment and retention of high caliber professionals. Each of the ESC Funds will be structured as a limited liability company, limited partnership, corporation, business trust or other entity organized under the laws of the state of Delaware or another U.S. jurisdiction. Each ESC Fund will be identical in all material respects (other than investment objectives and strategies, vesting terms, form of organization and related structural and operative provisions contained in the constitutive documents of such funds). Each ESC Fund will be an ''employees' security company'' within the meaning of section 2(a)(13) of the Act and will operate as a diversified or non-diversified management investment company. Citadel will control the ESC Funds within the meaning of section 2(a)(9) of the Act.

3. Each managing member of an ESC Fund or person acting in a similar capacity will be an Affiliate of Citadel LLC (a ''Managing Member''). Any member or partner of, or otherwise investor in, an ESC Fund is a ''Member.'' The Managing Member of each ESC Fund will manage, operate and control such ESC Fund and will have the authority to delegate investment management responsibility with respect to the acquisition, management and disposition of Portfolio Investments, as defined below, to Citadel LLC or any person (as defined under the Act) that is an Affiliate of Citadel LLC (each, a ''Citadel Entity''). Any Citadel Entity that is delegated the responsibility of making investment decisions for an ESC Fund will be registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act''), if required under applicable law.

4. The Managing Member, a Member, Citadel, Citadel Entity or any employees of the Managing Member or Citadel may be entitled to receive a performance-based fee or profits allocation (a ''carried interest'').[1] All ESC Fund investments are referred to as ''Portfolio Investments.''

5. Interests in an ESC Fund will be issued without registration in reliance on section 4(2) of the Securities Act of

[1] A ''carried interest'' is a fee paid or an allocation made to the Managing Member, a Member or the Citadel Entity acting as the investment adviser to an ESC Fund based on net gains in addition to the amount allocable to such entity in proportion to its invested capital. A Managing Member, Member or Citadel Entity that is registered as an investment adviser under the Advisers Act may be paid or allocated carried interest only if permitted by rule 205–3 under the Advisers Act.

1933 (the ''Securities Act''), Regulation D and/or Regulation S under the Securities Act and may be acquired only by ''Eligible Employees'' and ''Qualified Participants'' in each case defined below. Prior to issuing Interests to an Eligible Employee either directly or through a related Qualified Participant, a Managing Member must reasonably believe that the Eligible Employee will be a sophisticated investor capable of understanding and evaluating the risks of participation in an ESC Fund without the benefit of regulatory safeguards.

6. An ''Eligible Employee'' is an individual who is a current or former employee, officer or partner of Citadel or a director of Citadel that is an ''interested person'' as defined under the Act, and that is an ''accredited investor'' under rule 501(a)(5) or rule 501(a)(6) of Regulation D [(''Accredited Investor'')]. A ''Qualified Participant'' is an entity that is a Qualified Investment Vehicle (as defined below) and, if purchasing an Interest (as defined below) directly from an ESC, comes within one of the categories of an ''accredited investor'' under 501(a) of Regulation D. A ''Qualified Investment Vehicle'' is (a) a trust of which the trustee, grantor and/or beneficiary is an Eligible Employee or (b) a partnership, corporation or other entity controlled by an Eligible Employee. A Qualified Investment Vehicle that is not an Accredited Investor will not be permitted to invest in an ESC Fund.

7. The terms of an ESC Fund will be fully disclosed to each Eligible Employee and, if applicable, to a Qualified Participant, prior to admission to the ESC Fund. Each Eligible Employee and Qualified Participant will be furnished with access to the offering documents, including a copy of the operating agreement or other organizational documents of the relevant ESC Fund (''Operating Agreement''). The Managing Member will send each person who was a Member at any time during the fiscal year then ended (except for the first year of operations of an ESC Fund if no investment activities took place in such fiscal year), audited financial statements within 180 days after the end of the fiscal year. For purposes of this requirement ''audit'' shall have the meaning defined in rule 1–02(d) of Regulation S–X. In addition, as soon as practicable after the end of the ESC Fund's tax year, a report will be transmitted to each Member showing such Member's share of income, gains, losses, credits, deductions, and other tax items for U.S. federal income tax purposes, resulting from such ESC Fund's operations during that year.

8. Interests in the ESC Funds will be non-transferable except (i) to the extent cancelled or (ii) with the prior written consent of the Managing Member and, in any event, no person or entity will be admitted into an ESC Fund as a Member unless such person or entity is an Eligible Employee, a Qualified Participant of an Eligible Employee, or a Citadel Entity. Interests in the ESC Funds will be issued without a sales load or similar fee.

9. Ownership interests (''Interests'') in an ESC Fund may be acquired on a voluntary basis or be offered through a long-term incentive program to qualified Eligible Employees (the ''Long-Term Points Program''). Interests in a ''Participation Points ESC Fund'' may only be acquired through the Long-Term Points Program. Pursuant to the Long-Term Points Program, Eligible Employees may be issued Participation Points on the basis of, among other things, personal performance and/or firm-wide or relevant team performance results. An Eligible Employee may voluntarily acquire an Interest in a ''non-Participation Points ESC Fund.'' An Eligible Employee and/or its Qualified Participant may not make additional capital contributions to the ESC Fund in which it is invested after such Eligible Employee's employment with Citadel has terminated.

10. Both Participation Points ESC Funds and non-Participation Points ESC Funds may be offered as part of an investment program that includes vesting and cancellation provisions. In such circumstances, some or all of an Eligible Employee's Interest at the commencement of the program will be treated as being ''unvested,'' and ''vesting'' will occur only as certain conditions are satisfied under the terms of the investment program. The portion of an Eligible Employee's Interest that is ''unvested'' at the time of termination of such Eligible Employee's employment by Citadel may be subject to (a) cancellation and/or (b) the imposition of different terms and conditions, which would be described in the Operating Agreement and/or offering documents of the relevant ESC Fund and/or in other written correspondence issued to such Eligible Employee.

11. With respect to Participation Points ESC Funds, a Member will become vested in his/her Interest if (a) he/she remains employed by Citadel through a specified date and he/she has satisfied, among other things, all of the certain applicable employment and post-employment obligations (including non-competition, non-solicitation, non-disclosure and notice obligations). Non-Participation Points ESC Funds may or may not provide for vesting provisions. An Eligible Employee that purchases an Interest in a non-Participation Points ESC Fund will be immediately vested in such Interest to the extent of such purchase.

12. With respect to a non-Participation Points ESC Fund that does not provide for vesting provisions, an Eligible Employee's entire Interest may be subject to repurchase by the Managing Member and/or the imposition of different terms and conditions upon termination of such Eligible Employee's employment by Citadel, as described in the Operating Agreement and/or offering documents of the relevant ESC Fund and/or in other written correspondence issued to such Eligible Employee. Upon any repurchase of an Eligible Employee's vested Interests, the Managing Member will at a minimum pay to the Eligible Employee the lesser of (a) the amount actually paid by the by the Eligible Employee to acquire the Interest plus interest, less prior distributions and (b) the fair market value of the Interests determined at the time of repurchase by the Managing Member. The terms of any repurchase or cancellation of Interests will apply equally to an Eligible Employee and any Qualified Participant of such Eligible Employee.

13. Subject to the terms of the applicable Fund Operating Agreement and/or offering documents, an ESC Fund will be permitted to enter into transactions involving (i) a Citadel Entity, (ii) any Member or person or entity affiliated with a Member or (iii) an investment fund or separate account, organized in part for the benefit of investors who are not Affiliates of Citadel and over which a Citadel Affiliate exercises investment discretion (a ''Citadel Third Party Fund''). Prior to entering into any of these transactions, the Managing Member will make the findings required in Condition 1 below. A Citadel Entity (including the Managing Member) also may be compensated for providing services or financing from entities in which an ESC Fund (directly or indirectly) makes an investment, from competitors of such entities or from other unaffiliated persons or entities.

14. The investment objective of each ESC Fund will be set forth in the ESC Fund's offering documents. Each ESC Fund (directly or indirectly through its investments in Citadel Third Party Funds) may be engage in various investment strategies implemented by Citadel in markets around the world.[2]

[2] Applicants are not requesting any exemption from any provision of the Act or any rule

An ESC Fund may invest directly in securities and similar investments (including, without limitation, exchange-traded funds, mutual funds and index funds) and/or may invest all or substantially all of its assets in Citadel Third Party Funds. An ESC Fund will not acquire any security issued by a registered investment company if, immediately after the acquisition, such ESC Fund will own more than 3% of the outstanding voting stock of the registered investment company.

15. If the Managing Manager or a Citadel Entity makes a loan to an ESC Fund, the loan would bear interest at a rate no less favorable to the ESC Fund than the rate that could be obtainable in an arm's-length transaction. An Eligible Employee will not borrow from any person if the borrowing would cause any person not named in section 2(a)(13) of the Act to own outstanding securities of the ESC Fund (other than short-term paper). Any borrowing by an ESC Fund will be non-recourse to the Members.

Applicants' Legal Analysis

1. Section 6(b) of the Act provides, in part, that the Commission will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the Commission will consider, in determining the provisions of the Act from which the employees' securities companies should be exempt, the company's form of organization and capital structure, the persons owning and controlling its securities, the price of the company's securities and the amount of any sales load, how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company, in relevant part, as any investment company all of whose securities (other than short-term paper) are beneficially owned (a) By current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

2. Section 7 of the Act generally prohibits investment companies that are not registered under section 8 of the Act from selling or redeeming their securities. Section 6(e) of the Act provides that, in connection with any order exempting an investment company from any provision of section 7, certain provisions of the Act, as specified by the Commission, will be applicable to the investment company and other persons dealing with the investment company as though the investment company were registered under the Act. Applicants request an order under sections 6(b) and 6(e) of the Act exempting the Applicants and any ESC Funds from all provisions of the Act, except section 9 and sections 36 through 53 and the rules and regulations under those sections. With respect to sections 17 and 30 of the Act, and the rules and regulations thereunder, and rule 38a–1 under the Act, the exemption is limited as set forth in the application.

3. Section 17(a) generally prohibits any affiliated person of a registered investment company, or any affiliated person of an affiliated person, acting as principal, from knowingly selling or purchasing any security or other property to or from the investment company. Applicants requests an exemption from section 17(a) to permit: (a) A Citadel Entity or a Citadel Third Party Fund (or any affiliated person of such Third Party Fund), acting as principal, to engage in any transaction directly or indirectly with any ESC Fund or any company controlled by such ESC Fund; (b) any ESC Fund to invest in or engage in any transaction with any Citadel Entity, or Citadel Third Party Fund, acting as principal, (i) in which such ESC Fund, any company controlled by such ESC Fund or any Citadel Entity or Citadel Third Party Fund has invested or will invest; or (ii) with which such ESC Fund, any company controlled by such ESC Fund or any Citadel Entity or Citadel Third Party Fund is or will otherwise become affiliated.

4. Applicants submit that an exemption from section 17(a) is consistent with the purposes of each ESC Fund and the protection of investors and is necessary to promote the basic purpose of such ESC Fund. Applicants state that the Members of each ESC Fund will be fully informed of the possible extent of such ESC Fund's dealings with Citadel and, as professionals with experience in financial services businesses, Members will be able to understand and evaluate the attendant risks. Applicants assert that the community of interest among the Members in each ESC Fund and Citadel is the best insurance against any risk of abuse.

5. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from participating in any joint enterprise or joint arrangement with the company unless authorized by the Commission. Applicants request relief to permit affiliated persons of each ESC Fund or affiliated persons of such persons to participate in, or effect any transaction in connection with, any joint enterprise or joint arrangement or profit-sharing plan in which an ESC Fund or a company controlled by such ESC Fund is a participant.

6. Applicants assert that compliance with section 17(d) would cause an ESC Fund to forego investment opportunities simply because a Member or any other affiliated person of the ESC Fund (or any affiliate of such a person) also had, or contemplated making, a similar investment. Applicants also submit that co-investment opportunities with Citadel are advantageous to Eligible Employees because (a) the resources of Citadel enable it to analyze investment opportunities to the extent that Eligible Employees would have neither the time nor resources to duplicate, (b) investments made by Citadel will not be generally available to investors even if the financial status of the Eligible Employees would enable them to otherwise participate in such opportunities and (c) Eligible Employees will be able to pool their resources in co-investments, thus achieving greater diversification of their individual portfolios. Applicants note that each ESC Fund will be primarily organized for the benefit of Eligible Employees as an incentive for them to remain with Citadel and for the generation and maintenance of goodwill through an investment in Citadel Third Party Funds. Applicants assert that the flexibility to structure co-investments and joint investments will not involve abuses of the type section 17(d) and rule 17d–1 were designed to prevent.

7. Side-by-side investments held by a Citadel Third Party Fund, or by a Citadel Entity in a transaction in which the Citadel investment was made pursuant to a contractual obligation to a Citadel Third Party Fund will not be subject to condition 3 below. Applicants note that Citadel is likely to invest its own capital in Citadel Third Party Fund investments and that such investments will be subject to substantially the same terms as those applicable to such Citadel Third Party Fund, except otherwise disclosed in the offering documents and/or Operating Agreement of the relevant ESC Fund. In addition, applicants assert that the relationship of an ESC Fund to a Citadel Third Party

thereunder that may govern the eligibility of an ESC Fund to invest in an entity relying on section 3(c)(1) or 3(c)(7) of the Act or any such entity's status under the Act.

Fund is fundamentally different from such ESC Fund's relationship to Citadel. Applicants contend that the focus of, and the rationale for, the protections contained in the requested relief are to protect the ESC Funds from any overreaching by Citadel in the employer/employee context, whereas the same concerns are not present with respect to the ESC Funds vis-à-vis the investors in a Citadel Third Party Fund.

8. Section 17(f) of the Act designates the entities that may act as investment company custodians, and rule 17f–1 under the Act imposes certain requirements when the custodian is a member of a national securities exchange. Applicants request an exemption from section 17(f) and rule 17f–1 to permit a Citadel Entity to act as custodian without a written contract. Applicants also request an exemption from the rule 17f–1(b)(4) requirement that an independent accountant periodically verify the assets held by the custodian. Applicants state that, given the community of interest of all the parties involved and the existing requirement for an independent audit, compliance with the rule's requirement would be unnecessary. Each ESC Fund will otherwise comply with all the provisions of rule 17f–1.

9. Applicants also request an exemption from rule 17f–2 to permit the following exceptions from the requirements of rule 17f–2: (a) An ESC Fund's investments may be kept in the locked files of the Managing Member (or a Citadel Entity) for purposes of paragraph (b) of the rule; (b) for purposes of paragraph (d) of the rule, (i) employees of the Managing Member (or a Citadel Entity) will be deemed to be employees of the ESC Funds, (ii) officers or managers of the Managing Member of an ESC Fund (or a Citadel Entity) will be deemed to be officers of the ESC Fund, and (iii) the Managing Member will be deemed to be the board of directors of the ESC Fund; and (c) in place of the verification procedure under paragraph (f) of the rule, verification will be effected quarterly by two high level employees of the Managing Member (or another Citadel Entity). Applicants expect that most of their investments may be evidenced only by partnership agreements, participation agreements or similar documents, rather than by negotiable certificates that could be misappropriated. Applicants believe that these instruments are most suitably kept in the files of the Managing Member (or a Citadel Entity), where they can be referred to as necessary.

10. Section 17(g) of the Act and rule 17g–1 under the Act generally require the bonding of officers and employees of a registered investment company who have access to its securities or funds. Rule 17g–1 requires that a majority of directors who are not interested persons take certain actions and give certain approvals relating to fidelity bonding. Applicants request exemptive relief to permit the Managing Member, regardless of whether it is deemed an interested person of the ESC Funds, to take actions and make determinations set forth in the rule. Applicants state that the ESC Funds are unable to comply with Rule 17g–1 because the ESC Funds will not have a board of directors and that the Managing Member of the ESC Fund will be an interested person of the ESC Funds. Applicants also state that the ESC Funds will comply with all other requirements of rule 17g–1, except that the Applicants request an exemption from the requirements of paragraphs (g) and (h) of rule 17g–1 (relating to the filing of copies of fidelity bonds and related information with the Commission and relating to the provision of notices to the board of directors), and an exemption from the requirements of paragraph (j)(3) of rule 17g–1 that the ESCs comply with the fund governance standards defined in rule 0–1(a)(7).

11. Section 17(j) of the Act and paragraph (b) of rule 17j–1 under the Act make it unlawful for certain enumerated persons to engage in fraudulent or deceptive practices in connection with the purchase or sale of a security held or to be acquired by a registered investment company. Rule 17j–1 also requires that every registered investment company adopt a written code of ethics and that every access person of a registered investment company report personal securities transactions. Applicants request an exemption from the provisions of rule 17j–1, except for the anti-fraud provisions of paragraph (b), because they are unnecessary and burdensome as applied to the ESC Funds.

12. Applicants request an exemption from the requirements in sections 30(a), 30(b), and 30(e) of the Act, and the rules under those sections, that registered investment companies prepare and file with the Commission and mail to their shareholders certain periodic reports and financial statements. Applicants contend that the forms prescribed by the Commission for periodic reports have little relevance to an ESC Fund and would entail administrative and legal costs that outweigh any benefit to the Members of such ESC Fund. Applicants request exemptive relief to the extent necessary to permit each ESC Fund to report annually to its Members. Applicants also request an exemption from section 30(h) of the Act to the extent necessary to exempt the Managing Member of each ESC Fund, directors and officers of the Managing Member and any other persons who may be deemed to be members of an advisory board or an investment adviser (and affiliated persons thereof) of such ESC Fund from filing Forms 3, 4, and 5 under section 16 of the Exchange Act with respect to such ESC Fund. Applicants assert that, because there will be no trading market and the transfers of Interests will be severely restricted, these filings are unnecessary for the protection of investors and burdensome to those required to make them.

13. Rule 38a–1 requires investment companies to adopt, implement and periodically review written policies and procedures reasonably designed to prevent violation of the federal securities laws and to appoint a chief compliance officer. Each ESC Fund will comply will rule 38a–1(a), (c) and (d), except that (a) because the ESC Funds do not have board of directors, the Managing Member will fulfill the responsibilities assigned to a board of directors under the rule, (b) because the Managing Member does not have any disinterested members, approval by a majority of the disinterested board members required by rule 38a–1 will not be obtained, and (c) because the ESC Funds do not have any independent directors, the ESC Funds will comply with the requirement in rule 38a–1(a)(4)(iv) that the chief compliance officer meet with the independent directors by having the chief compliance officer meet with the Managing Member.

Applicants' Conditions

Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each proposed transaction to which an ESC Fund is a party otherwise prohibited by section 17(a) or section 17(d) of the Act and rule 17d–1 under the Act (the ''Section 17 Transactions'') will be effected only if the Managing Member determines that: (a) The terms of the Section 17 Transaction, including the consideration to be paid or received, are fair and reasonable to the Members of the ESC Fund and do not involve overreaching of the ESC Fund or its Members on the part of any person concerned and (b) the Section 17 Transaction is consistent with the interests of the Members of the ESC Fund, the ESC Fund's organizational documents and the ESC Fund's reports to its Members.

In addition, the Managing Member will record and will preserve a description of all Section 17 Transactions, the Managing Member's findings, the information or materials upon which the findings are based and the basis for the findings. All such records will be maintained for the life of the ESC Fund and at least six years thereafter, and will be subject to examination by the Commission and its staff. Each ESC Fund will preserve the accounts, books and other documents required to be maintained in an easily accessible place for at least the first two years.

2. The Managing Member will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any Section 17 Transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for any ESC Fund, or any affiliated person of such affiliated person, promoter or principal underwriter.

3. The Managing Member of each ESC Fund will not invest the funds of the ESC Fund in any investment in which a ''Co-Investor'' (as defined below) has acquired or proposes to acquire the same class of securities of the same issuer and where the investment involves a joint enterprise or other joint arrangement within the meaning of rule 17d–1 in which the ESC Fund and the Co-Investor are participants, unless any such Co-Investor, prior to disposing of all or part of its investment: agrees to (a) give the Managing Member sufficient, but not less than one day's notice of its intent to dispose of its investment; and (b) refrain from disposing of its investment unless the ESC Fund has the opportunity to dispose of its investment prior to or concurrently with, and on the same terms as, and *pro rata* with, the Co-Investor. The term ''Co-Investor'' with respect to any ESC Fund means any person who is: (a) An ''affiliated person'' (as defined in section 2(a)(3) of the Act) of the ESC Fund (other than a Citadel Third Party Fund); (b) a Citadel Entity; (c) an officer, director or employee of a Citadel Entity; or (d) an entity (other than a Citadel Third Party Fund) in which a Managing Member or an Affiliate of Citadel acts as a managing member or in a similar capacity so as to control the sale or other disposition of the entity's investments. The restrictions contained in this condition, however, shall not be deemed to limit or prevent the disposition of an investment by a Co-Investor: (a) to its direct or indirect wholly-owned subsidiary, to any company (a ''Parent'') of which the Co-Investor is a direct or indirect wholly-owned subsidiary or to a direct or indirect wholly-owned subsidiary of such Parent; (b) to immediate family members of the Co-Investor or a trust or other investment vehicle established for any such family member; or (c) when the investment is comprised of securities that are (i) listed on any exchange registered as a national exchange under section 6 of the Exchange Act; (ii) NMS stocks, pursuant to section 11A(a)(2) of the Exchange Act and rule 600(a) of Regulation NMS thereunder; (iii) government securities as defined in section 2(a)(16) of the Act, or (iv) listed or traded on any foreign securities exchange or board of trade that satisfies regulatory requirements under the law of the jurisdiction in which such foreign securities exchange or board of trade is organized similar to those that apply to a national securities exchange or a national market system for securities.

4. Each ESC Fund and its Managing Member will maintain and preserve, for the life of such ESC Fund and at least six years thereafter, such accounts, books, and other documents constituting the record forming the basis for the audited financial statements that are to be provided to the Members of such ESC Fund, and each annual report of such ESC Fund required to be sent to such Members, and agree that all such records will be subject to examination by the Commission and its staff. Each ESC Fund will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years after the life of such ESC Fund.

5. The Managing Member of each ESC Fund will send to each person who was a Member having an Interest in the ESC Fund at any time during the fiscal year then ended (except for the first fiscal year of operations of an ESC Fund if no investment activities took place in such fiscal year), audited financial statements with respect to those ESC Funds in which the Member held Interests. At the end of each fiscal year, the Managing Member will make a valuation or have a valuation made of all of the assets of the ESC Fund as of such fiscal year end in a manner consistent with customary practice with respect to the valuation of assets of the kind held by the ESC Fund. In addition, within 180 days after the end of each fiscal year of each ESC Fund or as soon as practicable thereafter, the Managing Member will send a report to each person who was a Member at any time during the fiscal year then ended, setting forth such tax information as shall be necessary for the preparation by the Member of his, her or its U.S. federal and state income tax returns and a report of the investment activities of the ESC Fund during that fiscal year.

6. If an ESC Fund makes purchases from, or sales to, an entity affiliated with the ESC Fund by reason of an officer, director or employee of Citadel (a) serving as an officer, director, managing member, general partner or investment adviser of the entity, or (b) having a 5% or more investment in the entity, such individual will not participate in the ESC Fund's determination of whether or not to effect the purchase or sale.

For the Commission, by the Division of Investment Management, under delegated authority.

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28351 Filed 11–1–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65641; File No. SR–Phlx–2011–137]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Exchange Rule 703 (Financial Responsibility and Reporting)

October 27, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 [2] thereunder, notice is hereby given that on October 25, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Exchange Rule 703, entitled ''Financial Responsibility and Reporting'' to clarify Rule text.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.nasdaqtrader.com/micro.aspx?id=PHLXRulefilings,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Exchange Rule 703, entitled ''Financial Responsibility and Reporting'' to clarify the Rule text. Specifically, the Exchange is proposing to add the words ''or its designee'' to Rule 703(c)(ii) to conform the text of the Rule to 703(f).

Exchange Rule 703 concerns a member's obligation to report certain financial information. Exchange Rule 703(c)(ii) provides that each member organization designated to the Exchange for financial responsibility pursuant to SEC Rule 17d–1 and acting as a market makers and/or options specialist shall, on forms prescribed by the Exchange, file certain reports listed within Rule 703, with the Exchange. The Exchange proposes to amend the language to indicate that the reports may be filed with the Exchange's designee as well.[3] Exchange Rule 703(f) currently states that all reports required to be filed with the Exchange shall be filed with the Exchange or its designee. The addition of ''or its designee'' to Exchange Rule 703(c)(ii) provides more clarity to the Rule and conforms the text of the Rule to 703(f).

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[4] in general, and furthers the objectives of Section 6(b)(5) of the Act[5] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The Exchange believes that its proposed amendment to Exchange Rule 703 will provide additional clarity to the Rule. While the Rule currently permits the Exchange to designate another person and/or entity to receive such reports referenced in Rule 703, the Exchange is amending the rule to make it clear that a designee is permitted to collect the reports referenced in Rule 703(c)(ii). The Exchange is not making a substantive amendment to this Rule but rather making the Rule clear for its members.

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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[6] and Rule 19b–4(f)(6)[7] thereunder.

The Exchange has requested that the Commission waive the requirement that the rule change, by its terms, not become operative for 30 days after the date of the filing, as set forth in Rule 19b–4(f)(6)(iii).[8] The Exchange proposes to make the proposed rule change operative immediately upon filing. The Commission has determined that waiving the 30-day operative delay is consistent with the protection of investors and the public interest, because the proposed rule change is not substantive and is merely clarifying an already existing requirement within the Rule. Accordingly, the Commission waives the 30-day operative delay requirement and designates the proposed rule change to be operative upon filing with the Commission.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2011–137 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–Phlx–2011–137. 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

[3] The Exchange's designee would be the Financial Industry Regulatory Authority (''FINRA''). The Exchange has a regulatory services agreement with FINRA and may designate FINRA to receive reports referenced in Exchange Rule 703.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[8] 17 CFR 240.19b–4(f)(6)(iii).

[9] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 a.m. and 3 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–Phlx–2011–137 and should be submitted on or before November 23, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28346 Filed 11–1–11; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65642; File No. SR–BX–2011–072]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the BOX Trading Rules To Retire the Additional Expiration Months Pilot Program and To Harmonize the Rules Regarding Listing Expirations With the Existing Rules of Other Exchanges

October 27, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 19, 2011, NASDAQ OMX BX, Inc. (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a non-controversial rule change under Rule 19b–4(f)(6) under the Act,[3] which renders the proposal 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] 17 CFR 240.19b–4(f)(6).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Rules of the Boston Options Exchange Group, LLC (''BOX'') to retire the Additional Expiration Months Pilot Program and to harmonize the BOX Trading Rules regarding listing expirations with the existing rules of other exchanges.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to retire the Additional Expiration Months Pilot Program (''Pilot Program'') and to amend the BOX Trading Rules regarding listing expirations. This filing is based on the existing rules of other options exchanges.[4]

Pursuant to Chapter IV, Section 6(e) of the BOX Trading Rules, the Exchange usually will open four expiration months for each class of options open for trading on BOX: the first two being the two nearest months, regardless of the quarterly cycle on which that class trades; the third and fourth being the next two months of the quarterly cycle previously designated by the Exchange for that specific class.

For competitive reasons, in 2010, a Pilot Program was established pursuant to which BOX could list up to an additional two expiration months, for a total of six expiration months for each class of options open for trading on BOX.[5] The filing to establish the Pilot Program was substantially similar in all material respects to a proposal of the International Securities Exchange, LLC (''ISE'').[6]

After ISE and BOX established their respective Pilot Programs, ISE submitted a filing in response to a PHLX filing regarding the listing of expirations.[7] In the PHLX filing, PHLX amended its rules that so that it could open ''at least one expiration month'' for each class of standard options open for trading on PHLX.[8] PHLX stated in its filing that this amendment was ''based directly on the recently approved rules of another options exchange, namely Chapter IV, Sections 6 and 8'' of NOM. Since PHLX's rules did not hard code an upper limit on the maximum number of expirations that may be listed per class, ISE believed that PHLX (and NOM) had the ability to list expirations that ISE would not be able to currently list under its rules. As a result, ISE amended its rules by adding new Supplementary Material .10 to ISE Rule 504 and Supplementary Material to .04 to ISE Rule 2009 to permit ISE to list additional expiration months on options classes opened for trading on ISE if such expiration months are opened for trading on at least one other national securities exchange.[9]

Because BOX had adopted a Pilot Program similar to ISE's, BOX adopted new Supplementary Material .09 to Chapter IV, Section 6 and Supplementary Material .03 to Chapter XIV, Section 10 of the BOX Trading Rules that permits BOX to list additional expiration months on options classes opened for trading on BOX if such expiration months are opened for trading on at least one other national securities exchange.[10]

[4] *See* Chicago Board Options Exchange, Incorporated (''CBOE'') Rule 5.5 (Series of Options Contracts Open for Trading, NASDAQ Options Market (''NOM'') Chapter IV, Section 6 (Series of Options Contracts Open for Trading) and NASDAQ OMX PHLX, LLC (''PHLX'') Rule 1012 (Series of Options Open for Trading). *See also* Securities Exchange Act Release Nos. 65241 (August 31, 2011), 76 FR 55249 (September 7, 2011) (SR–CBOE–2011–080); 57478 (March 12, 2008), 73 FR 14521 (March 18, 2008) (SR–NASDAQ–2007–004 and SR–NASDAQ–2007–080); and 63700 (January 11, 2011) 76 FR 2931 (January18, 2011) (SR–PHLX–2011–04). The PHLX filing was based on NOM's existing rules.

[5] *See* Securities Exchange Act Release No. 63321 (November 16, 2010), 75 FR 71163 (November 22, 2010) (SR–BX–2010–077).

[6] *See* Securities Exchange Act Release No. 63104 (October 14, 2010), 75 FR 64773 (October 20, 2010) (SR–ISE–2010–91).

[7] *See* Securities Exchange Act Release No. 64343 (April 26, 2011), 76 FR 24546 (May 2, 2011) (SR–ISE–2011–26).

[8] *See id.* at 24546–24547.

[9] *See id.* at 24547.

[10] *See* Securities Exchange Act Release No. 64570 (May 31, 2011), 76 FR 32383 (June 6, 2011) (SR–BX–2011–029).

Now that BOX has the ability to match the expiration listings of other exchanges [11] (that may exceed six expirations and may occur on a regular basis) the Exchange believes that the Pilot Program is no longer necessary and is proposing to retire it. To affect this change, the Exchange is proposing to delete Supplementary Material .08 to Chapter IV, Section 6 that sets forth the terms of the Pilot Program, which is currently scheduled to expire on October 31, 2011.

In addition, BOX's ability to match the expirations listed by other exchanges is set forth in Supplementary Material .09 to Chapter IV, Section 6. This provision, however, only provides BOX with the ability to match expirations *initiated* by other options exchanges. To encourage competition and to place BOX on a level playing field, BOX should have the same ability as PHLX and NOM to initiate expirations. Therefore, as proposed the BOX Trading Rules will be harmonized with the rules of PHLX and NOM by clarifying that BOX will open at least one expiration month and one series of for each class open for trading on the Exchange. To affect this change, the Exchange is proposing to amend the text of Chapter IV, Section 6(b) of the BOX Trading Rules to track the rule text of NOM Chapter IV, Section 6 and PHLX Rule 1012, and to delete Section 6(e) in Chapter IV of the BOX Rules.

BOX believes the proposed rule change is proper, and indeed necessary, in light of the need to have rules that do not put BOX at a competitive disadvantage. This proposal puts BOX in the same position as PHLX and NOM and provides BOX with the same ability to initiate and match identical expirations across exchanges for products that are multiply-listed and fungible with one another. BOX believes that the proposed rule change should encourage competition and be beneficial to traders and market participants by providing them with a means to trade on BOX securities that are initiated by BOX and listed and traded on other exchanges.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') [12] and the rules and regulations thereunder and, in particular, the requirements of Section 6(b) of the Act.[13] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [14] requirements that the rules of an exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the proposed rule change will permit BOX to accommodate requests made by BOX Options Participants and other market participants to list additional expiration months and thus encourage competition without harming investors or the public interest.

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.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not significantly affect the protection of investors or the public interest, does not impose any significant burden on competition, and, by its terms, does not become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and Rule 19b–4(f)(6) thereunder.[16]

The Exchange has requested that the Commission waive the 30-day operative delay. The Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because the proposal will allow BOX to initiate the listing of series with the same range of expiration months as are available to its competitor exchanges, subject to certain conditions. Therefore, the Commission designates the proposal operative upon filing.[17]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2011–072 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–BX–2011–072. 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 a.m. and 3 p.m. Copies of such filing

[11] *See* Supplementary Material .09 to Chapter IV, Section 6 of the BOX Rules.

[12] 15 U.S.C. 78s(b)(1).

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(5).

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rules impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 publicly available. All submissions should refer to File Number SR–BX–2011–072 and should be submitted on or before November 23, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28347 Filed 11–1–11; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65646, File No. SR–BATS–2011–033]

Self-Regulatory Organizations; BATS Exchange, Inc.; Order Approving Proposed Rule Change To Amend and Restate the Second Amended and Restated Certificate of Incorporation of BATS Global Markets, Inc.

October 27, 2011.

I. Introduction

On August 29, 2011, BATS Exchange, Inc. (''BATS'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the certificate of incorporation (''Certificate of Incorporation'') of BATS Global Markets, Inc. (''Corporation'') in connection with its anticipated initial public offering of shares of its Class A Common Stock (the ''IPO''). The proposed rule change was published for comment in the **Federal Register** on September 14, 2011.[3] The Commission received no comment letters regarding the proposal. This order approves the proposed rule change.

II. Description of the Proposal

On May 13, 2011, the Corporation filed a registration statement on Form S–1 with the Commission to register shares of Class A Common Stock (as defined below) and disclose its intention to conduct its IPO and to list those shares for trading on the Exchange. In connection with its IPO, the Exchange filed this proposed rule change to amend and restate the Corporation's current Second Amended and Restated Certificate of Incorporation and adopt a Third Amended and Restated Certificate of Incorporation (''New Certificate of Incorporation'').

A. Reclassification of Common Stock and Additional Authorized Shares

The Exchange has proposed to revise the Certificate of Incorporation to reclassify the Corporation's existing common stock, ''Voting Common Stock'' and ''Non-Voting Common Stock.'' This reclassification will result in two classes of common stock, Class A and Class B. Class A will be designated as either ''Class A Common Stock'' or ''Non-Voting Class A Common Stock.'' Class B will be designated as either ''Class B Common Stock'' or ''Non-Voting Class B Common Stock.'' In connection with this reclassification, the Exchange has proposed certain voting rights,[4] transfer restrictions[5] and conversion features[6] for each class. The Class A Common Stock will have the right to one vote per share, while the Class B Common Stock will have the right to 2½ votes per share.

The Exchange notes that the purpose of the reclassification of the Corporation's common stock is to encourage the Corporation's existing strategic investors to remain strategic investors of the Corporation after the IPO.[7] In its proposal, BATS states that the Class B holders will in aggregate control a meaningful, but less than majority, percentage of the vote on matters coming before the stockholders.[8] The Exchange also notes that the transfer restrictions balance the ability of existing strategic investors to orderly sell shares in the open market, while at the same time retaining strategic benefits to the Corporation of their significant ownership for a certain period of time, through their holdings of Class B shares.[9] Finally, the Exchange notes that its automatic conversion features are intended to ensure that only those investors with a significant economic investment in the company (approximately 2%) will own the Class B Common Stock.[10]

The proposed New Certificate of Incorporation would increase the number of shares the Corporation would be authorized to issue and would also give the Corporation the authority to issue 40 million shares of Preferred Stock, par value $0.01 per share.[11]

B. Limitations on Ownership and Voting Power

As noted by the Exchange, the proposal maintains and enhances the limitations on aggregate ownership and total voting power that exist under the current Certificate of Incorporation.[12] The Exchange has also proposed to aggregate all shares of Class A Common Stock, Non-Voting Class A Common Stock, Class B Common Stock, Non-Voting Class B Common Stock, and any series of Preferred Stock of the Corporation as a single class of capital stock of the Corporation for purposes of determining compliance with the ownership and voting limitations. The proposed New Certificate of Incorporation would explicitly include non-voting stock in the calculation of ownership applicable to non-Member shareholders.[13]

C. Bylaws and Future Amendments to the Certificate of Incorporation

Currently, the Certificate of Incorporation provides that either the Board of Directors or shareholders may adopt, amend, or repeal the Bylaws of the Corporation. The proposal would modify this provision so that, upon the change in ownership,[14] stockholders

[18] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 65298 (September 8, 2011), 76 FR 56840 (September 14, 2011) (''Notice'').

[4] *See generally* proposed Section 4.04(a) of the New Certificate of Incorporation.

[5] *See generally* proposed Section 4.04(b) of the New Certificate of Incorporation.

[6] *See generally* proposed Section 4.04(c) of the New Certificate of Incorporation. Among the conversion features proposed, the Corporation proposes to have Class B shares automatically convert into Class A shares upon a Class B holder owning less than a 4,960,491 (approximately 2%) of the Corporation's outstanding common stock. *See* proposed Section 4.04(c)(v)(B) of the New Certificate of Incorporation.

[7] *See* Notice *supra* note 3, at 76 FR at 56841.

[8] *See id.*

[9] *See id.*

[10] *See id.*

[11] *See* proposed Section 4.01 of the proposed New Certificate of Incorporation. The total number of authorized shares the Corporation has authority to issue is 614,607,649.

[12] The relevant provisions of the Certificate of Incorporation impose a 40% ownership limit on the amount of capital stock of the Corporation that any person, either alone or together with its related persons, may own, directly or indirectly, of record or beneficially; a 20% ownership limit on the amount of capital stock of the Corporation that any member of the Exchange, either alone, or together with its related persons, may own directly or indirectly, of record or beneficially, and prohibit any person, either alone or together with its related persons, from having or exercising more than 20% of the voting power of the capital stock of the Corporation. *See* proposed Section 5.01(a)(i)–(iii) of the New Certificate of Incorporation.

[13] *See* proposed Section 5.01(b)(1) of the New Certificate of Incorporation.

[14] ''Change of Ownership'' would be defined as a transaction or series of transactions which results

Continued

may only adopt, amend, or repeal the Bylaws upon the affirmative vote of at least 70% of the total voting power of all outstanding shares of the Corporation.[15]

D. Other Amendments

The proposal will amend and restate various other provisions of the current Certificate of Incorporation in a manner that the Exchange believes are intended to reflect provisions that are more customary for publicly-owned companies (such as those relating to the indemnification of directors and business combinations, among others).

III. Discussion

After careful review of the proposal, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposal is consistent with Section 6(b)(1) of the Act,[17] which requires a national securities exchange to be so organized and have the capacity to carry out the purposes of the Act and to enforce compliance by its members and persons associated with the provisions of the Act.

The Commission notes that the Exchange has represented that the proposed rule change relates solely to the Certificate of the Incorporation of the Corporation and that the Exchange will continue to be governed by its existing certificate of incorporation and by-laws.[18] The Exchange has also represented that the Corporation will continue to directly and solely hold all the stock in, and voting power of, the Exchange and that the Exchange will continue to operate pursuant to its existing governance structure.[19]

The Commission further notes that the Exchange has represented that the proposed rule change will maintain and enhance the existing ownership and voting limitations in the Certificate of Incorporation.[20] To this end, the Exchange has proposed to aggregate all classes of Common Stock and any Preferred Stock (if issued) of the Corporation for purposes of determining stockholder compliance with its ownership and voting limitations.[21] The proposed rule change would also include non-voting common stock in the calculations of such ownership limitations. As a result, the Commission believes that the proposed rule change should effectively maintain and bolster the ownership and voting limits currently in place for the Corporation consistent with Section 6(b)(1) of the Exchange Act.

The Commission believes that the enhanced ownership and voting limitations should minimize the potential that a person, including members, could improperly interfere with or restrict the ability of the Commission or the Exchange to effectively carry out their regulatory oversight responsibilities under the Exchange Act. In addition, these limitations should protect against the instance whereby a member's interest in an exchange or an entity controlling the exchange becomes so large as to cast doubt on whether the exchange can fairly and objectively exercise its self-regulatory responsibilities with respect to that member.

III. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[22] that the proposed rule change (SR–BATS–2011–033) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28349 Filed 11–1–11; 8:45 am]

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in the beneficial owners of the Class B Common Stock and Non-Voting Class B Common Stock owning in the aggregate less than a majority of the total voting power of all outstanding securities of the Corporation then entitled to vote generally in the election of directors, voting together as a single class. *See* proposed Section 6.01(b) of the New Certificate of Incorporation.

[15] *See* proposed Section 9.02(b) of the New Certificate of Incorporation.

[16] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(1).

[18] *See* Notice, *supra* note 3, 76 FR at 56840.

[19] *See id.*

[20] *See supra* note 12 (discussing the limitations of ownership of capital stock of the Corporation to 40% for any Person and 20% for any member and voting power of capital stock of the Corporation to 20% for any Person).

[21] *See* proposed Section 5.01(b)(i) of the New Certificate of Incorporation.

[22] 15 U.S.C. 78s(b)(2).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65647, File No. SR–BYX–2011–021]

Self-Regulatory Organizations; BATS Y–Exchange, Inc.; Order Approving Proposed Rule Change To Amend and Restate the Second Amended and Restated Certificate of Incorporation of BATS Global Markets, Inc.

October 27, 2011.

I. Introduction

On August 29, 2011, BATS Y–Exchange, Inc. (''BYX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend the certificate of incorporation (''Certificate of Incorporation'') of BATS Global Markets, Inc. (''Corporation'') in connection with its anticipated initial public offering of shares of its Class A Common Stock (the ''IPO''). The proposed rule change was published for comment in the **Federal Register** on September 14, 2011.[3] The Commission received no comment letters regarding the proposal. This order approves the proposed rule change.

II. Description of the Proposal

On May 13, 2011, the Corporation filed a registration statement on Form S–1 with the Commission to register shares of Class A Common Stock (as defined below) and disclose its intention to conduct its IPO and to list those shares for trading on the Exchange. In connection with its IPO, the Exchange filed this proposed rule change to amend and restate the Corporation's current Second Amended and Restated Certificate of Incorporation and adopt a Third Amended and Restated Certificate of Incorporation (''New Certificate of Incorporation'').

A. Reclassification of Common Stock and Additional Authorized Shares

The Exchange has proposed to revise the Certificate of Incorporation to reclassify the Corporation's existing common stock, ''Voting Common Stock'' and ''Non-Voting Common Stock.'' This reclassification will result in two classes of common stock, Class A and Class B. Class A will be designated as either ''Class A Common Stock'' or ''Non-

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 65299 (September 8, 2011), 76 FR 56833 (September 14, 2011) (''Notice'').

Voting Class A Common Stock.'' Class B will be designated as either ''Class B Common Stock'' or ''Non-Voting Class B Common Stock.'' In connection with this reclassification, the Exchange has proposed certain voting rights,[4] transfer restrictions,[5] and conversion features [6] for each class. The Class A Common Stock will have the right to one vote per share, while the Class B Common Stock will have the right to 2½ votes per share.

The Exchange notes that the purpose of the reclassification of the Corporation's common stock is to encourage the Corporation's existing strategic investors to remain strategic investors of the Corporation after the IPO.[7] In its proposal, BYX states that the Class B holders will in aggregate control a meaningful, but less than majority, percentage of the vote on matters coming before the stockholders.[8] The Exchange also notes that the transfer restrictions balance the ability of existing strategic investors to orderly sell shares in the open market, while at the same time retaining strategic benefits to the Corporation of their significant ownership for a certain period of time, through their holdings of Class B shares.[9] Finally, the Exchange notes that its automatic conversion features are intended to ensure that only those investors with a significant economic investment in the company (approximately 2%) will own the Class B Common Stock.[10]

The proposed New Certificate of Incorporation would increase the number of shares the Corporation would be authorized to issue and would also give the Corporation the authority to issue 40 million shares of Preferred Stock, par value $0.01 per share.[11]

B. Limitations on Ownership and Voting Power

As noted by the Exchange, the proposal maintains and enhances the limitations on aggregate ownership and total voting power that exist under the current Certificate of Incorporation.[12] The Exchange has also proposed to aggregate all shares of Class A Common Stock, Non-Voting Class A Common Stock, Class B Common Stock, Non-Voting Class B Common Stock, and any series of Preferred Stock of the Corporation as a single class of capital stock of the Corporation for purposes of determining compliance with the ownership and voting limitations. The proposed New Certificate of Incorporation would explicitly include non-voting stock in the calculation of ownership applicable to non-Member shareholders.[13]

C. Bylaws and Future Amendments to the Certificate of Incorporation

Currently, the Certificate of Incorporation provides that either the Board of Directors or shareholders may adopt, amend, or repeal the Bylaws of the Corporation. The proposal would modify this provision so that, upon the change in ownership,[14] stockholders may only adopt, amend, or repeal the Bylaws upon the affirmative vote of at least 70% of the total voting power of all outstanding shares of the Corporation.[15]

D. Other Amendments

The proposal will amend and restate various other provisions of the current Certificate of Incorporation in a manner that the Exchange believes are intended to reflect provisions that are more customary for publicly-owned companies (such as those relating to the indemnification of directors and business combinations, among others).

III. Discussion

After careful review of the proposal, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposal is consistent with Section 6(b)(1) of the Act, [17] which requires a national securities exchange to be so organized and have the capacity to carry out the purposes of the Act and to enforce compliance by its members and persons associated with the provisions of the Act.

The Commission notes that the Exchange has represented that the proposed rule change relates solely to the Certificate of the Incorporation of the Corporation and that the Exchange will continue to be governed by its existing certificate of incorporation and by-laws.[18] The Exchange has also represented that the Corporation will continue to directly and solely hold all the stock in, and voting power of, the Exchange and that the Exchange will continue to operate pursuant to its existing governance structure.[19]

The Commission further notes that the Exchange has represented that the proposed rule change will maintain and enhance the existing ownership and voting limitations in the Certificate of Incorporation.[20] To this end, the Exchange has proposed to aggregate all classes of Common Stock and any Preferred Stock (if issued) of the Corporation for purposes of determining stockholder compliance with its ownership and voting limitations.[21] The proposed rule change would also include non-voting common stock in the calculations of such ownership limitations. As a result, the Commission believes that the proposed rule change should effectively maintain and bolster the ownership and voting limits currently in place for the Corporation consistent with Section 6(b)(1) of the Exchange Act.

The Commission believes that the enhanced ownership and voting limitations should minimize the

[4] *See generally* proposed Section 4.04(a) of the New Certificate of Incorporation.

[5] *See generally* proposed Section 4.04(b) of the New Certificate of Incorporation.

[6] *See generally* proposed Section 4.04(c) of the New Certificate of Incorporation. Among the conversion features proposed, the Corporation proposes to have Class B shares automatically convert into Class A shares upon a Class B holder owning less than a 4,960,491 (approximately 2%) of the Corporation's outstanding common stock. *See* proposed Section 4.04(c)(v)(B) of the New Certificate of Incorporation.

[7] *See* Notice *supra* note 3, at 76 FR at 56835.

[8] *See id.*

[9] *See id.*

[10] *See id.*

[11] *See* proposed Section 4.01 of the proposed New Certificate of Incorporation. The total number of authorized shares the Corporation has authority to issue is 614,607,649.

[12] The relevant provisions of the Certificate of Incorporation impose a 40% ownership limit on the amount of capital stock of the Corporation that any person, either alone or together with its related persons, may own, directly or indirectly, of record or beneficially; a 20% ownership limit on the amount of capital stock of the Corporation that any member of the Exchange, either alone, or together with its related persons, may own directly or indirectly, of record or beneficially, and prohibit any person, either alone or together with its related persons, from having or exercising more than 20% of the voting power of the capital stock of the Corporation. *See* proposed Section 5.01(a)(i)–(iii) of the New Certificate of Incorporation.

[13] *See* proposed Section 5.01(b)(1) of the New Certificate of Incorporation.

[14] ''Change of Ownership'' would be defined as a transaction or series of transactions which results in the beneficial owners of the Class B Common Stock and Non-Voting Class B Common Stock owning in the aggregate less than a majority of the total voting power of all outstanding securities of the Corporation then entitled to vote generally in the election of directors, voting together as a single class. *See* proposed Section 6.01(b) of the New Certificate of Incorporation.

[15] *See* proposed Section 9.02(b) of the New Certificate of Incorporation.

[16] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(1).

[18] *See* Notice, *supra* note 3, 76 FR at 56834.

[19] *See id.*

[20] *See supra* note 12 (discussing the limitations of ownership of capital stock of the Corporation to 40% for any Person and 20% for any member and voting power of capital stock of the Corporation to 20% for any Person).

[21] *See* proposed Section 5.01(b)(i) of the New Certificate of Incorporation.

potential that a person, including members, could improperly interfere with or restrict the ability of the Commission or the Exchange to effectively carry out their regulatory oversight responsibilities under the Exchange Act. In addition, these limitations should protect against the instance whereby a member's interest in an exchange or an entity controlling the exchange becomes so large as to cast doubt on whether the exchange can fairly and objectively exercise its self-regulatory responsibilities with respect to that member.

III. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[22] that the proposed rule change (SR–BYX–2011–021) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28350 Filed 11–1–11; 8:45 am]

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[22] 15 U.S.C. 78s(b)(2).

[23] 7 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65644; File No. SR–Phlx–2011–123]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Order Granting Approval of Proposed Rule Change Relating to the Quarterly Trading Requirements Applicable to Registered Options Traders

October 27, 2011.

I. Introduction

On August 24, 2011, NASDAQ OMX PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to change the quarterly trading requirements applicable to Registered Options Traders (''ROTs''). The proposed rule change was published for comment in the **Federal Register** on September 9, 2011.[3] The Commission received no comment letters on the proposal. This order approves the proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 65257 (September 2, 2011), 76 FR 55996.

II. Description of the Proposal

The Exchange proposes to modify the quarterly trading requirements applicable to ROTs. ROTs can be either Streaming Quote Traders (''SQTs''), Remote SQTs (''RSQTs'') or non-SQT ROTs. The quarterly trading requirements apply to two types of ROTs: SQTs and non-SQT ROTs.

Currently, Phlx Rule 1014 contains two quarterly trading requirements—in person and in assigned. First, Commentary .01 requires that in order for an ROT (other than an RSQT or a Remote Specialist) to receive specialist margin treatment for off-floor orders in any calendar quarter, the ROT must execute the greater of 1,000 contracts or 80% of his total contracts that quarter in person (not through the use of orders) and 75% of his total contracts that quarter in assigned options.

Second, the ''in assigned'' quarterly trading requirement in current Commentary .03 requires that, except for unusual circumstances, at least 50% of the trading activity in any quarter (measured in terms of contract volume) of an ROT (other than an RSQT) shall ordinarily be in classes of options to which he is assigned. Temporarily undertaking the obligations of paragraph (c) of Phlx Rule 1014 at the request of a member of the Exchange in non-assigned classes of options shall not be deemed trading in non-assigned option contracts.

The Exchange proposes to amend Commentary .01 to adopt a new quarterly requirement such that an ROT (other than an RSQT or a Remote Specialist) would be required to trade 1,000 contracts and 300 transactions on the Exchange each quarter. Transactions executed in the trading crowd where the contra-side is an ROT would not be included. The Exchange proposes that this requirement would be a pure trading requirement, not limited to assigned options and in person trading. Accordingly, the new trading requirement could be fulfilled with trades and contracts that are not in assigned options and not executed in person.

In addition, the Exchange proposes to amend the in person trading requirement in Commentary .01 in two ways. First, the Exchange proposes to exclude transactions executed in the trading crowd where the contra-side is an ROT from the existing in person trading requirement. Second, the Exchange proposes to permit non-SQT ROTs to use orders entered in person to meet the in person trading requirement. The Exchange represents that the only other way to participate in trades other than through the use of orders is by quoting; while SQTs quote electronically by ''streaming'' quotations into the Exchange, non-SQT ROTs may only quote verbally in response to floor brokers representing orders in the trading crowd. The Exchange believes that the limitation on the use of orders with respect to non-SQT ROTs is obsolete, as, over time, following the movement toward a more electronic trading platform in options, it has become difficult for such ROTs to comply with the trading requirement without using orders. The Exchange represents that non-SQT ROTs can only comply with the in person quarterly trading requirement by participating in crowd trades, which they cannot control, in terms of frequency.

The Exchange believes that the proposed new trading requirement coupled with the proposed changes to the existing ''in person'' trading requirement should encourage a more regular presence and thus result in more active market making. In addition, Phlx states that excluding transactions where the contra-side is another ROT should encourage more regular and active market making.

III. Discussion

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[4] Specifically, the Commission finds that the proposal is consistent with Section 6(b)(5) of the Act,[5] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission believes that the proposed changes to the trading requirements applicable to ROTs should encourage more active market making and thereby promote the provision of liquidity to the market. In particular, by excluding in crowd ROT-to-ROT transactions from the quarterly trading requirements applicable to a ROT, the proposal should help to encourage the regular posting of liquidity. The Commission believes that these

[4] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[5] 15 U.S.C. 78f(b)(5).

proposed changes to the quarterly trading requirements should enhance the market making function performed by ROTs and thereby serve to maintain fair and orderly markets and generally promote the protection of investors and the public interest.

IV. Conclusion

It Is Therefore Ordered, pursuant to Section 19(b)(2) of the Act,[6] that the proposed rule change (SR–Phlx–2011–123) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28372 Filed 11–1–11; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(2).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–65645; File No. SR–FINRA–2011–059]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Proposed Rule Change To Adopt FINRA Rule 3230 (Telemarketing) in the FINRA Consolidated Rulebook

October 27, 2011.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 13, 2011, Financial Industry Regulatory Authority, Inc. (''FINRA'') (f/k/a National Association of Securities Dealers, Inc. (''NASD'')) filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been substantially prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to adopt NASD Rule 2212 (Telemarketing) as FINRA Rule 3230 (Telemarketing) in the consolidated FINRA rulebook, subject to certain amendments. The proposed rule change would delete Incorporated NYSE Rule 440A (Telephone Solicitation) and Incorporated NYSE Rule Interpretation 440A/01. Additionally, the proposed rule change would adopt provisions that are substantially similar to the telemarketing rules of the Federal Trade Commission (''FTC'').

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

As part of the process of developing a new consolidated rulebook (''Consolidated FINRA Rulebook''),[3] FINRA is proposing to adopt NASD Rule 2212 (Telemarketing) as FINRA Rule 3230 (Telemarketing) with changes discussed below. The proposed rule change would delete Incorporated NYSE Rule 440A[4] (Telephone Solicitation) and Incorporated NYSE Rule Interpretation 440A/01 as they are, in main part, duplicative of NASD Rule 2212. However, as further described below, the proposed rule change would incorporate certain provisions of NYSE Rule 440A and its Interpretation into new FINRA Rule 3230. Further, the proposed rule change adds provisions that are substantially similar to FTC rules that prohibit deceptive and other abusive telemarketing acts or practices as described below.

NASD Rule 2212 and NYSE Rule 440A are similar rules that require members to maintain do-not-call lists, limit the hours of telephone solicitations, and prohibit members from using deceptive and abusive acts and practices in connection with telemarketing. The Commission directed FINRA and NYSE to enact these telemarketing rules in accordance with the Telemarketing Consumer Fraud and Abuse Prevention Act of 1994 (''Prevention Act'').[5] The Prevention Act requires the Commission to promulgate or direct any national securities exchange or registered securities association to promulgate, rules substantially similar to the FTC rules to prohibit deceptive and other abusive telemarketing acts or practices.[6]

In 2003, the FTC and the Federal Communications Commission (''FCC'') established requirements for sellers and telemarketers to participate in the national do-not-call registry.[7] Pursuant to the Prevention Act, the Commission requested that FINRA and NYSE amend their telemarketing rules to include a requirement that their members participate in the national do-not-call registry. In 2004, the Commission approved amendments to NASD Rule 2212 requiring member firms to participate in the national do-not-call registry.[8] The following year, the Commission approved amendments to NYSE Rule 440A, which were similar to the NASD rule amendments, but included additional provisions regarding the use of caller identification information, pre-recorded messages, telephone facsimiles, and computer advertisements.[9]

As mentioned above, the Prevention Act requires the Commission to promulgate, or direct any national securities exchange or registered securities association to promulgate, rules substantially similar to the FTC rules to prohibit deceptive and other abusive telemarketing acts or practices.[10] Earlier this year, Commission staff directed FINRA to conduct a review of its telemarketing rule and propose rule amendments that provide protections that are at least as strong as those provided by the FTC's

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The current FINRA rulebook consists of (1) FINRA Rules; (2) NASD Rules; and (3) rules incorporated from NYSE (''Incorporated NYSE Rules'') (together, the NASD Rules and Incorporated NYSE Rules are referred to as the ''Transitional Rulebook''). While the NASD Rules generally apply to all FINRA members, the Incorporated NYSE Rules apply only to those members of FINRA that are also members of the NYSE (''Dual Members''). The FINRA Rules apply to all FINRA members, unless such rules have a more limited application by their terms. For more information about the rulebook consolidation process, *see Information Notice,* March 12, 2008 (Rulebook Consolidation Process).

[4] For convenience, the proposed rule change refers to Incorporated NYSE Rules as NYSE Rules.

[5] 15 U.S.C. 6101–6108.

[6] 15 U.S.C. 6102.

[7] *See* 68 FR 4580 (January 29, 2003); 68 FR 44144 (July 25, 2003); CG Docket No. 02–278, FCC 03–153, (adopted June 26, 2003; released July 3, 2003).

[8] *See* Securities Exchange Act Release No. 49055 (January 12, 2004), 69 FR 2801 (January 20, 2004) (approval order).

[9] *See* Securities Exchange Act Release No. 52579 (October 7, 2005), 70 FR 60119 (October 14, 2005) (approval order).

[10] *See supra* note 6.

telemarketing rules.[11] Commission staff had concerns ''that the SRO [self-regulatory organization] rules overall have not kept pace with the FTC's rules, and thus may no longer meet the standards of the Prevention Act.'' [12]

Proposed FINRA Rule 3230

The proposed rule change would adopt NASD Rule 2212 into the Consolidated FINRA Rulebook as FINRA Rule 3230 (Telemarketing) in the consolidated FINRA rulebook, subject to certain amendments. The proposed rule change would incorporate certain unique aspects of NYSE Rule 440A and its Interpretation. Additionally, the proposed rule change would make amendments and adopt provisions that are substantially similar to rules promulgated by the FTC pursuant to the Prevention Act.

First, the proposed rule change would adopt into new FINRA Rule 3230 similar caller identification information provisions contained in NYSE Rule 440A(h). These provisions provide that members engaging in telemarketing must transmit caller identification information and are explicitly prohibited from blocking caller identification information. The telephone number provided must permit any person to make a do-not-call request during normal business hours. Inclusion of these caller identification information provisions in the proposed rule will not create any new obligations on broker-dealers as they are already subject to identical provisions under FCC regulations.[13]

The proposed rule change would not incorporate the additional provisions in NYSE Rule 440A regarding pre-recorded messages and the use of telephone facsimile or computer advertisements.[14] Similar provisions were never adopted by the FTC under the Prevention Act and thus are not required to be part of SEC or SRO rules. Moreover, these provisions in the NYSE rule are duplicative of similar FCC regulations that are applicable to broker-dealers.[15]

Second, the proposed rule change would adopt a provision that is similar to NYSE Rule Interpretation 440A/01 as Supplementary Material. The provision reminds firms that the rule does not affect the obligation of any member or person associated with a member that engages in telemarketing to comply with relevant state and federal laws and rules, including the rules of the FCC relating to telemarketing practices and the rights of telephone consumers. The proposed rule change would not incorporate the remainder of NYSE Rule Interpretation 440A/01 because the requirement for a member to make and maintain a list of persons who do not want to receive telephone solicitations is duplicative of an existing provision in the NASD rule.[16]

Third, the proposed rule change, as directed by the Commission staff, would make amendments and adopt provisions that are substantially similar to FTC rules that prohibit deceptive and other abusive telemarketing acts or practices as described below.

Maintenance of Do-Not-Call Lists

Proposed FINRA Rule 3230(d)(6) would maintain the requirement in NASD Rule 2212(d)(6) that a member making an outbound telephone call must maintain a record of a caller's request not to receive further calls. However, the proposed rule change would delete the requirement that a member honor a firm-specific do-not-call request for five years from the time the request is made. Commission staff directed FINRA to delete this provision because the time for which the firm-specific opt-out must be honored under the FTC's Telemarketing Sales Rule [17] is indefinite, rather than five years as currently provided in the rule.[18]

Wireless Communications

NASD Rule 2212(e) states that the provisions set forth in the rule are applicable to members telemarketing or making telephone solicitations calls to wireless telephone numbers. Proposed FINRA Rule 3230(e) would clarify that the application of the rule also applies to persons associated with a member making outbound telephone calls to wireless telephone numbers.

Outsourcing Telemarketing

NASD Rule 2212(f) states that if a member uses another entity to perform telemarketing services on its behalf, the member remains responsible for ensuring compliance with all provisions contained in the rule. Proposed FINRA Rule 3230(f) would clarify that members must consider whether the entity or person that a member uses for outsourcing, must be appropriately registered or licensed, where required.

Unencrypted Consumer Account Numbers

Proposed FINRA Rule 3230(h) would prohibit a member or person associated with a member from disclosing or receiving, for consideration, unencrypted consumer account numbers for use in telemarketing. The proposed rule change is substantially similar to the FTC's provision regarding unencrypted consumer account numbers.[19] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[20] Additionally, the proposed rule change would define ''unencrypted'' as not only complete, visible account numbers, whether provided in lists or singly, but also encrypted information with a key to its decryption. The proposed definition is substantially similar to the view taken by the FTC.[21]

Submission of Billing Information

Proposed FINRA Rule 3230(i) would require, for any telemarketing transaction, a member or person associated with a member to obtain the express informed consent of the person to be charged, and to be charged using the identified account. If the telemarketing transaction involves preacquired account information and a free-to-pay conversion feature, the member or person associated with a member would have to: (1) Obtain from the customer, at a minimum, the last four digits of the account number to be charged; (2) obtain from the customer an express agreement to be charged and to be charged using the identified account number; and (3) make and maintain an audio recording of the entire telemarketing transaction. For any other telemarketing transaction involving preacquired account information, the member or person associated with a member would have to: (1) Identify the account to be charged with sufficient specificity for the customer to understand what account will be charged; and (2) obtain from the customer an express agreement to be charged and to be charged using the identified account number. The proposed rule change is substantially similar to the FTC's provision regarding the submission of billing information.[22] The FTC provided a discussion of the provision when it was adopted pursuant to the Prevention Act.[23]

[11] *See* Letter from Robert W. Cook, Director, Division of Trading and Markets, SEC, to Richard G. Ketchum, Chairman and Chief Executive Officer, FINRA, dated May 10, 2011.

[12] *Id.*

[13] *See* 47 CFR 64.1601.

[14] *See* NYSE Rule 440A(e), (g), (j)(3), (6), (8).

[15] *See* 47 CFR 64.1200.

[16] *See* NASD Rule 2212(d)(6).

[17] *See* 16 CFR 310.

[18] *See supra* note 11.

[19] *See* 16 CFR 310.4(a)(6).

[20] *See* FTC, *Telemarketing Sales Rule,* 68 FR 4580 (January 29, 2003) at 4615.

[21] *See id.* at 4616.

[22] *See* 16 CFR 310.4(a)(7).

[23] *See* FTC, *supra* note 20, at 4615.

Abandoned Calls

Proposed FINRA Rule 3230(j) would prohibit a member or person associated with a member from abandoning any outbound telemarketing call. The abandoned calls prohibition would be subject to a ''safe harbor'' under proposed subparagraph (j)(2) that requires: (1) The member or person associated with a member to employ technology that ensures abandonment of no more than three percent of all calls answered by a person, measured over the duration of a single calling campaign, if less than 30 days, or separately over each successive 30-day period or portion thereof that the campaign continues; (2) the member or person associated with a member, for each telemarketing call placed, allows the telephone to ring for at least 15 seconds or four rings before disconnecting an unanswered call; (3) whenever a person associated with a member is not available to speak with the person answering the telemarketing call within two seconds after the person's completed greeting, the member or person associated with a member promptly plays a recorded message stating the name and telephone number of the member or person associated with a member on whose behalf the call was placed; and (4) the member to maintain records documenting compliance with the ''safe harbor.'' The proposed rule change is substantially similar to the FTC's provisions regarding abandoned calls.[24] The FTC provided a discussion of the provisions when they were adopted pursuant to the Prevention Act.[25]

Prerecorded Messages

Proposed FINRA Rule 3230(k) would prohibit a member or person associated with a member from initiating any outbound telemarketing call that delivers a prerecorded message without a person's express written agreement to receive such calls. The proposed rule change also would require that all prerecorded telemarketing calls provide specified opt-out mechanisms so that a person can opt out of future calls. The prohibition would not apply to a prerecorded message permitted for compliance with the ''safe harbor'' for abandoned calls under proposed subparagraph (j)(2). The proposed rule change is substantially similar to the FTC's provisions regarding prerecorded messages.[26] The FTC provided a discussion of the provisions when they were adopted pursuant to the Prevention Act.[27]

Credit Card Laundering

Proposed FINRA Rule 3230(l) would prohibit credit card laundering, the practice of depositing into the credit card system a sales draft that is not the result of a credit card transaction between the cardholder and the member. Except as expressly permitted, the proposed rule change would prohibit a member or person associated with a member from: (1) Presenting to or depositing into, the credit card system for payment, a credit card sales draft generated by a telemarketing transaction that is not the result of a telemarketing credit card transaction between the cardholder and the member; (2) employing, soliciting, or otherwise causing a merchant, or an employee, representative or agent of the merchant, to present to or to deposit into the credit card system for payment, a credit card sales draft generated by a telemarketing transaction that is not the result of a telemarketing credit card transaction between the cardholder and the merchant; or (3) obtaining access to the credit card system through the use of a business relationship or an affiliation with a merchant, when such access is not authorized by the merchant agreement or the applicable credit card system. The proposed rule change is substantially similar to the FTC's provisions regarding credit card laundering.[28] The FTC provided a discussion of the provisions when they were adopted pursuant to the Prevention Act.[29]

Definitions

Proposed FINRA Rule 3230(m) would adopt definitions that are substantially similar to the FTC's definitions.[30] The proposed rule change would adopt substantially similar definitions of ''acquirer,''[31] ''billing information,''[32] ''caller identification service,''[33] ''cardholder,''[34] ''charitable contribution,''[35] ''credit,''[36] ''credit card,''[37] ''credit card sales draft,''[38] ''credit card system,''[39] ''customer,''[40] ''donor,''[41] ''free-to-pay conversion,''[42] ''merchant,''[43] ''merchant agreement,''[44] ''outbound telephone call,''[45] ''person''[46] and ''preacquired account information.''[47] Additionally, the proposed rule change amends the definition of ''telemarketing'' to track the FTC definition and deletes the reference to ''telephone solicitation.'' The FTC provided a discussion of each definition when they were adopted pursuant to the Prevention Act.[48]

Technical and Conforming Changes

The proposed rule change also would make a number of minor technical and conforming changes. First, proposed FINRA Rule 3230(m) would renumber and make minor technical changes to the terms ''account activity,'' ''broker-dealer of record'' and ''established business relationship.'' Second, proposed FINRA Rule 3230 would amend paragraphs (a), (b) and (c) by replacing the term ''telephone solicitation'' with the term ''outbound telephone call.'' Third, proposed FINRA Rule 3230(d) would replace the term ''telemarketing call'' with the term ''outbound telephone call.'' Fourth, the proposed rule change would update a reference to an ''established business relationship'' in subparagraph (a)(1)(A). Finally, the proposed rule change would amend paragraph (b) to clarify that a signed, written agreement may be obtained electronically under the E-Sign Act.

FINRA will announce the implementation date of the proposed rule change in a *Regulatory Notice* to be published no later than 90 days following Commission approval. The implementation date will be no later than 180 days following Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[49] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in

[24] *See* 16 CFR 310.4(b)(1)(iv); *see also* 16 CFR 310.4(b)(4).

[25] *See* FTC, *supra* note 20, at 4641.

[26] *See* 16 CFR 310.4(b)(1)(v).

[27] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 73 FR 51164 (August 29, 2008).

[28] *See* 16 CFR 310.2.

[29] *See* Federal Trade Commission, *Telemarketing Sales Rule,* 60 FR 43842 (August 23, 1995) at 43852.

[30] *See* 16 CFR 310.2.

[31] *See* 16 CFR 310.2(a).

[32] *See* 16 CFR 310.2(c).

[33] *See* 16 CFR 310.2(d).

[34] *See* 16 CFR 310.2(e).

[35] *See* 16 CFR 310.2(f).

[36] *See* 16 CFR 310.2(h).

[37] *See* 16 CFR 310.2(i).

[38] *See* 16 CFR 310.2(j).

[39] *See* 16 CFR 310.2(k).

[40] *See* 16 CFR 310.2(l).

[41] *See* 16 CFR 310.2(n).

[42] *See* 16 CFR 310.2(p).

[43] *See* 16 CFR 310.2(s).

[44] *See* 16 CFR 310.2(t).

[45] *See* 16 CFR 310.2(v).

[46] *See* 16 CFR 310.2(w).

[47] *See* 16 CFR 310.2(x).

[48] *See* FTC, *supra* note 29, at 43843; *see also* FTC, *supra* note 20, at 4587.

[49] 15 U.S.C. 78*o*–3(b)(6).

general, to protect investors and the public interest. FINRA believes that the proposed rule change will protect investors and the public interest by continuing to prohibit deceptive and other abusive telemarketing acts or practices.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2011–059 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–FINRA–2011–059. 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; 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–FINRA–2011–059 and should be submitted on or before November 23, 2011.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[50]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2011–28348 Filed 11–1–11; 8:45 am]

BILLING CODE 8011–01–P

[50] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 7670]

Advisory Committee to the U.S. Section of the Inter-American Tropical Tuna Commission (Committee Renewal)

SUMMARY: The Department of State announces the renewal of the charter for the Advisory Committee to the U.S. Section of the Inter-American Tropical Tuna Commission (IATTC) for an additional two years. The Advisory Committee to the U.S. Section of the IATTC may be terminated only by law. In accordance with the provisions of the Federal Advisory Committee Act (92), a new Charter must be issued on a biennial basis from the date the current Charter was approved and filed with Congress and the Library of Congress.

The General Advisory Committee to the U.S. Section of the IATTC was established pursuant to Section 4 of the Tuna Conventions Act of 1950 (16 U.S.C. 953, as amended), the implementing statute for the IATTC Convention. The goal of the Advisory Committee is to serve the U.S. Section to the IATTC, including the Department of State, as advisors on matters relating to international conservation and management of stocks of tuna and dolphins, in the eastern tropical Pacific Ocean, and in particular on the development of U.S. policies and positions associated with such matters.

The Committee is composed of representatives of the major U.S. tuna harvesting, processing, and marketing sectors, as well as recreational fishing and environmental interests, formulating specific policy recommendations for the U.S. Section to the IATTC.

The Advisory Committee will continue to follow the procedure prescribed by the Federal Advisory Committee Act (FACA). Notice of meetings is published in the **Federal Register** in advance as required by FACA and meetings are open to the public unless a determination is made in accordance with Section 10 of the FACA that a meeting or a portion of the meeting should be closed to the public.

FOR FURTHER INFORMATION CONTACT: David F. Hogan, IATTC GAC Designated Federal Official, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, U.S. Department of State, Washington, DC 20520, Phone: (202) 647–2335.

Dated: October 20, 2011.

William Meara,

Acting, Deputy Assistant Secretary for Oceans and Fisheries, Department of State.

[FR Doc. 2011–28429 Filed 11–1–11; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. MC–F 21041]

National Express Acquisition Corporation—Control—Petermann Partners, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice Tentatively Approving and Authorizing Finance Transaction.

SUMMARY: National Express Acquisition Corporation (NEAC) and National

Express Corporation (NEC), both noncarriers, have filed an application under 49 U.S.C. 14303 for NEAC's acquisition of control of Petermann Partners, Inc. (PPI), a noncarrier, and the passenger motor carriers PPI controls: Beck Bus Transportation Corp. (MC–143528); Petermann Northeast, LLC (MC–723926); Petermann Northwest, LLC (MC–638608); Petermann Southwest, LLC (MC–644996); Petermann STSA, LLC (which has filed for registration in FMCSA Docket No. MC–749360); MV Student Transportation, Inc. (MC–148934); Carrier Management, Inc. (no MC number); and Petermann Ltd. (MC–364668) (collectively, Petermann Carriers). The Board has tentatively approved and authorized the transaction, and, if no opposing comments are timely filed, this notice will be the final Board action. Persons wishing to oppose the application must follow the rules under 49 CFR 1182.5 and 1182.8.

DATES: Comments must be filed by December 16, 2011. Applicants may file a reply by December 30, 2011. If no comments are filed by December 16, 2011, this notice is effective on that date.

ADDRESSES: Send an original and 10 copies of any comments referring to Docket No. MC–F 21041 to: Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, send one copy of comments to the Applicants' representative: Andrew K. Light, Scopelitis, Garvin, Light, Hanson & Feary, P.C., 10 W. Market Street, Suite 1500, Indianapolis, IN 46204.

FOR FURTHER INFORMATION CONTACT: Julia M. Farr, (202) 245–0359. Federal Information Relay Service (FIRS) for the hearing impaired: 1-(800) 877–8339.

SUPPLEMENTARY INFORMATION: A British Corporation, National Express Group, PLC, controls NEC and NEAC, both of which are noncarrier holding companies incorporated in Delaware. NEC controls Vogel Bus Company, Inc. (MC–274520) (Vogel) and Durham School Services, L.P. (MC–163066) (Durham), both of which are motor carriers providing interstate charter passenger services to the public.[1] PPI is a noncarrier holding company incorporated in Delaware. All of the Petermann Carriers primarily provide school bus transportation. Their interstate charter operations, which are subject to the Board's jurisdiction, are limited and often provided in school buses.

Under the proposed transaction, NEAC seeks permission to acquire, directly or indirectly, all of the shares of PPI. Applicants state that NEC's ''operational infrastructure will be relied upon heavily for the actual operation of [the Petermann Carriers].'' Accordingly, because of this and the fact that NEC controls 2 carriers, NEC has been included as an applicant in an abundance of caution.

Under 49 U.S.C. 14303, the Board must approve and authorize a transaction it finds consistent with the public interest, taking into consideration at least: (1) The effect of the transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees. Applicants have submitted information, as required by 49 CFR 1182.2, including the information to demonstrate that the proposed transaction is consistent with the public interest under 49 U.S.C. 14303(b), and a statement that the 12-month aggregate gross operating revenues of all motor carrier parties and all motor carriers controlling, controlled by, or under common control with any party exceeded $2 million.

Applicants state that: (1) The proposed transaction will have no impact on the adequacy of transportation services available to the public, because the operations of the Petermann carriers will continue to be provided by the same companies under the same name, as part of the NEC corporate family, an organization with experience in passenger transportation; and (2) the proposed transaction will have no fixed charges. Applicants also state that the proposed transaction will not have substantial impacts on employees or labor conditions because NEC does not anticipate a measurable reduction in force or change in compensation levels and/or benefits, although NEC states that it is possible that a limited number of back-office and/or managerial personnel could be affected. Additional information, including a copy of the application, may be obtained from the applicants' representative.

On the basis of the application, the Board finds that the proposed acquisition of control is consistent with the public interest and should be tentatively approved and authorized. If any opposing comments are timely filed, this finding will be deemed vacated and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the application. *See* 49 CFR 1182.6(c). If no opposing comments are filed by the expiration of the comment period, this notice will take effect automatically and will be the final Board action.

The parties' application and Board decisions and notices are available on our Web site at WWW.STB.DOT.GOV.

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

It is ordered:

1. The proposed finance transaction is approved and authorized, subject to the filing of opposing comments.

2. If timely opposing comments are filed, the findings made in this notice will be deemed as having been vacated.

3. This notice will be effective December 16, 2011, unless timely opposing comments are filed.

4. A copy of this decision will be served on: (1) U.S. Department of Transportation, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue NW., Washington, DC 20530; and (3) the U.S. Department of Transportation, Office of the General Counsel, 1200 New Jersey Avenue SE., Washington, DC 20590.

Decided: October 28, 2011.

By the Board, Chairman Elliott, Vice Chairman Begeman, and Commissioner Mulvey.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2011–28408 Filed 11–1–11; 8:45 am]

BILLING CODE 4915–01–P

[1] The core business of Vogel and Durham is transporting students to and from school, a type of transportation that is not subject to Board jurisdiction. *See* 49 U.S.C. 13506(a)(1). Vogel and Durham also provide interstate charter services (using both school buses and motor coaches), which is subject to the Board's jurisdiction.

DEPARTMENT OF THE TREASURY

Office of the Secretary

List of Countries Requiring Cooperation With an International Boycott

In accordance with section 999(a)(3) of the Internal Revenue Code of 1986, the Department of the Treasury is publishing a current list of countries which require or may require participation in, or cooperation with, an international boycott (within the meaning of section 999(b)(3) of the Internal Revenue Code of 1986).

On the basis of the best information currently available to the Department of the Treasury, the following countries require or may require participation in, or cooperation with, an international boycott (within the meaning of section

999(b)(3) of the Internal Revenue Code of 1986).

Kuwait
Lebanon
Libya
Qatar
Saudi Arabia
Syria
United Arab Emirates
Yemen

Iraq is not included in this list, but its status with respect to future lists remains under review by the Department of the Treasury.

Dated: October 25, 2011.

Michael J. Caballero,

International Tax Counsel (Tax Policy).

[FR Doc. 2011–28310 Filed 11–1–11; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Additional Designations, Foreign Narcotics Kingpin Designation Act

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (''OFAC'') is publishing the names of 2 entities and 3 individuals whose property and interests in property have been blocked pursuant to the Foreign Narcotics Kingpin Designation Act (''Kingpin Act'') (21 U.S.C. 1901–1908, 8 U.S.C. 1182).

DATES: The designation by the Director of OFAC of the 2 entities and 3 individuals identified in this notice pursuant to section 805(b) of the Kingpin Act is effective on October 27, 2011.

FOR FURTHER INFORMATION CONTACT: Assistant Director, Compliance Outreach & Implementation, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220, tel.: (202) 622–2490.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

This document and additional information concerning OFAC are available on OFAC's Web site (*http://www.treas.gov/ofac*) or via facsimile through a 24-hour fax-on-demand service, tel.: (202) 622–0077.

Background

The Kingpin Act became law on December 3, 1999. The Kingpin Act establishes a program targeting the activities of significant foreign narcotics traffickers and their organizations on a worldwide basis. It provides a statutory framework for the President to impose sanctions against significant foreign narcotics traffickers and their organizations on a worldwide basis, with the objective of denying their businesses and agents access to the U.S. financial system and the benefits of trade and transactions involving U.S. companies and individuals.

The Kingpin Act blocks all property and interests in property, subject to U.S. jurisdiction, owned or controlled by significant foreign narcotics traffickers as identified by the President. In addition, the Secretary of the Treasury consults with the Attorney General, the Director of the Central Intelligence Agency, the Director of the Federal Bureau of Investigation, the Administrator of the Drug Enforcement Administration, the Secretary of Defense, the Secretary of State, and the Secretary of Homeland Security when designating and blocking the property and interests in property, subject to U.S. jurisdiction, of persons who are found to be: (1) Materially assisting in, or providing financial or technological support for or to, or providing goods or services in support of, the international narcotics trafficking activities of a person designated pursuant to the Kingpin Act; (2) owned, controlled, or directed by, or acting for or on behalf of, a person designated pursuant to the Kingpin Act; or (3) playing a significant role in international narcotics trafficking.

On October 27, 2011, the Director of OFAC designated 2 entities and 3 individuals whose property and interests in property are blocked pursuant to section 805(b) of the Foreign Narcotics Kingpin Designation Act.

The list of designees is as follows:

Entities

1. AUTOS MINI, Avenida Delante, No. 1806, Colonia Costa Bella, Ensenada, Baja California, Mexico; (ENTITY) [SDNTK]
2. AUTODROMO CULIACAN RACE PARK, Blvd. Universitarios No. 196 Ote., Piso 4, Colonia Tierra Blanca, Culiacan, Sinaloa, Mexico; Carretera Libre, Culiacan-Mazatlan KM 8, Culiacan, Sinaloa, Mexico; Constitucion No. 1006 Pte., Esquina con Victoria, Colonia Jorge Almada, Culiacan, Sinaloa, Mexico; (ENTITY) [SDNTK]

Individuals

1. AVENDANO OJEDA, Martin Guadencio (a.k.a. OJEDA AVENDANO, Martin; a.k.a. AVENDANO LOPEZ, Martin; a.k.a. AVENDANO, Mariano; a.k.a. NARANJO, Carlos); c/o AUTOS MINI, Ensenada, Baja California, Mexico; c/o AUTODROMO CULIACAN, Culiacan, Sinaloa, Mexico; San Bernardino, Colombia; Iguala, Guerrero, Mexico; Ensenada, Baja California, Mexico; Mexicali, Baja California, Mexico; La Paz, Baja California Sur, Mexico; Avenida Jose Lopez Portillo No. 2031, Culiacan, Sinaloa, Mexico; Calle Antonio Caso No. 500, Colonia Aurora, Culiacan, Sinaloa, Mexico; Calle Amapola No. 12, Colonia 10 de Mayo, Culiacan, Sinaloa, Mexico; Calle Venustiano Carranza No. 34, Colonia Centro, Comondu, Baja California Sur, Mexico; Avenida Delante No. 1806, Colonia Miguel Hidalgo, Ensenada, Baja California, Mexico; DOB 14 Nov 1968; Alt. DOB 14 Nov 1966; POB Culiacan, Sinaloa, Mexico; Citizen Mexico; Nationality Mexico; R.F.C. AEOM–681114–818 (Mexico); (INDIVIDUAL) [SDNTK]
2. AVENDANO OJEDA, Hector Manuel, c/o AUTODROMO CULIACAN, Culiacan, Sinaloa, Mexico; Calle Antonio Caso No. 500, Colonia Aurora, Culiacan, Sinaloa, Mexico; Calle Mision de Sab Gabriel Arcangel No 2335, Interior A, Colonia Real Nueva Galicia, Culiacan, Sinaloa, Mexico; DOB 02 Nov 1971; POB Sinaloa, Mexico; Citizen Mexico; Nationality Mexico; C.U.R.P. AEOH711102HSLVJC08 (Mexico); R.F.C. AEOH–711102–I99 (Mexico); (INDIVIDUAL) [SDNTK]
3. AVENDANO OJEDA, Sergio, Calle Paseo Humaya No. 1466, Colonia Rincon de Guadalupe, Culiacan, Sinaloa, Mexico; Calle Delante No. 1806, Colonia Miguel Hidalgo, Ensenada, Baja California, Mexico; Calle Amapola No. 21, Colonia Diez de Mayo, Culiacan de Rosales, Culiacan, Sinaloa, Mexico; DOB 31 Mar 1980; POB Baja California Sur, Mexico; Citizen Mexico; Nationality Mexico; C.U.R.P. AEOS800331HBSVJR06 (Mexico); R.F.C. AEOS–800331–QH2 (Mexico); (INDIVIDUAL) [SDNTK]

Dated: October 27, 2011.

Adam J. Szubin,

Director, Office of Foreign Assets Control.

[FR Doc. 2011–28390 Filed 11–1–11; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of Expanded Pricing Grid for Precious Metals Products Containing Platinum and Gold—Excluding Commemorative Gold Coins

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint published a document in the **Federal Register** on January 6, 2009, outlining the new pricing methodology for numismatic products containing platinum and gold. Since that time, the price of platinum and gold has increased considerably, and is approaching the upper bracket of the pricing grid. As a result, it is necessary to expand the pricing grid by adding additional pricing brackets.

FOR FURTHER INFORMATION CONTACT: B.B. Craig, Associate Director for Sales and Marketing, United States Mint, 801 Ninth Street NW., Washington, DC 20220; or call (202) 354–7500.

31 U.S.C., 9701(b)(2)(B).

Dated: October 13, 2011.

Richard A. Peterson,

Deputy Director, United States Mint.

PRICING CRITERIA

Criteria No.	Current range in use	Weekly average London fix	Wednesday London P.M. fix	New range to be used
1	XX to YY	Same as Current Range	Same as Current Range	No Change to Range Currently in Use.
2	XX to YY	Outside Current Range (either up or down 1 or more levels).	Outside Current Range and agrees with Weekly Average.	Change—Use Range of Both.
3	XX to YY	Outside Current Range (either up or down 1 or more levels).	Still Within Current Range	No Change to Range Currently in Use.
4	XX to YY	Same as Current Range	Outside Current Range (either up or down).	No Change to Range Currently in Use.
5	XX to YY	Outside Current Range (either up or down one level).	Outside Current Range, in the Same Direction as Weekly Average but in a Different Range.	Change—Use Range of Weekly Average.
6	XX to YY	Outside Current Range (either up or down 1 or more levels).	Outside Current Range, in opposite Direction as Weekly Average.	No Change to Range Currently in Use.
7	XX to YY	Outside Current Range (either up or down more than 1 level).	Outside Current Range in the Same Direction as Weekly Average but in a Different Range.	Change—Use Range of Weekly Average.

Note: The United States Mint reserves the right to discontinue sale of gold numismatic products in the event that the selling price of United States Mint gold bullion products begin approaching the sale price of the gold numismatic products.

PRICING OF NUMISMATIC PRODUCTS CONTAINING GOLD COINS

Average price of gold		American Buffalo gold proof	American Eagle gold proof	American Eagle gold uncirculated	First Spouse 24K proof	First Spouse 24K uncirculated
$500.00 to $549.99	1 oz	$810.00	$785.00	$778.00		
	½ oz		406.00		$429.00	$416.00
	¼ oz		215.50			
	1/10 oz		100.50			
	4 coins		1,458.00			
$550.00 to $599.99	1 oz	860.00	835.00	828.00		
	½ oz		431.00		454.00	441.00
	¼ oz		228.00			
	1/10 oz		105.50			
	4 coins		1,550.50			
$600.00 to $649.99	1 oz	910.00	885.00	878.00		
	½ oz		456.00		479.00	466.00
	¼ oz		240.50			
	1/10 oz		110.50			
	4 coins		1,643.00			
$650.00 to $699.99	1 oz	960.00	935.00	928.00		
	½ oz		481.00		504.00	491.00
	¼ oz		253.00			
	1/10 oz		115.50			
	4 coins		1,735.50			
$700.00 to $749.99	1 oz	1,010.00	985.00	978.00		
	½ oz		506.00		529.00	516.00
	¼ oz		265.50			
	1/10 oz		120.50			
	4 coins		1,828.00			
$750.00 to $799.99	1 oz	1,060.00	1,035.00	1,028.00		
	½ oz		531.00		554.00	541.00
	¼ oz		278.00			
	1/10 oz		125.50			

PRICING OF NUMISMATIC PRODUCTS CONTAINING GOLD COINS—Continued

Average price of gold		American Buffalo gold proof	American Eagle gold proof	American Eagle gold uncirculated	First Spouse 24K proof	First Spouse 24K uncirculated
	4 coins		1,920.50			
$800.00 to $849.99	1 oz	1,110.00	1,085.00	1,078.00		
	½ oz		556.00		579.00	566.00
	¼ oz		290.50			
	1/10 oz		130.50			
	4 coins		2,013.00			
$850.00 to $899.99	1 oz	1,160.00	1,135.00	1,128.00		
	½ oz		581.00		604.00	591.00
	¼ oz		303.00			
	1/10 oz		135.50			
	4 coins		2,105.50			
$900.00 to $949.99	1 oz	1,210.00	1,185.00	1,178.00		
	½ oz		606.00		629.00	616.00
	¼ oz		315.50			
	1/10 oz		140.50			
	4 coins		2,198.00			
$950.00 to $999.99	1 oz	1,260.00	1,235.00	1,228.00		
	½ oz		631.00		654.00	641.00
	¼ oz		328.00			
	1/10 oz		145.50			
	4 coins		2,290.50			
$1,000.00 to $1,049.99	1 oz	1,310.00	1,285.00	1,278.00		
	½ oz		656.00		679.00	666.00
	¼ oz		340.50			
	1/10 oz		150.50			
	4 coins		2,383.00			
$1,050.00 to $1,099.99	1 oz	1,360.00	1,335.00	1,328.00		
	½ oz		681.00		704.00	691.00
	¼ oz		353.00			
	1/10 oz		155.50			
	4 coins		2,475.50			
$1,100.00 to $1,149.99	1 oz	1,410.00	1,385.00	1,378.00		
	½ oz		706.00		729.00	716.00
	¼ oz		365.50			
	1/10 oz		160.50			
	4 coins		2,568.00			
$1,150.00 to $1,199.99	1 oz	1,460.00	1,435.00	1,428.00		
	½ oz		731.00		754.00	741.00
	¼ oz		378.00			
	1/10 oz		165.50			
	4 coins		2,660.50			
$1,200.00 to $1,249.99	1 oz	1,510.00	1,485.00	1,478.00		
	½ oz		756.00		779.00	766.00
	¼ oz		390.50			
	1/10 oz		170.50			
	4 coins		2,753.00			
$1,250.00 to $1,299.99	1 oz	1,560.00	1,535.00	1,528.00		
	½ oz		781.00		804.00	791.00
	¼ oz		403.00			
	1/10 oz		175.50			
	4 coins		2,845.50			
$1,300.00 to $1,349.99	1 oz	1,610.00	1,585.00	1,578.00		
	½ oz		806.00		829.00	816.00
	¼ oz		415.50			
	1/10 oz		180.50			
	4 coins		2,938.00			
$1,350.00 to $1,399.99	1 oz	1,660.00	1,635.00	1,628.00		
	½ oz		831.00		854.00	841.00
	¼ oz		428.00			
	1/10 oz		185.50			
	4 coins		3,030.50			
$1,400.00 to $1,449.99	1 oz	1,710.00	1,685.00	1,678.00		
	½ oz		856.00		879.00	866.00
	¼ oz		440.50			
	1/10 oz		190.50			
	4 coins		3,123.00			
$1,450.00 to $1,499.99	1 oz	1,760.00	1,735.00	1,728.00		
	½ oz		881.00		904.00	891.00
	¼ oz		453.00			
	1/10 oz		195.50			

PRICING OF NUMISMATIC PRODUCTS CONTAINING GOLD COINS—Continued

Average price of gold		American Buffalo gold proof	American Eagle gold proof	American Eagle gold uncirculated	First Spouse 24K proof	First Spouse 24K uncirculated
	4 coins		3,215.50			
$1,500.00 to $1,549.99	1 oz	1,810.00	1,785.00	1,778.00		
	½ oz		906.00		929.00	916.00
	¼ oz		465.50			
	1/10 oz		200.50			
	4 coins		3,308.00			
$1,550.00 to $1,599.99	1 oz	1,860.00	1,835.00	1,828.00		
	½ oz		931.00		954.00	941.00
	¼ oz		478.00			
	1/10 oz		205.50			
	4 coins		3,400.50			
$1,600.00 to $1,649.99	1 oz	1,910.00	1,885.00	1,878.00		
	½ oz		956.00		979.00	966.00
	¼ oz		490.50			
	1/10 oz		210.50			
	4 coins		3,493.00			
$1,650.00 to $1,699.99	1 oz	1,960.00	1,935.00	1,928.00		
	½ oz		981.00		1,004.00	991.00
	¼ oz		503.00			
	1/10 oz		215.50			
	4 coins		3,585.50			
$1,700.00 to $1,749.99	1 oz	2,010.00	1,985.00	1,978.00		
	½ oz		1,006.00		1,029.00	1,016.00
	¼ oz		515.50			
	1/10 oz		220.50			
	4 coins		3,678.00			
$1,750.00 to $1,799.99	1 oz	2,060.00	2,035.00	2,028.00		
	½ oz		1,031.00		1,054.00	1,041.00
	¼ oz		528.00			
	1/10 oz		225.50			
	4 coins		3,770.50			
$1,800.00 to $1,849.99	1 oz	2,110.00	2,085.00	2,078.00		
	½ oz		1,056.00		1,079.00	1,066.00
	¼ oz		540.50			
	1/10 oz		230.50			
	4 coins		3,863.00			
$1,850.00 to $1,899.99	1 oz	2,160.00	2,135.00	2,128.00		
	½ oz		1,081.00		1,104.00	1,091.00
	¼ oz		553.00			
	1/10 oz		235.50			
	4 coins		3,955.50			
$1,900.00 to $1,949.99	1 oz	2,210.00	2,185.00	2,178.00		
	½ oz		1,106.00		1,129.00	1,116.00
	¼ oz		565.50			
	1/10 oz		240.50			
	4 coins		4,048.00			
$1,950.00 to $1,999.99	1 oz	2,260.00	2,235.00	2,228.00		
	½ oz		1,131.00		1,154.00	1,141.00
	¼ oz		578.00			
	1/10 oz		245.50			
	4 coins		4,140.50			
$2,000.00 to $2,049.99	1 oz	2,310.00	2,285.00	2,278.00		
	½ oz		1,156.00		1,179.00	1,166.00
	¼ oz		590.50			
	1/10 oz		250.50			
	4 coins		4,233.00			
$2,050.00 to $2,099.99	1 oz	2,360.00	2,335.00	2,328.00		
	½ oz		1,181.00		1,204.00	1,191.00
	¼ oz		603.00			
	1/10 oz		255.50			
	4 coins		4,325.50			
$2,100.00 to $2,149.99	1 oz	2,410.00	2,385.00	2,378.00		
	½ oz		1,206.00		1,229.00	1,216.00
	¼ oz		615.50			
	1/10 oz		260.50			
	4 coins		4,418.00			
$2,150.00 to $2,199.99	1 oz	2,460.00	2,435.00	2,428.00		
	½ oz		1,231.00		1,254.00	1,241.00
	¼ oz		628.00			
	1/10 oz		265.50			

PRICING OF NUMISMATIC PRODUCTS CONTAINING GOLD COINS—Continued

Average price of gold		American Buffalo gold proof	American Eagle gold proof	American Eagle gold uncirculated	First Spouse 24K proof	First Spouse 24K uncirculated
	4 coins		4,510.50			
$2,200.00 to $2,249.99	1 oz	2,510.00	2,485.00	2,478.00		
	½ oz		1,256.00		1,279.00	1,266.00
	¼ oz		640.50			
	1/10 oz		270.50			
	4 coins		4,603.00			
$2,250.00 to $2,299.99	1 oz	2,560.00	2,535.00	2,528.00		
	½ oz		1,281.00		1,304.00	1,291.00
	¼ oz		653.00			
	1/10 oz		275.50			
	4 coins		4,695.50			
$2,300.00 to $2,349.99	1 oz	2,610.00	2,585.00	2,578.00		
	½ oz		1,306.00		1,329.00	1,316.00
	¼ oz		665.50			
	1/10 oz		280.50			
	4 coins		4,788.00			
$2,350.00 to $2,399.99	1 oz	2,660.00	2,635.00	2,628.00		
	½ oz		1,331.00		1,354.00	1,341.00
	¼ oz		678.00			
	1/10 oz		285.50			
	4 coins		4,880.50			
$2,400.00 to $2,449.99	1 oz	2,710.00	2,685.00	2,678.00		
	½ oz		1,356.00		1,379.00	1,366.00
	¼ oz		690.50			
	1/10 oz		290.50			
	4 coins		4,973.00			
$2,450.00 to $2,499.99	1 oz	2,760.00	2,735.00	2,728.00		
	½ oz		1,381.00		1,404.00	1,391.00
	¼ oz		703.00			
	1/10 oz		295.50			
	4 coins		5,065.50			
$2,500.00 to $2,549.99	1 oz	2,810.00	2,785.00	2,778.00		
	½ oz		1,406.00		1,429.00	1,416.00
	¼ oz		715.50			
	1/10 oz		300.50			
	4 coins		5,158.00			
$2,550.00 to $2,599.99	1 oz	2,860.00	2,835.00	2,828.00		
	½ oz		1,431.00		1,454.00	1,441.00
	¼ oz		728.00			
	1/10 oz		305.50			
	4 coins		5,250.50			
$2,600.00 to $2,649.99	1 oz	2,910.00	2,885.00	2,878.00		
	½ oz		1,456.00		1,479.00	1,466.00
	¼ oz		740.50			
	1/10 oz		310.50			
	4 coins		5,343.00			
$2,650.00 to $2,699.99	1 oz	2,960.00	2,935.00	2,928.00		
	½ oz		1,481.00		1,504.00	1,491.00
	¼ oz		753.00			
	1/10 oz		315.50			
	4 coins		5,435.50			
$2,700.00 to $2,749.99	1 oz	3,010.00	2,985.00	2,978.00		
	½ oz		1,506.00		1,529.00	1,516.00
	¼ oz		765.50			
	1/10 oz		320.50			
	4 coins		5,528.00			
$2,750.00 to $2,799.99	1 oz	3,060.00	3,035.00	3,028.00		
	½ oz		1,531.00		1,554.00	1,541.00
	¼ oz		778.00			
	1/10 oz		325.50			
	4 coins		5,620.50			
$2,800.00 to $2,849.99	1 oz	3,110.00	3,085.00	3,078.00		
	½ oz		1,556.00		1,579.00	1,566.00
	¼ oz		790.50			
	1/10 oz		330.50			
	4 coins		5,713.50			
$2,850.00 to $2,899.99	1 oz	3,160.00	3,135.00	3,128.00		
	½ oz		1,581.00		1,604.00	1,591.00
	¼ oz		803.00			
	1/10 oz		335.50			

PRICING OF NUMISMATIC PRODUCTS CONTAINING GOLD COINS—Continued

Average price of gold		American Buffalo gold proof	American Eagle gold proof	American Eagle gold uncirculated	First Spouse 24K proof	First Spouse 24K uncirculated
	4 coins		5,805.50			
$2,900.00 to $2,949.99	1 oz	3,210.00	3,185.00	3,178.00		
	½ oz		1,606.00		1,629.00	1,616.00
	¼ oz		815.50			
	1/10 oz		340.50			
	4 coins		5,898.00			
$2,950.00 to $2,999.99	1 oz	3,260.00	3,235.00	3,228.00		
	½ oz		1,631.00		1,654.00	1,641.00
	¼ oz		828.00			
	1/10 oz		345.50			
	4 coins		5,990.50			

PRICING OF NUMISMATIC PRODUCTS CONTAINING PLATINUM COINS

Average price of platinum		American Eagle platinum proof
$550.00 to $649.99	1 oz	$892.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$650.00 to $749.99	1 oz	992.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$750.00 to $849.99	1 oz	1,092.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$850.00 to $949.99	1 oz	1,192.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$950.00 to $1,049.99	1 oz	1,292.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,050.00 to $1,149.99	1 oz	1,392.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,150.00 to $1,249.99	1 oz	1,492.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,250.00 to $1,349.99	1 oz	1,592.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,350.00 to $1,449.99	1 oz	1,692.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,450.00 to $1,549.99	1 oz	1,792.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,550.00 to $1,649.99	1 oz	1,892.00
	½ oz	

PRICING OF NUMISMATIC PRODUCTS CONTAINING PLATINUM COINS—Continued

Average price of platinum		American Eagle platinum proof
	¼ oz	
	1/10 oz	
	4 coins	
$1,650.00 to $1,749.99	1 oz	1,992.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,750.00 to $1,849.99	1 oz	2,092.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,850.00 to $1,949.99	1 oz	2,192.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$1,950.00 to $2,049.99	1 oz	2,292.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,050.00 to $2,149.99	1 oz	2,392.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,150.00 to $2,249.99	1 oz	2,492.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,250.00 to $2,349.99	1 oz	2,592.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,350.00 to $2,449.99	1 oz	2,692.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,450.00 to $2,549.99	1 oz	2,792.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,550.00 to $2,649.99	1 oz	2,892.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,650.00 to $2,749.99	1 oz	2,992.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,750.00 to $2,849.99	1 oz	3,092.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,850.00 to $2,949.99	1 oz	3,192.00
	½ oz	
	¼ oz	
	1/10 oz	
	4 coins	
$2,950.00 to $3,049.99	1 oz	3,292.00
	½ oz	
	¼ oz	

PRICING OF NUMISMATIC PRODUCTS CONTAINING PLATINUM COINS—Continued

Average price of platinum		American Eagle platinum proof
	1/10 oz	
	4 coins	
$3,050.00 to $3,149.99	1 oz	3,392.00
	1/2 oz	
	1/4 oz	
	1/10 oz	
	4 coins	
$3,150.00 to $3,249.99	1 oz	3,492.00
	1/2 oz	
	1/4 oz	
	1/10 oz	
	4 coins	
$3,250.00 to $3,349.99	1 oz	3,592.00
	1/2 oz	
	1/4 oz	
	1/10 oz	
	4 coins	
$3,350.00 to $3,449.99	1 oz	3,692.00
	1/2 oz	
	1/4 oz	
	1/10 oz	
	4 coins	

[FR Doc. 2011–28354 Filed 11–1–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

United States Mint

Pricing for the American Eagle 25th Anniversary Silver Coin Set

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing the price of the American Eagle 25th Anniversary Silver Coin Set. The coin set will be offered for sale at a price of $299.95.

FOR FURTHER INFORMATION CONTACT: B. B. Craig, Associate Director for Sales and Marketing; United States Mint; 801 9th Street NW., Washington, DC 20220; or call (202) 354–7500.

Authority: 31 U.S.C. 5111, 5112 & 9701 .

Richard A. Peterson,

Deputy Director, United States Mint.

[FR Doc. 2011–28327 Filed 11–1–11; 8:45 am]

BILLING CODE 4810–02–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 425

Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 425

[CMS–1345–F]

RIN 0938–AQ22

Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule implements section 3022 of the Affordable Care Act which contains provisions relating to Medicare payments to providers of services and suppliers participating in Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program. Under these provisions, providers of services and suppliers can continue to receive traditional Medicare fee-for-service (FFS) payments under Parts A and B, and be eligible for additional payments if they meet specified quality and savings requirements.

DATES: These regulations are effective on January 3, 2012.

FOR FURTHER INFORMATION CONTACT: Rebecca Weiss, (410) 786–8084, Facsimile: (410) 786–8005, Email address: *aco@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

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Regulations Text

Acronyms

ACO Accountable Care Organization
AHRQ Agency for Healthcare Research and Quality
BAA Business Associate Agreements
BCBSMA Blue Cross Blue Shield of Massachusetts
BIPA Benefits Improvement and Protection Act
CAD Coronary Artery Disease
CAHPS Consumer Assessment of Health Providers and Systems
CAHs Critical Access Hospitals
CBIC Competitive Bidding Implementation Contractor
CBSA Core Based Statistical Area
CHCs Community Health Centers
CHIP Children's Health Insurance Program
CMP Civil Monetary Penalties
CMS Centers for Medicare & Medicaid Services
CNM Certified Nurse Midwife
CMS–HCC CMS Hierarchal Condition Category
COPD Chronic Obstructive Pulmonary Disease
CP Certified Psychologist
CSW Clinical Social Worker
CWF Common Working File
DHHS Department of Health and Human Services
DOB Date of Birth
DOJ Department of Justice
DRA Deficit Reduction Act of 2005 (Pub. L. 109–171)
DSH Disproportionate Share Hospital
DUA Data use Agreement
E&M Evaluation and Management
EHR Electronic Health Record
ESRD End Stage Renal Disease
eRx Electronic Prescribing Incentive Program
FFS Fee-for-service
FQHCs Federally Qualified Health Centers
FTC Federal Trade Commission
GAO Government Accountability Office
GPCI Geographic Practice Cost Index
GPRO Group Practice Reporting Option
HAC Hospital Acquired Conditions
HCAHPS Hospital Consumer Assessment of Health care Provider and Systems
HCC Hierarchal Condition Category
HCPCS Healthcare Common Procedure Coding System
HHAs Home Health Agencies
HICN Health Insurance Claim Number
HIPAA Heath Insurance Portability and Accountability Act of 1996
HIE Health Information Exchange
HIT Health Information Technology
HITECH Health Information Technology for Economic and Clinical Health
HMO Health Maintenance Organization
HRSA Health Resources and Services Administration
HVBP Hospital Value Based Purchasing
IME Indirect Medical Education
IOM Institute of Medicine
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
IRS Internal Revenue Service
LTCHs Long-Term Acute Care Hospitals
MA Medicare Advantage
MAPCP Multipayer Advanced Primary Care Practice
MedPAC Medicare Payment Advisory Commission
MHCQ Medicare Health Care Quality
MMA Medicare Prescription Drug, Improvement, and Modernization Act
MS–DRGs Medicare Severity-Adjusted Diagnosis Related Groups
MSP Minimum Savings Percentage
MSR Minimum Savings Rate
NCQA National Committee for Quality Assurance
NCCCN North Carolina Community Care Network
NP Nurse Practitioner
NPI National Provider Identifier
NQF National Quality Forum
OIG Office of Inspector General
OMB Office of Management and Budget
PA Physician Assistant
PACE Program of All Inclusive Care for the Elderly
PACFs Post-Acute Care Facilities
PCMH Patient Centered Medical Home
PFS Physician Fee Schedule
PGP Physician Group Practice
PHI Protected health information
POS Point of Service
PPO Preferred provider organization
PPS Prospective Payment System
PQRI Physician Quality Reporting Initiative
PQRS Physician Quality Reporting System
PRA Paperwork Reduction Act
PSA Primary Service Areas
RFI Request for Information
RHCs Rural Health Clinics
RIA Regulatory Impact Analysis
SNFs Skilled Nursing Facilities
SSA Social Security Administration
SSN Social Security Number
TIN Taxpayer Identification Number

I. Background

A. Introduction and Overview of Value-Based Purchasing

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of Public Law 111–148. Collectively known as the Affordable Care Act, these public laws include a number of provisions designed to improve the quality of Medicare services, support innovation and the establishment of new payment models, better align Medicare payments with provider costs, strengthen program integrity within Medicare, and put Medicare on a firmer financial footing.

Many provisions within the Affordable Care Act implement value-based purchasing programs; section 3022 requires the Secretary to establish the Medicare Shared Savings Program (Shared Savings Program), intended to encourage the development of Accountable Care Organizations (ACOs) in Medicare. The Shared Savings Program is a key component of the Medicare delivery system reform initiatives included in the Affordable Care Act and is a new approach to the delivery of health care aimed at: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in Medicare Parts A and B expenditures. We refer to this approach throughout this final rule as the three-part aim.

Value-based purchasing is a concept that links payment directly to the quality of care provided and is a strategy that can help transform the current payment system by rewarding providers for delivering high quality, efficient clinical care. In the April 7, 2011 **Federal Register** (76 FR 19528), we published the Shared Savings Program proposed rule. In the proposed rule, we

discussed our experience implementing value based purchasing concepts. In addition to improving quality, value-based purchasing initiatives seek to reduce growth in health care expenditures.

We view value-based purchasing as an important step to revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of merely increased volume. For a complete discussion, including our goals in implementing value-based purchasing initiatives, please refer to section I.A. of the proposed rule (76 FR 19530).

B. Statutory Basis for the Medicare Shared Savings Program

Section 3022 of the Affordable Care Act amended Title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to the Act to establish a Shared Savings Program that promotes accountability for a patient population, coordinates items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. A detailed summary of the provisions within section 3022 of the Affordable Care Act is in section I.B. of the proposed rule (see 76 FR 19531).

C. Overview of the Medicare Shared Savings Program

The intent of the Shared Savings Program is to promote accountability for a population of Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery, and incent higher value care. As an incentive to ACOs that successfully meet quality and savings requirements, the Medicare Program can share a percentage of the achieved savings with the ACO. Under the Shared Savings Program, ACOs will only share in savings if they meet both the quality performance standards and generate shareable savings. In order to fulfill the intent of the Shared Savings Program as established by the Affordable Care Act, we stated in the proposed rule that we will focus on achieving the three-part aim consisting of: (1) Better care for individuals; (2) better health for populations; and (3) lower growth in expenditures.

In developing the Shared Savings Program, and in response to stakeholder suggestions, we have worked very closely with agencies across the Federal government to develop policies to encourage participation and ensure a coordinated and aligned inter- and intra-agency program implementation. The result of this effort is the release of several documents that potential participants are strongly encouraged to review. These documents are described in more detail in section II.C.5. of this final rule, and include: (1) A joint CMS and DHHS OIG interim final rule with comment period published elsewhere in this issue of the **Federal Register** entitled Medicare Program; Final Waivers in Connection With the Shared Savings Program; (2) IRS Notice 2011–20 and other applicable IRS guidance viewable on www.irs.gov; and (3) a Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program issued by the FTC and DOJ (collectively, the Antitrust Agencies).

In this final rule we have made significant modifications to reduce burden and cost for participating ACOs. These modifications include: (1) Greater flexibility in eligibility to participate in the Shared Savings Program; (2) multiple start dates in 2012; (3) establishment of a longer agreement period for those starting in 2012; (4) greater flexibility in the governance and legal structure of an ACO; (5) simpler and more streamlined quality performance standards; (6) adjustments to the financial model to increase financial incentives to participate; (7) increased sharing caps; (8) no down-side risk and first-dollar sharing in Track 1; (9) removal of the 25 percent withhold of shared savings; (10) greater flexibility in timing for the evaluation of sharing savings (claims run-out reduced to 3 months); (11) greater flexibility in antitrust review; and (12) greater flexibility in timing for repayment of losses; and (13) additional options for participation of FQHCs and RHCs.

D. Public Comments Received on the Proposed Rule

We received approximately 1,320 public comments on the April 7, 2011 proposed rule (76 FR 19528). These public comments addressed issues on multiple topics and here, rather than throughout the regulation, we extend our great appreciation for the input. We received some comments that were outside the scope of the proposed rule and therefore not addressed in this final rule (for example, suggested changes to the physician fee schedule, or suggestions on other Affordable Care Act provisions). Summaries of the public comments that are within the scope of the proposals and our responses to those comments are set forth in the various sections of this final rule under the appropriate headings. In this final rule, we have organized the document by presenting our proposals, summarizing and responding to the public comment for the proposal(s), and describing our final policy.

Comment: We received comments expressing support for the proposed design of the Shared Savings Program, as well as comments disagreeing with it. Those in disagreement generally found the proposed requirements to be too prescriptive and burdensome. Other commenters expressed their disagreement with a program they perceive as limiting access to necessary care.

Response: We appreciate all the feedback we received. We have been encouraged by the level of engagement by stakeholders in this rulemaking process. We thank all of the commenters for helping us develop the Shared Savings Program. Where possible we have tried to reduce or eliminate prescriptive or burdensome requirements that could discourage participation in the Shared Savings Program. We have also been vigilant in protecting the rights and benefits of FFS beneficiaries under traditional Medicare to maintain the same access to care and freedom of choice that existed prior to the implementation of this program. These provisions can be found throughout this final rule.

Comment: Two commenters encouraged CMS to make the PGP demonstration a national program. In contrast, a few commenters stated concern about insufficient testing of the Shared Savings Program as a demonstration program prior to this final rule. The commenters acknowledged the PGP demonstration as the precursor, but stated that our proposals deviated too far from the PGP demonstration. One commenter noted the PGP demonstration consisted of large health organizations that had access to $1.75 million in capital and while half of the participants shared in savings, none had a complete return on their investment. They suggested that CMS continue to create demonstration projects for shared savings initiatives and delay the implementation of the Shared Savings Program. One commenter suggested phasing in the program. Specifically, the commenter suggested that we start small and periodically assess the program's requirements to determine which policies promote success and which create barriers.

Response: The Shared Savings Program adopts many of the program aspects of the PGP demonstration, but some adjustments were necessary in

order to create a national program. We removed a few of the proposed deviations from the PGP demonstration from this final rule. For example, under the policies we are implementing in this final rule, Shared Savings Program participants may choose to enter a ''shared savings'' only track that will not require repayment of losses. The statute does not authorize us to delay the establishment of the Shared Savings Program. But, it is important to note that the Shared Savings Program is a voluntary program. Organizations that are not ready to participate can begin the transition towards a more coordinated delivery system, incorporating policies that promote success for the early participants and join the program at such time as they are ready. Additionally, the Innovation Center will continue to test program models that may influence policies adopted for future agreement periods for the Shared Savings Program. We intend to assess the policies for the Innovation Center's models and the Shared Savings Program to determine how well they are working and if there are any modifications that would enhance them.

Comment: One commenter expressed concern that we appeared to be limiting participation in the Shared Savings Program to 5 million beneficiaries and 100 to 200 ACOs.

Response: We assume this commenter was referring to the Regulatory Impact Analysis section of our proposed rule where our Office of the Actuary estimated that up to 5 million beneficiaries would receive care from providers participating in ACOs. That figure was an estimate based on the proposed program requirements and the anticipated level of interest and participation of providers based on the requirements. After making programmatic changes based on commenter feedback, we believe the policies implemented in this final rule will be more attractive to participants and have a positive impact on those estimates. Please note that as a voluntary national program, any and all groups of providers and suppliers that meet the eligibility criteria outlined in this final rule are invited to participate.

Comment: Many commenters requested CMS issue an interim final rule, rather than a final rule, in order to have flexibility to modify the proposals in the proposed rule. One commenter suggested the 60-day comment period did not provide enough time to analyze and comment on the proposed rule given the volume and complexity of the specific proposals as related to tribal health organizations and other public health providers.

Response: In the proposed rule, we not only outlined our proposals for implementing the Shared Savings Program, but also provided detailed information on other alternatives we had considered and we sought comment on both our proposed policies and the other alternatives. The public comments submitted in response to the proposed rule have provided us with additional information and background regarding not only our proposed policies, but also the alternatives we considered. In response to the public comments, we have made significant changes to a number of our proposed policies. Nevertheless, we believe the policies in this final rule remain consistent with the overall framework for the program initially laid out in the proposed rule. As a result, we do not believe that there is any benefit to publishing this rule as an interim final rule rather than a final rule. We also believe 60 days represented a sufficient amount of time for interested parties to submit their comments on the proposed rule. We received many detailed comments in response to the proposed rule within the 60-day comment period. We also note that a 60-day comment period is consistent with the requirements of section 1871(b)(1) of the Act and is the standard timeframe used for many of our proposed rules.

Comment: Many commenters were concerned that the Shared Savings Program has similar characteristics to some forms of managed care where it is possible to achieve savings through inappropriate reductions in patient care. Some commenters, for example, asserted that the Shared Savings Program is a capitated model that is not in the best interest of patients. Other commenters, such as beneficiaries and beneficiary advocates, indicated that beneficiaries should retain their right to see any doctor of their choosing. We also received comments expressing concern that, as with some managed care approaches, the Shared Savings program essentially transfers the locus of responsibility for health care away from the patient, which is not as effective as more consumer-driven approaches. Another commenter expressed concern that assignment of beneficiaries to an ACO participating in the Shared Savings Program indicates that the program is a new version of managed care. One commenter suggested using the current Medicare Advantage (MA) structure to serve as the foundation of the Shared Savings Program. The commenter argued that MA plans are better suited to take on risk and provide care that meets many of the goals of the Shared Savings Program, and allowing these entities to participate will enable the program to reach a larger population. Additionally, a commenter requested information on why CMS is creating new policies for compliance, marketing and ownership instead of using policies already in place by MA plans. A few commenters claimed other countries tried this model and failed.

Response: It is important to note that the Shared Savings Program is not a managed care program. Medicare FFS beneficiaries retain all rights and benefits under traditional Medicare. Medicare FFS beneficiaries retain the right to see any physician of their choosing, and they do not enroll in the Shared Savings Program. Unlike managed care settings, the Shared Savings Program ''assignment'' methodology in no way implies a lock in or enrollment process. To the contrary, it is a process based exclusively on an assessment of where and from whom FFS beneficiaries have chosen to receive care during the course of each performance period. The program is also not a capitated model; providers and suppliers continue to bill and receive FFS payments rather than receiving lump sum payments based upon the number of assigned beneficiaries. The design of the Shared Savings Program places the patient at the center. It encourages physicians, through the eligibility requirements, to include their patients in decision making about their health care. While we frequently relied on our experience in other Medicare programs, including MA, to help develop program requirements for the Shared Savings Program, there are often times when the requirements deviate precisely because the intent of this program is not to recreate MA. Unlike MA, this program's design retains FFS flexibility and freedom of choice available under Medicare Parts A and B which necessitates different program requirements. Lastly, in order for an ACO to share in savings the ACO must meet quality standards and program requirements that we will be monitoring. We will monitor the ACO's compliance with these requirements, as described in section II.H. of this final rule, with a special focus on ACOs that attempt to avoid at-risk patients. The purpose of the Shared Savings Program is to achieve savings through improvements in the coordination and quality of care, and not through avoiding certain beneficiaries or placing limits on beneficiary access to needed care.

Comment: One commenter suggested CMS provide funding to Regional Health Improvement Collaboratives to assist in educating Medicare beneficiaries about the program and to help enable the collection and reporting of data on patient experience. In addition, one commenter recommended the creation of a national surveillance database during ACOs implementation to guide osteoporosis prevention, intervention and treatment efforts. The commenter suggested that a national database would help reduce mortality and costs associated with preventable hip fractures due to osteoporosis.

Response: Both are excellent suggestions. Unfortunately, we are not in a position to implement these recommendations for this program at this time. The comment suggesting funding for Regional Health Improvement Collaboratives is beyond the scope of the proposed rule. We note, however, that the Innovation Center is currently accepting innovative solutions aimed at improving care delivery at their Web site, *Innovations.cms.gov*.

Comment: One commenter suggested CMS address the comments received from the November 17, 2010 RFI.

Response: In the proposed rule, we summarized many of the comments we received in response to the RFI, and these comments informed many of the policy choices made in the proposed rule. In addition, the RFI comments are publicly available at *regulations.gov.* Accordingly, we will not be addressing the entirety of those comments in this final rule; however any RFI comments we determined pertinent to this final rule may appear.

Comment: One commenter expressed concern over CMS' example of reducing unnecessary hospital visits as one way that ACOs could improve care. The commenter explained that the excess revenue created by additional ER visits helps to sustain other services provided by a hospital that may not bring in as much revenue. The commenter concluded the reduction in visits would eventually lead to the closure of many small rural hospitals. A similar comment stated that encouraging coordination and reducing fragmented care will reduce hospital reimbursements.

Response: The focus of the Shared Savings Program is to provide coordinated care to Medicare FFS beneficiaries. The program aims to provide higher quality care across the continuum of care; this may include additional office visits, as opposed to ER visits, for patients who do not require emergency services. Cost shifting is of great concern to us both within the Shared Savings Program and outside of the program. We believe it is in the patient's best interest to receive care in the proper setting and to receive emergency services only in times of emergency. Incurring costs for unnecessary care, or care provided in an inappropriate care setting, can be harmful to beneficiaries and payers alike. For more information about cost shifting related to the Shared Savings Program refer to section II.H.4. of this final rule.

E. Reorganization of the Regulations Text

We have revised the proposed regulations text to reflect the final policies adopted in this final rule. We have also made significant revisions to the structure and organization of the regulations text in order to correspond more closely with the organization of the preamble to this final rule and to make it easier to locate specific provisions within the regulations text.

II. Provisions of the Proposed Rule, Summary of and Responses to Public Comments, and the Provisions of the Final Rule

A. Definitions

For purposes of the proposed rule, we defined three terms used throughout the discussion: Accountable care organization (ACO), ACO participant, and ACO provider/supplier. We encourage the reader to review these definitions in § 425.20. We incorporated comments on these definitions into the discussion that follows.

B. Eligibility and Governance

1. General Requirements

a. Accountability for Beneficiaries

Section 1899(b)(2)(A) of the Act requires participating ACOs to ''be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.'' To satisfy this requirement, we proposed that an ACO executive who has the authority to bind the ACO must certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to us on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO. We further proposed that this certification would be included as part of the ACO's application and participation agreement.

Comment: A commenter suggested that providers should not be held liable for unmanageable patients and/or those patients that refuse treatment altogether. Other commenters recommended that we not hold an ACO accountable for those patients who choose to decline to have CMS share their claims data with the ACO. Another commenter suggested that CMS require ACOs to state specifically in their applications the processes used to assure that Medicare patients have access to relatively costly but medically necessary procedures, such as transplantation.

Response: In order to retain beneficiary freedom of choice under traditional FFS Medicare, the basis for beneficiary assignment to ACOs is where, and from whom, they choose to receive a plurality of their primary care services during the performance year. ACOs must be willing to become accountable for total quality, cost, and overall care of these Medicare FFS beneficiaries. An ACO will not receive an assignment of those beneficiaries that choose not to receive care from ACO providers. Beneficiaries who choose to receive care from ACO providers, regardless of whether they are ''unmanageable'' or noncompliant with treatment recommendations may become part of the ACO's assigned population. Since patient-centeredness is an integral part of this program, we believe such beneficiaries represent an excellent opportunity for ACOs to create, implement, and improve upon patient-centered processes that improve patient engagement. We note that avoidance of such beneficiaries, as described in more detail in section II.H.3. of this final rule, will result in termination of an ACO's participation agreement. Similarly, in the interest of beneficiary engagement and transparency, we believe it is important to provide beneficiaries with an opportunity to decline data sharing. As discussed in greater detail in section II.B.4. of this final rule, a process for beneficiaries to decline data sharing provides an opportunity for ACOs to explain to patients how access to their personal health information will help the ACO improve the quality of its care. We believe that requiring an ACO executive who has the authority to bind the ACO to certify to the best of his or her knowledge, information, and belief that the ACO participants are willing to become accountable for, and to report to us on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO provides sufficient assurance that the ACO will be accountable for its assigned beneficiaries. By allowing ACOs to determine how they will satisfy this requirement, we will afford ACOs the flexibility needed to demonstrate their

commitment to beneficiary accountability in a manner which is most suited to their own ACO model.

Final Decision: We are finalizing our policy regarding certification of accountability for beneficiaries described in (76 FR 19544) as proposed without change (§ 425.100 and 425.204).

b. Agreement Requirement

Section 1899(b)(2)(B) of the Act requires participating ACOs to ''enter into an agreement with the Secretary to participate in the program for not less than a 3-year period * * *.'' For the first round of the Shared Savings Program, we proposed to limit participation agreements to a 3-year period. We sought comments on this proposal regarding the initial consideration of a longer agreement period.

If the ACO is approved for participation, we proposed that an authorized executive—specifically, an executive who has the ability to bind the ACO must certify to the best of his or her knowledge, information, and belief that its ACO participants and its ACO providers/suppliers agree to the requirements set forth in the agreement between the ACO and us, and sign a participation agreement and submit the signed agreement to us. We proposed that the participation agreement would also include an acknowledgment that all contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other entities furnishing services related to ACO activities would require compliance with the ACO's obligations under the agreement. Additionally, we expressed our intention that all ACOs, ACO participants, and ACO providers/suppliers Shared Savings Program would be subject to the requirements of the agreement between the ACO and CMS and that all certifications submitted on behalf of the ACO in connection with the Shared Savings Program application, agreement, shared savings distribution or otherwise extend to all parties with obligations to which the particular certification applies.

An authorized executive of the ACO would sign the participation agreement after its approval for participation. Finally, we proposed that the ACO would be responsible for providing a copy of the agreement to its ACO participants and ACO providers/suppliers. We solicited comment on this proposal, including any additional measures or alternative means that we should consider to fulfill this requirement.

Comment: Commenters requested that CMS define the term authorized executive when stating that an authorized executive of the ACO must sign the participation agreement.

Response: As we stated in the proposed rule, an authorized executive is an executive of the ACO who has the ability to bind the ACO to comply with all of the requirements for participation in the Shared Savings Program.

Final Decision: We are finalizing this proposal regarding agreements as described previously under § 425.208 and § 425.210.

Further, as described in § 425.200, the ACO's agreement period will be for not less than 3 years, consistent with statute, although some agreement periods may be longer than 3 years.

c. Sufficient Number of Primary Care Providers and Beneficiaries

Section 1899(b)(2)(D) of the Act requires participating ACOs to ''include primary care ACO professionals that are sufficient for the number of Medicare FFS beneficiaries assigned to the ACO * * *'' and that at a minimum, ''the ACO shall have at least 5,000 such beneficiaries assigned to it * * *.'' Physician patient panels can vary widely in the number of FFS Medicare beneficiaries served. In section II.E. of this final rule, we discuss our assignment methodology and how its use in the assignment of beneficiaries during the baseline years in order to establish a historical per capita cost benchmark against which the ACO's evaluation during each year of the agreement period would take place. In the proposed rule, we stated we believed it would be reasonable to assume that if by using this assignment algorithm the ACO demonstrates a sufficient number of beneficiaries to fulfill this eligibility requirement for purposes of establishing a benchmark, then the ACO would also demonstrate that it contains a sufficient number of primary care professionals to provide care to these beneficiaries. We stated we believed it was also reasonable to assume the ACO would continue to approximate this number of beneficiaries in each year of the agreement period. Thus, we proposed that for purposes of eligibility under section 1899(b)(2)(D) of the Act, an ACO would be determined to have a sufficient number of primary care ACO professionals to serve the number of Medicare beneficiaries assigned to it if the number of beneficiaries historically assigned over the 3-year benchmarking period using the ACO participant TINs exceeds the 5,000 threshold for each year. We solicited comment on this proposal as well as any additional guidance to consider for meeting these requirements.

We recognize that while an ACO could meet the requirements in section 1899(b)(2) of the Act when it applies to participate in the Shared Savings Program, circumstances may change during the course of the agreement period. We discussed the importance of maintaining at least 5,000 assigned beneficiaries with respect to both eligibility of the ACO to participate in the program and the statistical stability for purposes of calculating per capita expenditures and assessing quality performance. Therefore, we considered what action, if any, should be taken in the event the number of beneficiaries assigned to the ACO falls below 5,000 in a given performance year. Specifically, we considered whether an ACO's participation in the program should be terminated or its eligibility for shared savings be deferred if the number of beneficiaries drops below 5,000. We considered several options including immediate termination, termination following a CAP, scaling shared savings payments to reflect the population change, or taking no action against the ACO. After weighting all these options, we concluded that a reasonable compromise would balance the statutory requirements and program incentives, while still recognizing expected variations in an ACO's assigned population. Thus, if an ACO's assigned population falls below 5,000 during the course of the agreement period, we proposed to issue a warning and place the ACO on a corrective action plan (CAP). For the performance year for which we issued the warning to the ACO, we proposed that the ACO would remain eligible for shared savings. We further proposed termination of the ACO's participation agreement if the ACO failed to meet the eligibility criterion of having more than 5,000 beneficiaries by the completion of the next performance year. The ACO would not be eligible to share in savings for that year. We also reserved the right to review the status of the ACO while on the corrective action plan and terminate the agreement on the basis that the ACO no longer meets eligibility requirements. We requested comment on this proposal and on other potential options for addressing situations where the assigned beneficiary population falls below 5,000 during the course of an agreement period.

Comment: Commenters generally agreed that an ACO must have a strong primary care foundation with a sufficient number of providers to meet the needs of the population it serves. Additionally, commenters suggested

that there must be strong collaboration among multidisciplinary team members to ensure care coordination and patient centered care.

Some commenters recommended that ACOs should be required to demonstrate sufficiency in the number, type, and location of providers available to provide care to the beneficiaries. Other commenters noted that the proposed rule did not mention any requirement that the ACO demonstrate sufficiency in the number, type and location of all providers available to provide multi-disciplinary care to the beneficiaries.

Some commenters recommended that the minimum threshold of beneficiaries be increased to as high as 20,000 beneficiaries to reduce uncertainties in achieving program goals while other commenters believed that the 5,000 beneficiary threshold will preclude smaller and rural entities from participating in the Shared Savings Program as forfeiture of any shared savings and termination in the year following the corrective action plan would be too financially risky when the initial start up costs are taken into account.

One commenter suggested that rather than maintain a strict 5,000 beneficiary threshold requirement, we should provide leeway to ACOs to allow for a 10 percent variation from the beneficiary minimum threshold.

Response: Congress established the 5,000 beneficiary requirement under section 1899(b)(2)(D) of the Act. A minimum threshold is important with respect to both the eligibility of the ACO to participate in the program and to the statistical stability for purposes of calculating per capita expenditures and assessing quality performance as described in section II.D. of this final rule. However, the expanded assignment methodology discussed in section II.E. of this final rule should allow more beneficiaries to be assigned to those ACOs that might have initially been ''too close'' to the threshold, increasing the ability for smaller ACOs to participate. We do not believe this warrants an increase in the threshold number of assigned beneficiaries as that could prohibit the formation of ACOs in both smaller and rural health care markets, and possibly considered contrary to statutory intent. Additionally, the expanded assignment methodology discussed in section II.E. of this final rule should allow the assignment of more beneficiaries which should make the additional flexibility offered by allowing for a 10 percent variation in the assigned population unnecessary.

We do not believe that we should be prescriptive in setting any requirements for the number, type, and location of the providers/suppliers that are included as ACO participants. Unlike managed care models that lock in beneficiaries to a network of providers, beneficiaries assigned to an ACO may receive care from providers and suppliers both inside and outside the ACO. ACOs represent a new model for the care of FFS beneficiaries and for practitioners to focus on coordination of care efforts. During the initial implementation of the Shared Savings Program, we believe that potential ACOs should have the flexibility to create an organization and design their models in a manner they believe will achieve the three-part aim without instituting specific requirements.

Final Decision: We are finalizing our proposals without change (§ 425.110).

d. Identification and Required Reporting on Participating ACO Professionals

Section 1899(b)(2)(E) of the Act requires ACOs to ''provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements * * *, and the determination of payments for shared savings * * *.'' As discussed in this section of the final rule, we are defining an ACO operationally as a legal entity that is comprised of a group of ACO participants as defined in § 425.20.

Based on our experience, we recognized that the TIN level data alone would not be entirely sufficient for a number of purposes in the Shared Savings Program. In particular, National Provider Identifier (NPI) data would be useful to assess the quality of care furnished by an ACO. For example, NPI information would be necessary to determine the percentage of registered HITECH physicians and other practitioners in the ACO (discussed in section II.F. of this final rule). NPI data would also be helpful in our monitoring of ACO activities (which we discuss in section II.H. of this final rule). Therefore, we proposed to require that organizations applying to be an ACO must provide not only their TINs but also a list of associated NPIs for all ACO professionals, including a list that separately identifies physicians that provide primary care.

We proposed that the ACO maintain, update, and annually report to us the TINs of its ACO participants and the NPIs associated with the ACO providers/suppliers. We believe that requiring this information offers the level of transparency needed to implement the Shared Savings Program. We welcomed comments on our proposal to require reporting of TINs along with information about the NPIs associated with the ACO.

Additionally, as we discussed in the proposed rule, the first step in developing a method for identifying an ACO, ACO participants, and ACO providers/suppliers is to establish a clear operational method of identifying an ACO that correctly associates its health care professionals and providers with the ACO. The operational identification is critical for implementation of the program and for determining, for example, benchmarking, assignment of beneficiaries, and other functions. Section 1899(a)(1)(A) of the Act defines ACOs as ''groups of providers of services and suppliers'' who work together to manage and coordinate care for Medicare FFS beneficiaries. More specifically, the Act refers to group practice arrangements, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between hospitals and ACO professionals, hospitals employing ACO professionals, or other combinations that the Secretary determines appropriate.

We proposed to identify an ACO operationally as a collection of Medicare enrolled TINs, defined as ACO participants. More specifically, we proposed an ACO would be identified operationally as a set of one or more ACO participants currently practicing as a ''group practice arrangement'' or in a ''network'' such as where ''hospitals are employing ACO professionals'' or where there are ''partnerships or joint ventures of hospitals and ACO professionals'' as stated under section 1899(b)(1)(A) through (E) of the Act. For example, Shared Savings Programs TIN would identify a single group practice that participates in the Shared Savings Program. The set of TINs of the practices would identify a network of independent practices that forms an ACO. We proposed to require that organizations applying to be an ACO provide their ACO participant Medicare enrolled TINs and NPIs. We can systematically link each TIN or NPI to an individual physician specialty code.

We also proposed that ACO participants on whom beneficiary assignment is based, would be exclusive to one ACO agreement in the Shared Savings Program. Under our proposal, this exclusivity would only apply to ACO participants who bill Medicare for the services rendered by primary care

physicians (defined as physicians with a designation of internal medicine, geriatric medicine, family practice and general practice, as discussed later in this final rule).

However, we acknowledged the importance of competition in the marketplace to improving quality of care, protecting access to care for Medicare beneficiaries, and preventing fraud and abuse. Therefore, under our proposal, ACO participants upon which beneficiary assignment was not dependent (for example, acute care hospitals, surgical and medical specialties, RHCs, and FQHCs) would be required to agree to participate in the Medicare ACO for the term of the agreement, but would not be restricted to participation in a single ACO.

Comment: Several commenters recommended that CMS maintain the list of TINs and NPIs. Additionally, some commenters recommended that CMS allow ACOs to verify any data reported in association with the ACO prior to these data being made public.

Response: Section 1899(b)(2)(E) of the Act requires ACOs to ''provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements * * *, and the determination of payments for shared savings * * *.'' As discussed previously, we will need both the TINs of all ACO participants and the NPIs associated with ACO providers/suppliers in order to assign beneficiaries to ACOs appropriately and accurately. Because section 1899(b)(2)(E) of the Act requires ACOs to provide us with the information we determine is necessary to support assignment, we believe it is consistent with this statutory requirement to require that ACOs maintain, update, and annually report to us those TINs and NPIs that are participants of their respective ACO. Since ACOs will be maintaining, updating, and annually reporting these TINs and NPIs to us, they will have ultimate review capabilities and it will not be necessary for us to provide them an additional opportunity to verify the names of ACO participants and ACO providers/suppliers before making this information available to the public. We note that, in order to ensure the accurate identification of any ACO, its participants, and its providers/suppliers, we may request additional information (for example, CMS Certification Numbers, mailing addresses, etc.) in the application process. We will identify any such additional information in the application materials.

Comment: One commenter stated that our assessment of billing practices was incorrect because ''beginning on May 23, 2008, all health care providers, including those enrolled in the Medicare and Medicaid program, are required by the NPI Final Rule published on January 23, 2004, to submit claims using their NPI'' but also notes that physicians participating in the Medicare program must enroll using their NPI and if they are billing through a group practice reassign their benefits to the group practice.

Response: It is true that individuals and group practices must enroll in the Medicare program under unique NPIs. It is also true that NPIs (whether for an individual practitioner or a group practice for reassigned benefits) must be included on bills to the Medicare program. However, bills to the Medicare program must also include the TIN of the billing practitioner or group practice. As we stated in the proposed rule, not all physicians and practitioners have Medicare enrolled TINs. In the case of individual practitioners, however, their SSN may be their TIN. While providers are required to have an NPI for identification and to include the NPI in billing, billing is always through a TIN, whether that is an EIN or a SSN. We successfully employed TINs in the PGP demonstration for purposes of identifying the participating organizations, and the rules cited by the commenters did not pose any obstacle to doing so. We believe that we can operationally proceed on the same basis under the Shared Savings Program.

Comment: Some commenters supported the proposal to use TINs as an organizing concept for ACOs. These commenters observed, for example, that this policy was consistent with the beginning of the PGP demonstration, under which the assignment of Medicare beneficiaries would start with the TIN of the organization providing the plurality of the visits with further assignment to a primary care provider. However, a number of other commenters requested that we reevaluate the proposal to employ TINs for identification of ACOs and assignment purposes. Some of these commenters suggested that the use of NPIs would recognize the realities of diverse systems, provide greater flexibility, and allow systems to designate those portions of the system which can most appropriately constitute an ACO. Other commenters similarly endorsed the use of NPIs as providing greater flexibility and more precision in identifying ACOs and assigning beneficiaries. One observed that using NPIs would also allow CMS and ACOs to track saving and quality improvements achieved by individual practitioners, as well as afford greater flexibility for systems to expand an ACO gradually to incorporate practitioners and components of the system.

Response: We are finalizing our proposal to define the ACO operationally by its Medicare enrolled ACO participants' TINs. Using TINs provides a direct link between the beneficiary and the practitioner(s) providing the services for purposes of beneficiary assignment. Using TINs also makes it possible for us to take advantage of infrastructure and methodologies already developed for group-level reporting and evaluation. We believe this option affords us the most flexibility and statistical stability for monitoring and evaluating quality and outcomes for the population of beneficiaries assigned to the ACO. In contrast, adopting NPIs would create much greater operational complexity because individual NPIs move much more frequently between different organizations and practices. TINs are much more stable, and thus provide much greater precision in identifying ACOs. Furthermore, identifying through TINs avoids the necessity of making the NPIs upon which assignment is based exclusive to one ACO, thus allowing these NPIs (although not TINs) to participate in more than one ACO.

Comment: Several commenters requested clarification about the use of TINs in identifying ACOs and assigning beneficiaries. Some inquired about the establishment of parameters of an ACO across a large health system with diverse and sometimes geographically remote components. Some of these commenters noted that large systems often employ a single TIN, so that the use of TINs for identification purposes would require inclusion of all the members of the system in a single ACO, even if these members are geographically remote from each other and otherwise diverse. One observed: ''Such remote entities may have a limited opportunity to participate in care coordination, and may in fact be better suited to participate in another more local ACO.'' A large clinic similarly observed that ''the use of TINs could pose a problem for large health systems.'' The owner of outpatient rehabilitation clinics in several States inquired how it would choose a single ACO in which to participate in order to serve the needs of patients in multiple States. Another asked whether it is permissible for some members of a

group practice to participate in the Shared Savings Program while others do not, adding their ''strong belief'' that participation in an ACO of some but not all providers in a group ''must be allowed.'' Another asked ''how CMS will account for the alignment of the beneficiary, signed up/enrolled with the PCP if the NP or PA saw the patient and billed using their individual NPI (which is linked to the ''PCP' physician's Tax ID), but the credit is not being assigned to the PCP physician because s/he isn't billing for the services. This could create a big gap and problem in the allocation process.'' Another commenter asked how the program would handle the situation in which a healthcare system has multiple TINs.

Response: We proposed to define an ACO operationally as a collection of Medicare enrolled TINs (that is, ACO participants). Therefore, in cases in which a healthcare system has multiple TINs, the collection of the system's TINs precisely identifies the ACO which consists of that health system. We understand the commenters' interest in the greater flexibility of, for example, including only parts of a large system with one TIN in an ACO. However, some level of exclusivity is necessary in order for the assignment process to function correctly, and especially to ensure the accurate assignment of beneficiaries to one and only one ACO. Use of TINs rather than NPIs provides the greatest degree of flexibility consistent with this requirement. Therefore, we are unable to allow, for example, a large health system with one TIN to include only parts of the system in an ACO. Systems that extend over several States can similarly choose more than one ACO for parts of their system only if they have multiple TINs. In order for a beneficiary to be assigned to an ACO in which his or her primary care physician is participating, the physician would have to bill for primary care services furnished to the beneficiary under a TIN included in that ACO.

Comment: Many commenters objected to the exclusivity of primary care physicians on the grounds that that such exclusivity could be disruptive of their current practice patterns, which may involve the assignment of patients to a number of ACOs. Some objected that the proposed lock in was unfair.

Another commenter complained that we did not sufficiently address the reasons for the lock in. Some commenters suggested methods to avoid the potential confusions that could occur in assigning beneficiary without our proposed lock in. For example, one commenter observed potential avoidance of this problem by creating incentives (for example, no deductibles and reduced co-insurance for primary care physician services) for patients to prospectively identify a primary care physician in an ACO. The commenter maintained that patients need to be accountable as well as the participating physicians and providers. Furthermore, the commenter contended that identification of a primary care physician does not have to limit patient choice in any way, but simply provides an alternative method for identifying the population of patients for which the ACO is responsible while getting more engaged patients to think about having a usual source of care. Alternatively, the commenter recommended that CMS should prospectively allow patients to choose their own Medicare ACO. This would relieve CMS from the proposed and flawed beneficiary attribution method that currently limits primary care physicians to participate in only one Medicare ACO.

Several other commenters opposed the lock in but suggested that, if we retain it, the final rule should—

- Permit primary care physicians to elect consideration as specialists without taking into account their evaluation and management services for the purpose of aligning beneficiaries with an ACO;
- Permit specialists to elect to be treated as primary care physicians whose evaluation and management services will be considered for beneficiary alignment; and
- Permit primary care physicians to participate in ACOs on an individual basis, rather than through their group practice entities or employers.

In either case, the final rule should encourage providers to work collaboratively to achieve savings and enhance care by allowing ACOs to arrange for medical services using contracted providers.

Another commenter requested that we revisit this requirement and provide additional flexibility so that primary care providers could join more than one ACO or switch ACOs on an annual basis. Commenters suggested alternative assignment strategies that would allow participation in more than one ACO such as default assignment to practitioners who are only in one ACO or having practitioners assign patients to a particular ACO based on patient needs. Some commenters also argued for adopting a policy of voluntary beneficiary enrollment in an ACO, arguing in part that this policy would allow us to abandon the proposal restricting primary care physicians to participation in one ACO, which we proposed to prevent uncertainty in the assignment process. Other commenters specifically requested that rural physicians and ambulance providers be able to participate in multiple ACOs.

Response: We regret that some of the language in the preamble about the exclusivity of ACO participants (defined by the Medicare-enrolled billing TIN) created unnecessary confusion about the proposal. The point of our proposal was that, for us to appropriately evaluate ACO performance, we must evaluate performance based on a patient population unique to the ACO. Therefore, some ACO participants, specifically those that bill for the primary care services on which we proposed to base assignment, would have to be exclusive to an ACO, for the purpose of Medicare beneficiary assignment, for the duration of an agreement period. In the absence of such exclusivity and in a situation where an ACO participant is associated with two or more ACOs, it would be unclear which ACO would receive an incentive payment for the participant's efforts on behalf of its assigned patient population. Exclusivity of the assignment-based ACO participant TIN ensures unique beneficiary assignment to a single ACO. However, exclusivity of an ACO participant TIN to one ACO is not necessarily the same as exclusivity of individual practitioners (ACO providers/suppliers) to one ACO. We did state somewhat imprecisely in the preamble to the proposed rule that ''ACO professionals within the respective TIN on which beneficiary assignment is based, will be exclusive to one ACO agreement in the Shared Savings Program. This exclusivity will only apply to the primary care physicians.'' This statement appears to be the basis of the concerns expressed by many commenters, and we understand the reasons for those concerns. However, we stated the policy (76 FR 19563) we intended to propose more precisely elsewhere in the preamble, when we stated that ''[t]his exclusivity will only apply to primary care physicians (defined as physicians with a designation of internal medicine, geriatric medicine, family practice and general practice, as discussed later in this final rule) by whom beneficiary assignment is established *when billing under ACO participant TINs.* (Emphasis added). Similarly, in the proposed regulations text at § 425.5(c), we stated that ''each ACO must report to CMS the TINs of the ACO participants comprising the ACO along with a list of associated NPIs, at the beginning of each performance year and at other such times as specified by CMS. For purposes

of the Shared Savings Program, each ACO participant TIN upon which beneficiary assignment is dependent is required to commit to a 3-year agreement with CMS and will be exclusive to one ACO. ACO participant TINs upon which beneficiary assignment is not dependent are required to commit to a 3 year agreement to the ACO, and cannot require the ACO participant to be exclusive to a single ACO.''

Thus, the exclusivity necessary for the assignment process to work accurately requires a commitment of each assignment-based ACO participant to a single ACO for purposes of serving Medicare beneficiaries. It does not necessarily require exclusivity of each primary care physician (ACO provider/supplier) whose services are the basis for such assignment. For example, exclusivity of an ACO participant leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. Similarly, an individual NPI can move from one ACO to another during the agreement period, provided that he or she has not been billing under an individual TIN. A member of a group practice that is an ACO participant, where billing is conducted on the basis of the group's TIN, may move during the performance year from one group practice into another, or into solo practice, even if doing so involves moving from one ACO to another. This degree of flexibility is, in fact, one reason for our preference to use TINs to identify ACO participants over NPIs: adopting NPIs in place of TINs would result in the much stricter exclusivity rules for individual practitioners to which so many commenters objected, than the use of TINs to identify ACOs. This flexibility is limited, once again, only in cases where the ACO participant billing TIN and individual TIN are identical, as in the case of solo practitioners. Even in those cases, moreover, it was not our intent (and it is no part of the policy that we are adopting in this final rule) that an individual practitioner may not move from one practice to another. But while solo practitioners who have joined an ACO as an ACO participant and upon whom assignment is based may move during the agreement period, they may not participate in another ACO for purposes of the Shared Savings Program unless they will be billing under a different TIN in that ACO.

We are therefore finalizing our proposal that each ACO participant TIN is required to commit to an agreement with us. In addition, each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one ACO for purposes of the Shared Savings Program. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to a single ACO for purposes for the Shared Savings Program. As we discuss in section E found later in this final rule we are also providing for consideration of the primary care services provided by specialist physicians, PAs, and NPs in the assignment process subsequent to the identification of the ''triggering'' physician primary care services. We are therefore also extending our exclusivity policy to these ACO participants. That is, the TINs under which the services of specialists, PAs, and NPs are included in the assignment process would have to be exclusive to one ACO for purposes of the Shared Savings Program. (We emphasize that we are establishing this policy for purposes of Shared Savings Program ACOs only: Commercial ACOs may or may not wish to adopt a similar policy for their purposes.)

Comment: One commenter supported our use of primary care physicians for alignment and urged us to retain the policy of non-exclusivity for specialists in the final rule: ''CMS's use of primary care physicians to align beneficiaries with an ACO is an important design element and we urge the agency to retain this provision in the final rule. As constructed, an ACO participant upon which beneficiary assignment is not dependent must not be required to be exclusive to an ACO (§ 425.5(c)(3)). In the newly proposed Pioneer ACO regulation however, beneficiary assignment could be made on the basis of several categories of specialist physicians. Extending this Pioneer attribution scheme to the proposed Medicare Shared Savings/ACO program could result in decreased availability of specialist physicians and/or a reluctance of non-ACO providers to refer to those specialists who are concerned that patients will be diverted to other ACO providers. We urge CMS to maintain the current rules aligning beneficiaries solely on the basis of their use of primary care physicians.''

Response: We appreciate the comment. However, in the light of our decision to employ a step-wise assignment process (as discussed in section II.E. of this final rule), this final exclusivity policy will also apply to ACO participants upon which assignment is based in either the first or second steps of the assignment process. As a result, this exclusivity will apply to ACO participants under which both primary care physicians and specialists bill for primary care services considered in the assignment process. However, we emphasize again that individual provider NPIs are not exclusive to one ACO, only the ACO participant TINs under which providers bill for services that are included in the assignment of beneficiaries. When providers whose services are the basis of assignment bill under two or more TINs, each TIN would be exclusive to only one ACO, assuming they have both joined as participants, but the provider (primary care physician or specialist) would not be exclusive to one ACO.

Comment: Many commenters objected to our proposal that FQHCs and RHCs could not form independent ACOs, but only participate in ACOs that included other eligible entities (for example, hospitals, and physician group practices). However, one commenter welcomed the opportunity for FQHCs to participate in multiple ACOs.

Response: As we discuss in section II.E. of this final rule, we are revising our proposed policy to allow FQHCs and RHCs to form independent ACOs. We have also revised our proposed assignment methodology in order to permit claims for primary care services submitted by FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC or RHC (whether as an independent ACO or in conjunction with other eligible entities). As a consequence of this revised policy, the exclusivity of the ACO participants upon which beneficiary assignment is dependent also extends to the TINs of FQHCs and RHCs upon which beneficiary assignment will be dependent under the new policies discussed in section II.E. of this final rule.

Final Decision: We are finalizing our proposals regarding operational definition of an ACO as a collection of Medicare-enrolled TINs, the obligation of the ACO to identify their ACO participant TINs and NPIs on the application, the obligation of the ACO to update the list, and the required exclusivity of ACO participants upon whom assignment is based without change under sections 425.20, 425.204(5), 425.302(d), 425.306, respectively. We clarify that ACO participants upon which beneficiary assignment is not dependent are not required to be exclusive to a single Medicare Shared Savings Program ACO. This final exclusivity policy extends to the ACO participant TINs of FQHCs, RHCs and ACO participants that include NP, PAs, and specialists upon which beneficiary assignment will be dependent under the revised assignment methodology discussed in section II.E. of this final rule.

2. Eligible Participants

Section 1899(b) of the Act establishes eligibility requirements for ACOs participating in the Shared Savings Program. Section 1899(b)(1) of the Act allows several designated groups of providers of services and suppliers to participate as an ACO under this program, ''as determined appropriate by the Secretary,'' and under the condition that they have ''established a mechanism for shared governance.'' The statute lists the following groups of providers of services and suppliers as eligible to participate as an ACO:

- ACO professionals in group practice arrangements.
- Networks of individual practices of ACO professionals.
- Partnerships or joint venture arrangements between hospitals and ACO professionals.
- Hospitals employing ACO professionals.
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Section 1899(h)(1) of the Act defines an ''ACO professional'' as a physician (as defined in section 1861(r)(1) of the Act, which refers to a doctor of medicine or osteopathy), or a practitioner (as defined in section 1842(b)(18)(C)(i) of the Act, which includes physician assistants, nurse practitioners, and clinical nurse specialists). Section 1899(h)(2) of the Act also provides that, for purposes of the Shared Savings Program, the term ''hospital'' means a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Act, thus limiting the definition to include only acute care hospitals paid under the hospital inpatient prospective payment system (IPPS). Other providers of services and suppliers that play a critical role in the nation's health care delivery system, such as federally qualified health centers (FQHCs), rural health centers (RHCs), skilled nursing facilities (SNFs), nursing homes, long-term care hospitals (LTCHs), critical access hospitals (CAHs), nurse midwives, chiropractors, and pharmacists, among others, are not specifically designated as eligible participants in the Shared Savings Program under section 1899(b)(1) of the Act. Furthermore, while the statute enumerates certain kinds of provider and supplier groups that are eligible to participate in this program, it also provides the Secretary with discretion to tailor eligibility in a way that narrows or expands the statutory list of eligible ACO participants. Therefore, we explored several options: (1) Permit participation in the program by only those ACO participants that are specifically identified in the statute; (2) restrict eligibility to those ACO participants that would most effectively advance the goals of the program; or (3) employ the discretion provided to the Secretary under section 1899(b)(1)(E) of the Act to expand the list of eligible groups to include other types of Medicare-enrolled providers and suppliers identified in the Act. After evaluating the three alternatives, we decided to propose the third option.

Since the statute requires that beneficiary assignment be determined on the basis of utilization of primary care services provided by ACO professionals that are physicians, we considered whether it would be feasible for CAHs, FQHCs, and RHCs to form an ACO or whether it would be necessary for these entities to join with one of the four groups specified in section 1899(b)(1)(A)–(D) of the Act in order to meet statutory criteria. We especially considered the circumstances of CAHs, FQHCs, and RHCs because these entities play a critical role in the nation's health care delivery system, serving as safety net providers of primary care and other health care and social services. At the same time, we noted that the specific payment methodologies, claims billing systems, and data reporting requirements that apply to these entities posed some challenges in relation to their independent participation in the Shared Savings Program. In order for an entity to be able to form an ACO, it is necessary that we obtain sufficient data in order to carry out the necessary functions of the program, including assignment of beneficiaries, establishment and updating of benchmarks, and determination of shared savings, if any. As we discuss in section II.E. of this final rule, section 1899(c) of the Act requires the assignment of beneficiaries to an ACO based on their utilization of primary care services furnished by a physician. Thus, as required by the statute, the assignment methodology requires data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a MD/DO as opposed to NP, PA, or clinical nurse specialist), and the physician specialty in order to be able to assign beneficiaries to ACOs.

We proposed that because of the absence of certain data elements required for assignment of beneficiaries, it would not be possible for FQHCs and RHCs to participate in the Shared Savings Program by forming their own ACOs. We stated that as the Shared Savings Program developed, we would continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and in light of any such developments, we would consider whether it would be possible at some future date for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

In the proposed rule, we further considered whether CAHs could participate in the Shared Savings Program by forming an independent ACO. We noted the situation is somewhat more complicated with regard to CAHs because section 1834(g) of the Act provides for two payment methods for outpatient CAH services. We described the payment methods in detail and determined that current Medicare payment and billing policies could generally support the formation of an ACO by a CAH billing under section 1834(g)(2) (referred to as method II).

In summary, we proposed that the four groups specifically identified in section 1899(b)(1)(A)–(D) of the Act (various combinations of physicians, nurse practitioners, physician assistants, clinical nurse specialists, and acute care hospitals), and CAHs billing under method II, would have the opportunity, after meeting the other eligibility requirements, to form ACOs independently. In addition, the four statutorily identified groups, as well as CAHs billing under method II, could establish an ACO with broader collaborations by including additional ACO participants that are Medicare enrolled entities such as FQHCs and RHCs and other Medicare-enrolled providers and suppliers not originally included in the statutory definition of eligible entities.

We indicated in the proposed rule that we would consider whether it would be appropriate to expand the list of entities eligible to participate in the Shared Savings Program, either in the final rule or in future rulemaking, if we determined that it was feasible and consistent with the requirements of the program for more entities to participate as ACOs independently. In the interim, and until such time as FQHCs and RHCs would be eligible to form ACOs or have their patients assigned to an ACO, we proposed to provide an incentive for ACOs to include RHCs and FQHCs as ACO participants, by allowing ACOs that include such entities to receive a higher percentage of any shared savings under the program. We discuss our final policies regarding the determination of shared savings under the program in section II.G. of this final rule.

Comment: A large number of commenters requested an expansion of those entities eligible to participate in the Shared Savings Program. The commenters requested that entities such as, but not limited to, integrated delivery systems, emergency medical technicians (EMTs), paramedics, health plans, Medicare Advantage (MA) plans, Medicaid Managed Care Organizations, AEMTs, community based hospitals, DME Suppliers, home health agencies (HHAs), long-term care (LTC) facilities, in-patient rehabilitation facilities, hospice facilities, patient-centered medical homes, RHCs, FQHCs, and Method I CAHs be included as eligible entities. We received one comment inquiring whether non-PECOS (Provider Enrollment, Chain, and Ownership System) enrolled providers can participate as ACO providers/suppliers. PECOs is a directory containing the names, addresses, phone numbers, and specialties of physicians enrolled in Medicare. Other comments suggested that we establish ESRD and cancer care specific ACOs. We received a few comments in support of limiting those entities eligible to participate in the program. These comments suggested that implementation of the Shared Savings Program will demand significant changes to health care delivery, data sharing, and data integration among providers and disparate groups. Providing clear guidance on who can participate reduces confusion and uncertainty within the provider and hospital community.

Response: We agree that limiting eligibility could potentially reduce confusion but also agree that the inclusion of some additional entities as eligible to independently participate in the program could significantly increase the opportunity for success. Although the entities referenced in the comment, with the exception of CAHs billing under method II, RHCs and FQHCs, are not able to independently form ACOs, these entities are not prohibited from participating in the Shared Savings Program so long as they join as an ACO participant in an ACO containing one or more of the organizations that are eligible to form an ACO independently and upon which assignment could be made consistent with the statute and the assignment methodology discussed in section II.E. of this final rule. Thus, although we do not see the need to design distinct ESRD or cancer specific ACOs, neither of these providers types are in any manner excluded from participation in an ACO. This allows for the four groups specifically identified in section 1899(b)(1)(A) through (D) of the Act, and CAHs billing under method II, RHCs, and FQHCs to form ACOs independently. In addition, the four statutorily identified groups, as well as CAHs billing under method II, RHCs, and FQHCs could establish an ACO with broader collaborations by including additional Medicare-enrolled entities defined in the Act as ACO participants. This will afford ACOs the flexibility to include all types of providers and suppliers as ACO participants, as long as the ACO can satisfy the required eligibility standards. Finally, enrollment in the PECOs system, at this time, is not a condition of eligibility to participate in the Shared Savings Program.

Comment: Many commenters, including MedPAC and commenters representing rural health advocates and a wide range of beneficiary and provider groups, raised concerns about the proposal which would preclude FQHCs and RHCs from forming independent ACOs. The commenters raised this issue in reference to eligibility, beneficiary assignment, and benchmarking issues. There were also several comments that agreed with the additional sharing rates for ACOs that include FQHCs and RHCs.

Commenters generally supported eligibility approaches that would allow FQHCs/RHCs to join ACOs formed by other entities. Some commenters also generally supported our proposal that FQHCs/RHCs would not be required to be exclusive to a single ACO. Although commenters were generally appreciative of the proposal to provide a higher sharing rate for ACOs that include FQHCs and RHCs, some commenters believed this approach was flawed, too weak to be effective, and could undercut the objectives of the Shared Savings Program. Most commenters expressed general concerns that the CMS interpretation of the statute was incorrect and that the statute allows the agency to promulgate policies that will allow for full participation of FQHCs in the Shared Savings Program. Some commenters focused their detailed comments on FQHCs, but the concerns/issues they raised were generally similar to those commenters that also addressed RHCs.

Several commenters stated that CMS' conclusions are flawed and that the law allows the agency to promulgate policies that will allow for full FQHC participation in the Shared Savings Program. They believe that ''a system that does not allow for meaningful FQHC involvement undercuts the Congressional intent in establishing the ACO/Shared Savings Program and the broader goal of assuring quality cost efficient health care services to Medicare beneficiaries.'' They expressed fear that other payers such as Medicaid, CHIP and private health insurers will follow Medicare's approach and policies in developing their own ACO rules, leading to disparities in care. Another commenter suggested our proposal would prevent or limit dually eligible patients from receiving integrated care at FQHCs in light of State Medicaid efforts to create ACOs and our definition of ''at risk'' beneficiaries.

Other commenters argued that RHCs represent a particularly compelling case for ACO formation inclusion. They believe that the promise of better integrated outpatient care for rural Medicare beneficiaries must begin with RHCs. These commenters believe that the exclusion of RHCs from those eligible to form an ACO independently would only serve to exclude rural providers and the populations they serve from forming efficiency enhancing ACOs that might serve to counterbalance the inpatient service-favoring skew that they believe has developed out of many rural preferential payment provisions.

Response: In this final rule we are addressing the specific comments regarding beneficiary assignment and the establishment of benchmarks for ACOs that include FQHCs and/or RHCs in sections II.E. and II.G. (Assignment and Benchmark) of this final rule while general comments regarding the eligibility of FQHCs and RHCs to form ACOs independently are addressed here. In the proposed rule, we proposed to use discretion afforded by the statute under section 1899(b)(1)(E) to allow participation of any Medicare-enrolled provider/supplier as an ACO participant. Thus, entities such as FQHCs and RHCs were eligible to participate in the program under our original proposal. However, we agree that it is highly desirable to allow for FQHCs and RHCs to participate independently and to determine a way to include their beneficiaries in assignment. In order for this to be possible, in this final rule we are making modifications to the proposed assignment process to recognize the different payment methodologies and claims data that are used by FQHCs and RHCs as compared to the payment methodologies and claims data that are available for physician offices/clinics that are paid under the physician fee schedule. The discussion about assignment and benchmarking process is in sections II.E. (Assignment) and II.G. (Benchmarking) of this final rule. As a result, under the policies

established in this final rule, FQHCs and RHCs will be eligible to form ACOs and may also be ACO participants in ACOs formed by other entities. Additionally, Medicare enrolled entities may join independent FQHCs, RHCs, and method II billing CAH ACOs.

Comment: Some commenters supported our proposal to allow CAHs billing under method II to form ACOs. A few commenters also recommended allowing CAHs billing under method I to form independent ACOs by supplementing their normal billing information with any additional information needed to assign beneficiaries. For example, a commenter indicated that because most rural facilities act as de facto sole providers for their communities, CAHs and SCH's should be able to claim all beneficiaries in their primary catchment area. The commenter suggested doing so by having the rural providers submit the 75th percentile zip codes from their patient demographic data. These zip codes could then be compared to the Medicare beneficiary claims data, and if the claims data also show that the beneficiaries in those zip codes receive >50 percent of their primary care services within the zip codes of the rural ACO, then all of the beneficiaries in those zip codes could be assigned to the rural ACO.

Response: We do not agree with allowing CAHs billing under method I to independently form ACOs by simply claiming all beneficiaries in their primary catchment area. We do not believe that this would be consistent with the statutory requirement for assignment based on beneficiary utilization of primary care services furnished by a physician. Although we do not believe it would be appropriate for a CAH billing under method I to independently form an ACO, we would emphasize that we would encourage CAHs billing under method I to participate in the Shared Savings Program by establishing partnerships or joint venture arrangements with ACO professionals, just like other hospitals.

Comment: Some commenters suggested using CMS's demonstration authority to include FQHCs and RHCs in the Shared Savings Program or another Shared Savings Program. Others recommended that CMS should continue to work with providers and patients practicing and living in rural underserved areas to develop ACO models specifically designed to meet the unique healthcare delivery challenges facing rural underserved areas.

Response: We appreciate the comments suggesting the development of ACO models to address the special needs of rural areas and have forwarded them to our colleagues in the Innovation Center. We will consider any additional demonstrations focused on ACOs as part of the regular process for establishing CMS demonstrations. We note, however, that as discussed previously, under the policies adopted in this final rule, FQHCs and RHCs will be eligible to form an ACO independently or to participate in an ACO formed by other eligible entities.

Comment: A few commenters suggested that CMS should refine its strategies to facilitate development of practitioner-driven, rather than hospital-driven ACO's. Comments further suggested that at the very least, waiver authority should be established to enable the agency to waive hospital-oriented requirements for ACOs that consist solely of group practices.

Response: There is no requirement that an ACO include a hospital. Similarly, we have not established any ''hospital-oriented'' requirements. We have intentionally provided ACOs the flexibility to establish their organizations in such a manner that will most effectively define their preferred ACO model.

Final Decision: We are finalizing our proposals for identifying groups of providers of services and suppliers that may join to form an ACO under § 425.102. Specifically, the entities identified in section 1899(b)(1)(A) through (D) of the Act will be able to form ACOs, provided they meet all other eligibility requirements. Additionally, CAHs billing under method II, FQHCs, and RHCs may also form independent ACOs if they meet the eligibility requirements specified in this final rule. In addition, any Medicare enrolled entities not specified in the statutory definition of eligible entities in section 1899(b)(1)(A)–(D) of the Act can participate in the Shared Savings Program as ACO participants by joining an ACO containing one or more of the organizations eligible to form an ACO. Additionally, in response to comments and after further consideration of the available information, we have established a process by which primary care services furnished by FQHCs and RHCs will be included in the assignment process, as discussed in section II.E. of this final rule. As a result, FQHCs and RHCs will also be able to form ACOs independently, provided they meet all other eligibility requirements.

3. Legal Structure and Governance

Section 1899(b)(2)(C) of the Act requires an ACO to ''have a formal legal structure that would allow the organization to receive and distribute payments for shared savings'' to ''participating providers of services and suppliers.'' As previously noted, section 1899(b)(1) of the Act also requires ACO participants to have a ''mechanism for shared governance'' in order to be eligible to participate in the program. Operationally, an ACO's legal structure must provide both the basis for its shared governance as well as the mechanism for it to receive and distribute shared savings payments to ACO participants and providers/suppliers.

a. Legal Entity

In order to implement the statutory requirements that ACOs have a shared governance mechanism and a formal legal structure for receiving and distributing shared payments, we proposed that an ACO be an organization that is recognized and authorized to conduct its business under applicable State law and is capable of—(1) receiving and distributing shared savings; (2) repaying shared losses, if applicable; (3) establishing, reporting, and ensuring ACO participant and ACO provider/supplier compliance with program requirements, including the quality performance standards; and (4) performing the other ACO functions identified in the statute. We explained that it is necessary for each ACO to be constituted as a legal entity appropriately recognized and authorized to conduct its business under applicable State law and that it must have a TIN. However, we did not propose to require ACO enrollment in the Medicare program.

We did not propose that existing legal entities form a separate new entity for the purpose of participating in the Shared Savings Program. We stated that if the existing legal entity met the eligibility requirements to be an ACO, it may operate as an ACO in the Shared Savings Program. However, we proposed that if an entity, such as a hospital employing ACO professionals would like to include as ACO participants other providers/suppliers who are not already part of its existing legal structure, an ACO would have to establish a separate legal entity in order to provide all ACO participants a mechanism for shared governance.

We also proposed that each ACO certify that it is recognized as a legal entity under State law and authorized by the State to conduct its business. In addition, an ACO with operations in multiple States would have to certify that it is recognized as a legal entity in the State in which it was established

and that it is authorized to conduct business in each State in which it operates.

We solicited comment on our proposals regarding the required legal structure and other suitable requirements that we should consider adding in the final rule or through subsequent rulemaking. We also requested comment on whether requirements for the creation of a separate entity would create disincentives for the formation of ACOs and whether there were alternative approaches that could be used to achieve the aims of shared governance and decision making and provide the ability to receive and distribute payments for shared savings.

Comment: Many commenters opposed requiring ACOs formed among multiple ACO participants to form a separate legal entity, because it was costly, inefficient, and wasteful to do so (especially for small and medium-sized physician practices). These commenters also contend that forming a separate entity places such ACOs at a competitive disadvantage relative to integrated delivery systems (for example single-entity ACOs), it will likely have a chilling effect on the willingness of such providers and suppliers to participate in the program, and it disadvantages hospitals in States with a prohibition on the corporate practice of medicine.

Several commenters supported allowing multiple participant ACOs to form an entity by contract and not require a separate new entity. These commenters recommended that we permit ACOs comprised of multiple ACO participants to designate one of those ACO participants to function as the ''ACO'' for purposes of participation in the program, provided that such entity meets the criteria required of an ACO under the final rule. Another commenter suggested letting a division of an existing corporation serve as the legal entity for an ACO. Specifically, this comment noted that license-exempt, medical foundation clinics in California are often formed as either a division of a nonprofit corporation that owns and operates a hospital or have as their sole corporate member a nonprofit hospital, such as a nonprofit, license-exempt, medical foundation clinic. One commenter suggested that ACOs that have outcome-based contracts with private payers should have flexibility in forming their legal entities.

Many commenters supported the proposal not to require creation of a new distinct legal entity if one is already in place that meets the proposed criteria. Commenters stated that such a requirement is unnecessary to meet the objectives of the Shared Savings Program. Some commenters suggested existing organizations should not be forced to create whole new bureaucracies just to add a few participants to form an ACO.

Response: We continue to support our proposal that each ACO certify that it is recognized as a legal entity under State law. An ACO formed among two or more otherwise independent ACO participants (such as between a hospital and two physician group practices) will be required to establish a separate legal entity and to obtain a TIN. Although some comments opposed this requirement as burdensome, we continue to believe it is essential to protect against fraud and abuse and ensure that the ACO is accountable for its responsibilities under the Shared Savings Program by enabling us to audit and assess ACO performance. In addition, to the extent an ACO becomes liable for shared losses, we believe it is essential to be able to collect such monies from the ACO and its ACO participants.

For existing legal entities that otherwise meet the eligibility requirements, we agree with commenters that requiring the creation of a new separate legal entity would be inefficient. Existing legal entities which are eligible to be ACOs are permitted to continue to use their existing legal structure as long as they meet other eligibility and governance requirements explained in this final rule. However, as we proposed, if an existing legal entity adds ACO participants that will remain independent legal entities (such as through a joint venture among hospitals or group practices), it would have to create a new legal entity to do so. As discussed later in this section, we believe that creation of a new legal entity would be important to allow the newly added ACO participants to have a meaningful voice on the ACO's governing body. A separate legal entity, with such a governing body, is therefore essential to accomplish this policy objective.

Although we recognize that it may be possible for ACOs to establish outcome-based contracts that reinforce some of the policy objectives discussed in the proposed rule, we believe that the proposed legal structure requirement is necessary to protect against fraud and abuse and ensure the goals of the Shared Savings Program, and does not impose too large a burden, especially in light of the flexible governance structure discussed later in this section.

Comment: Several commenters suggested we address the interplay between Federal and State law governing ACO formation and operation. For example, commenters suggested we clarify whether the proposed legal entity requirements include requiring an ACO to obtain a certificate of authority if so required under State law. One commenter suggested that we clarify whether we are requiring that an ACO be recognized as an ACO under State law or whether we are requiring that the ACO be recognized to conduct business as a partnership, corporation, etc. under State law.

Other commenters suggested that we preempt State law or regulation of ACOs that limit the number of ACOs in a State. By contrast, another comment suggested that the Affordable Care Act did not preempt or otherwise supersede State laws prohibiting the corporate practice of medicine or otherwise alter the choice of legal entities available to ACOs for formation in particular States. In addition, some commenters recommended that we require that if an ACO assumes insurance risk, it should meet all the consumer protection, market conduct, accreditation, solvency, and other requirements consistent with State laws.

One commenter suggested that we require ACOs that operate in more than one State to attest that they operate under each State's rules rather than a blend of multiple States' rules for all business and other operational functions (including health information management, release of information, privacy/confidentiality, data quality, etc.). Some commenters suggested that the proposed definition of ''ACO'' would exclude entities organized pursuant to Federal and tribal law, and recommended that we also allow ACOs to be organized under Federal or tribal law as well.

Response: We continue to believe that an ACO should be recognized as a legal entity under State law and authorized by the State to conduct its business. We intended this requirement to ensure the ACO would be licensed to do business in the State consistent with all applicable State law requirements. Consequently, we are finalizing our proposal that an ACO that participates in the Shared Savings Program meet State law requirements to operate in that State. We are not requiring an ACO be licensed as an ACO under State law unless, however, State law requires such licensure.

We disagree with the commenters that participating in the Shared Savings Program ultimately involves insurance risk. ACO participants will continue to receive FFS payments for all services

furnished to assigned beneficiaries. It is only shared savings payments (and shared losses in the two-sided model) that will be contingent upon ACO performance. As a result, we believe that we will continue to bear the insurance risk associated with the care furnished to Medicare beneficiaries, but ACOs desiring to participate in Track 2 should consult their State laws.

To clarify, we are not preempting any State laws or State law requirements in this final rule. To the extent that State law affects an ACO's operations, we expect the ACO to comply with those requirements as an entity authorized to conduct business in the State. We do not believe it is necessary to make ACOs attest to do what they otherwise would be required to do under State law.

We agree with commenters that we do not want to exclude ACOs that are licensed under Federal or tribal law. Accordingly, we are modifying our original proposal to clarify that entities organized pursuant to Federal and tribal law will also be allowed to participate in the Shared Savings Program, as long as the entity is able to meet the participation requirements as outlined in this final rule.

Final Decision: We are finalizing our proposal that an ACO must be a legal entity for purposes of all program functions identified in this final rule. We are also finalizing commenters' suggestion that ACOs licensed under Federal or tribal law are eligible to participate in the Shared Savings Program. In addition, an ACO formed among multiple ACO participants must provide evidence in its application that it is a legal entity separate from any of its ACO participants. (§ 425.104)

b. Distribution of Shared Savings

As discussed previously, an ACO must be a legal entity appropriately recognized and authorized to conduct its business under State, Federal, or tribal law, and must be identified by a TIN. In the proposed rule we proposed to make any shared savings payments directly to the ACO as identified by its TIN, we noted that unlike the ACO participants and the ACO providers/suppliers that form the ACO, the legal entity that is the ACO may or may not be enrolled in the Medicare program. We acknowledged the potential for this proposal to raise program integrity concerns, because allowing shared savings payments to be made directly to a non-Medicare-enrolled entity would likely impede the program's ability to recoup overpayments as there would be no regular payments that could be offset. This is part of the rationale for requiring safeguards for assuring ACO repayment of shared losses described in section II.G. of this final rule. We solicited comment on our proposal to make shared savings payments directly to the ACO, as identified by its TIN. In addition, we solicited comment on our proposal to make shared savings payments to a non-Medicare-enrolled entity.

We proposed to require ACOs to provide a description in their application of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, how any shared savings will be used to align with the three-part aim. As we stated in the proposed rule, we believe this requirement would achieve the most appropriate balance among objectives for encouraging participation, innovation, and achievement of an incentive payment while still focusing on the three-part aim.

Comment: Several commenters recommended that CMS explicitly state that the ACO is required to demonstrate that ACO participants will be able to share in savings and that CMS outline exactly how the savings will be distributed while other commenters suggested that CMS work with the provider community to develop principles that ACOs should follow to ensure fair and equitable distribution of shared savings. Other commenters suggested that a requirement be established that some pre-determined portion of any shared savings be directed to improving patient care unless there is little room for improvement for ACOs in the final quality measures. A few commenters requested that standards be established regarding the length of time (ranging from 15 days to 90 days) an ACO has to actually share any savings generated with its respective providers. Finally, a commenter expressed concern that when partnering with a hospital-based system, primary care providers would not be rewarded for the significantly increased work that will be required on their part in order for an ACO to be successful. Instead this money would be used by the hospital system to replace lost revenue on the hospital side.

Response: We will make any shared savings payments directly to the ACO as identified by its TIN. As explained in the proposed rule, the statute does not specify how shared savings must be distributed, only that the ACO be a legal entity so that the ACO can accept and distribute shared savings. We do not believe we have the legal authority to dictate how shared savings are distributed, however, we believe it would be consistent with the purpose and intent of the statute to require the ACO to indicate as part of its application how it plans to use potential shared savings to meet the goals of the program. Consistent with the discussion found later in this final rule regarding the shared governance of an ACO, we anticipate that ACO participants would negotiate and determine among themselves how to equitably distribute shared savings or use the shared savings to meet the goals of the program.

Final Decision: We will finalize our proposals under § 425.204(d) without change.

c. Governance

Section 1899(b)(1) of the Act requires that an ACO have a ''mechanism for shared governance'' and section 1899(b)(2)(F) of the Act requires that an ''ACO shall have in place a leadership and management structure that includes clinical and administrative systems.'' However, the statute does not specify the elements that this shared governance mechanism or the accompanying leadership and management structures must possess. We proposed that such a governance mechanism should allow for appropriate proportionate control for ACO participants, giving each ACO participant a voice in the ACO's decision making process, and be sufficient to meet the statutory requirements regarding clinical and administrative systems.

We proposed that an ACO also must establish and maintain a governing body with adequate authority to execute the statutory functions of an ACO. The governing body may be a board of directors, board of managers, or any other governing body that provides a mechanism for shared governance and decision-making for all ACO participants, and that has the authority to execute the statutory functions of an ACO, including for example, to ''define processes to promote evidenced-based medicine and patient engagement, report on quality and cost measures, and coordinate care.'' We proposed that this body must be separate and unique to the ACO when the ACO participants are not already represented by an existing legal entity appropriately recognized and authorized to conduct its business under applicable State law. In those instances where the ACO is an existing legal entity that has a pre-existing board of directors or other governing body, we proposed that the ACO would not need to form a separate governing body. In this case, the existing entity's governing body would be the governing body of the ACO, and the ACO would be required to provide in its application

evidence that its pre-existing board of directors or other governing body, meets all other criteria required for ACO governing bodies. We also proposed that the ACO have a conflicts of interest policy that applies to members of the governing body. The conflicts of interest policy must require members of the governing body to disclose relevant financial interests. Further, the policy must provide a procedure for the ACO to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise. Such a policy also must address remedial action for members of the governing body that fail to comply with the policy.

We requested comment on whether these requirements for the creation of a governing body as a mechanism for shared governance would create disincentives for the formation of ACOs and whether there were alternative requirements that could be used to achieve the aims of shared governance and decision making. We also acknowledged that allowing existing entities to be ACOs would complicate our monitoring and auditing of these ACOs, and sought comment on this issue.

Comment: Although most comments supported the principle of ACO shared governance, many commenters opposed the separate governing body requirement. Some commenters stated that we exceeded our authority by imposing a separate governing body requirement. Other commenters suggested that the separate governing body requirement would discourage organizations from participating in the Shared Savings Program and increase their costs to do so. Commenters explained that existing entities already have relationships with commercial payers and it would not make sense for them to maintain multiple boards, because it is costly and organizationally complex to do so.

Many commenters urged us to provide flexibility so that ACOs could use their current governance process, as long as they can demonstrate how they will achieve shared governance on care delivery policies. Some commenters explained that hospitals and other large physician groups have governing bodies designed specifically for quality and outcome reviews and oversight for clinical integration and performance appraisal, training and discipline. Commenters suggested that ACOs can be effectively governed by an operating committee within their existing governance and management structure, as is a hospital medical staff governed semi-autonomously within a hospital's governance structure. Commenters also suggested that ACOs should be permitted to access existing assets and systems, such as advisory boards, so long as the ACO management committee exercises sufficient control over these processes with respect to ACO activities to generate ACO desired outcomes. Other commenters had specific concerns about how the separate entity requirement would apply to their current or planned organizational structure. One commenter, an integrated, State-wide health system, suggested that we permit it to operate as a State wide/multi-State ACO with various regional/local ACOs as its ACO participants. In this structure, the corporate organization would handle the claims processing, reporting, and distribution of savings and the financial backing for potential loss for the regional ACO healthcare operational units. The regional ACOs would have their own board and each regional ACO would be represented on the State-wide/multi-State board. This commenter claimed that this type of structure would take advantage of the cost savings that result from economies of scale for administrative and other functions, but would keep health care delivery local. Another commenter suggested allowing an ACO governing body's authority to be delegated from an existing governing body that possesses broad reserved powers.

One commenter suggested we clarify the responsibilities of the board as distinct from those of management. In this commenter's view, governing board's role should be one of oversight and strategic direction, holding management accountable to meeting goals of ACO. Another commenter suggested that the governance structure be organized more like a scientific advisory board that will analyze the results of the particular ACO's methodology for treating its patients.

Response: Our proposal to require an ACO to have a separate governing body unless it is an existing legal entity that has a pre-existing governing body is consistent with the proposed and final requirements regarding legal entity requirements discussed previously. Thus, we disagree with the commenters that suggested that such a requirement would discourage participation in the Shared Savings Program or disrupt existing relationships with commercial payers.

Moreover, for ACOs formed among otherwise independent ACO participants, we will finalize our proposal that these ACOs create an identifiable governing body. This requirement is consistent with our final rule that requires such ACOs to create a separate legal entity. Notwithstanding this requirement, we agree with commenters that ACOs formed among multiple otherwise independent ACO participants, should have flexibility to establish a mechanism for shared governance as required by statute. As discussed later in this section of this final rule, we are revising our specific proposals to provide ACO greater flexibility in the composition of their governing bodies.

We also agree with commenters who suggested that we should clarify the governing body's responsibilities. An ACO's governing body shall provide oversight and strategic direction, holding management accountable for meeting the goals of the ACO, which include the three-part aim. This responsibility is broader than ''care delivery processes'' as suggested by numerous commenters and, in fact, encompasses not only care delivery, but also processes to promote evidence-based medicine, patient engagement, reporting on quality and cost, care coordination, distribution of shared savings, establishing clinical and administrative systems, among other functions. We believe that because of these broad responsibilities, the governing body is ultimately responsible for the success or failure of the ACO.

We believe that an identifiable governing body is a reasonable prerequisite for eligibility to participate in the Shared Savings Program. As discussed previously, an existing legal entity is permitted to use its current governing body. An ACO formed among otherwise independent ACO participants must establish an identifiable governing body. A governing body that is identifiable can help insulate against conflicts of interest that could potentially put the interest of an ACO participant (in an ACO formed among otherwise independent ACO participants) before the interest of the ACO. In fact, we believe an identifiable governing body will facilitate accomplishing the ACO's mission.

Comment: Numerous commenters expressed support for the requirement that the governing body include all ACO participants. For example, one commenter supported the proposal, because such a requirement would also aid CMS, FTC, and DOJ in their efforts to thwart anti-competitive behavior among ACOs.

By contrast, many commenters suggested it would be unwieldy to have representatives from each participant on the governing body, because the governing body would be difficult to operate effectively. Other commenters

stated that an ACO should not, for example, have to include each solo-practitioner physician participant on the board. Some commenters suggested that a requirement for each ACO participant to be on the governing body would permit competitors to be on each other's boards and, thus, could be anticompetitive. Many commenters indicated that we should be concerned with the outcome of the program, not with who is on an ACO's board. One commenter suggested that ACO participants be shareholders, members, or other owners of the ACO, and the ACO participants would select the governing body members. Another commenter suggested that we require an ACO to demonstrate how ACO participants have a super-majority on a medical standards committee that has responsibility to define processes to promote evidenced-based medicine and patient engagement, report on quality and cost measures, and coordinate care. However, one commenter suggested that limiting a governance voice to physicians and hospitals reduces the chances that the aim CMS expresses of reduced dependence on inpatient care will be realized. Several commenters suggested that the requirement that all participants be on the governing body may conflict with State law requirements.

Response: Although we believe that each ACO participant should have a voice in the ACO's governance, we are convinced by the comments that there are many ways to achieve this objective without requiring that each ACO participant be a member of the ACO's governing body. Thus, we will not finalize our proposal that each Medicare-enrolled ACO participant TIN, or its representative, be on the ACO's governing body. We agree with commenters that the governing bodies could become unwieldy and lose their effectiveness if we were to finalize this proposal. Such a requirement, as the commenters explained, could conflict with State law requirements regarding governing body requirements. Instead we will require an ACO to provide meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. We disagree, however, with the comment that ACO participants who may be competitors outside of the ACO's activities necessarily raise competitive concerns when they jointly participate on the ACO's governing body. The ACO requires an integration of economic activity by ACO participants, and participants' participation in the governing body is in furtherance of that integration. Nonetheless, as explained in the final Antitrust Policy Statement, ACOs should refrain from, and implement appropriate firewalls or other safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services outside the ACO.

Comment: Commenters were divided in their support for the proportionate control requirement. Many commenters suggested that the proportionate share requirement is too rigid and inflexible. Several commenters stated that the concept of constituent or representative governance is antithetical to the most basic tenants of State corporation law, including the requirement of undivided loyalty applicable to members of a corporation's board of directors and the right of the shareholders of the for-profit corporation and members of nonprofit corporations to elect the governing body that is otherwise responsible for overseeing and directing the management of the corporation. Other commenters explained that the requirements are unnecessary because fiduciary decisions should be made in the best interests of the ACO as an entire organization and should not represent the individual interests of the ACO participants or any specific agendas. Other comments suggested that they would have to reconstitute their boards if we applied such a requirement. By contrast, many commenters supported this requirement if it were applied on a per participant basis, while others supported it if it were based on capital contributions.

Several commenters sought clarification as to how proportionate share should be assessed and suggested that we provide guidance to avoid tangled power struggles. Commenters suggested various methods, including: distribution of Medicare costs among the various participants in the ACO, capital contributions, per participant, equity dollars, dollars received, savings generated from operations, RVUs delivered, number of Medicare lives attributed, physicians within a TIN, or on any reasonable basis. One commenter suggested that proportionate control means representation of all specialists that provide care to an ACO's beneficiaries.

Response: In light of our decision to allow ACOs flexibility in how they establish their governing bodies, we will not finalize our proposal that each ACO participant have proportionate control of the ACO governing body.

Comment: Several commenters suggested that we require specialty practitioner representatives on the governing body, including specialists who have experience and expertise in hospice and palliative care, hematology, cataract surgery, endocrinology, surgery, mental health. Other commenters suggested that we require governing body representation of home health care and long-term care providers, the allied professions, and community stakeholders. One commenter sought a specific role for nurses on the governing body.

Another commenter suggested encouraging representation from local high-level public health officials on ACO governing bodies to help inform population health and cost-containment goals. One commenter suggested that at least one stakeholder on the board be a representative of a local hospital, regardless of whether any hospital is a participant in the ACO, because all care settings should be considered. One commenter suggested that we require ACO governing bodies to include local employers and multi-State large employer plan sponsors with experience in quality improvement and reporting and providing timely information to consumers on ACOs' governance boards to successfully improve quality, reduce unnecessary costs and drive through transformational change. Other commenters urged us to state that every professional service involved with the ACO be represented on the governing body.

Response: In light of our decision to allow ACOs flexibility in how they establish their governing bodies, we will not require representation of particular categories of providers and suppliers or other stakeholders.

Comment: Several commenters suggested we provide broad guidance on desired ACO outcomes and processes without specifying how an ACO's governing body achieves these outcomes. Other commenters suggested that we articulate the attributes of governance that we believe are important to ACOs (for example, importance of ACO participant input, the role of non-ACO participants in governance, or that ACOs that are tax-exempt entities would be expected to comply with exemption requirements) and then require the ACO to include a description in its application on how governance of ACO would align with these attributes. Other commenters suggested similar approaches, such as requiring the ACO applicant to describe its governing body and general rationale for its composition, how ACO participants and providers will achieve shared governance and decision-making such that they have significant input and control over decisions about how

care will be delivered and beneficiaries' voices heard. Commenters suggested that this flexibility would permit the ACO to determine the appropriate balance of incorporating direct participant involvement in the governance of the ACO, including board involvement, and also using operating committees where a more limited group of ACO participants would have significant input, direction and involvement in specific activities the ACO. Another commenter urged us to deem the governance structure of entities that are qualified for tax exemption under section 501(c)(3) of the Internal Revenue Code to meet the proposed governance requirements.

One commenter recommended that we require all ACOs: (1) To enact policies and procedures to ensure that physicians who participate in the ACO are free to exercise independent medical judgment; and (2) to adopt a conflict-of-interest disclosure policy to ensure that the governing body appropriately represents the interests of the ACO. One commenter suggested the ACO be governed by a Board of Directors that is elected by physicians in the ACO. Another commenter suggested in those cases where a hospital is part of an ACO, the governing board should be separate and independent of the hospital governing body. Several commenters urged us to require a majority of the ACO's governing body to be approved by ACO participants.

Response: We agree with commenters that we should articulate our views related to governance. We will finalize the requirement that the governing body provides oversight and strategic direction for the ACO, holding management accountable for meeting the goals of the ACO, which include the three-part aim. Members of the governing body shall have a fiduciary duty to put the ACO's interests before the interests of any one ACO participant or ACO provider/supplier. The governing body also must have a transparent governing process to ensure that we are able to monitor and audit the ACO as appropriate.

Final Decision: In sum, we are finalizing the requirement that an ACO must maintain an identifiable governing body with authority to execute the functions of the ACO as defined in this final rule, including but not limited to, the definition of processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinating care. The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities. The governing body must have a transparent governing process. The governing body members shall have a fiduciary duty to the ACO and must act consistent with that fiduciary duty. The ACO must have a conflicts of interest policy for the governing body. The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives. (§ 425.106).

d. Composition of the Governing Body

As we explained in the proposed rule, we believe that the ACO should be operated and directed by Medicare-enrolled entities that directly provide health care services to beneficiaries. We acknowledged, however, that small groups of providers often lack both the capital and infrastructure necessary to form an ACO and to administer the programmatic requirements of the Shared Savings Program and could benefit from partnerships with non-Medicare enrolled entities. For this reason, we proposed that to be eligible for participation in the Shared Savings Program, the ACO participants must have at least 75 percent control of the ACO's governing body. In addition, each of the ACO participants must choose an appropriate representative from within its organization to represent them on the governing body. We explained that these requirements would ensure that ACOs remain provider-driven, but also leave room for both non-providers and small provider groups to participate in the program.

Additionally, we proposed that ACOs provide for patient involvement in their governing process. We proposed that in order to satisfy this requirement, ACOs must include a Medicare FFS beneficiary serviced by the ACO on the ACO governing body. In order to safeguard against any conflicts of interest, we proposed that any patients included on an ACO's governing body, or an immediate family member, must not have a conflict of interest, and they must not be an ACO provider/supplier. We believed a conflict of interest standard was necessary to help effectuate our intent to ensure beneficiaries have a genuine voice in ACO governance. We sought comment on whether the requirement for beneficiary participation on the governing body should include a minimum standard for such participation. We also sought comment on the possible role of a Medicare beneficiary advisory panel to promote patient engagement in ACO governance.

Comment: Numerous commenters supported the proposed 75 percent threshold requirement for ACO participants and suppliers because they believe ACOs should be provider driven. Other commenters supported the 75 percent threshold because they believed that more than 25 percent non-participant investment could lead to disparities among Shared Savings Program stakeholders, create a conflict of interest, and impede the goal of efficient care delivery. One commenter urged us to clarify that up to 25 percent of the board can be represented by health plans and management companies. Several commenters sought clarification about how to assess the 75 percent requirement in the situation of hospital employment of providers, and whether it is the employer or the employee that must be represented.

By contrast, several commenters urged us to eliminate the 75 percent threshold because it is overly prescriptive, will prevent many existing integrated systems from applying, fails to acknowledge that governing bodies will balance representation across all the populations it covers for multiple payers that may, for instance, encourage participation of local businesses on the governing body, and will be unnecessarily disruptive to many organizations, especially those with consumer-governed boards. Several commenters suggested that we should recognize that each governing body will need to be structured differently depending on its historical makeup, the interest in participation, and other market dynamics. One commenter suggested that requiring the exact same governance structure for all ACOs risks creating inefficient bureaucracy that does not improve quality or reduce costs.

Several commenters also suggested that this restriction is likely to restrict ACO access to, and effective use of, multiple streams of capital for investing in high-value care. Other commenters argued that the restriction is likely to hinder formation of primary care physician-led organizations because they will not be able to implement effective care management and advanced information technology implementation, and lack the ability to negotiate and administer provider contracts without the participation of outside entities. Another commenter suggested the 75 percent requirement could have a chilling effect on the willingness of private payers to invest in and partner with ACOs.

Some commenters stated that the 75 percent requirement may conflict with IRS policy that requires governing bodies of tax-exempt entities to be comprised of a broad spectrum of

community members. Another commenter suggested that 501(c)(3) hospitals or health systems would find it difficult to form an ACO as a joint venture because the IRS requires those nonprofits to demonstrate that the joint venture is in the charity's interest and that charitable assets are not used for private inurement. Other commenters noted that the 75 percent requirement could conflict with State law requirements such as ones requiring governing boards of public hospitals to be elected, or that in order for nonprofit health care entities to maintain an exemption from certain State's business and occupation tax, paid employees cannot serve on the governing board. Other commenters suggested that we extend the same flexibility we proposed to provide to ACOs with regard to leadership and management structures to our governance requirements.

Response: We continue to believe that the 75-percent control requirement is necessary to ensure that ACOs are provider driven, as requested by the comments. The implication of this requirement is that non-Medicare enrolled entities, such as management companies and health plans may have less than 25 percent voting control of the ACO governing body. For example, if a hospital, two physician groups, and a health plan formed an ACO, the hospital and two physician groups must control at least 75 percent of the ACO governing body. We decline, as previously discussed, to require how the voting control of the hospital and two physicians groups is apportioned among them. Although we recognize commenters' concern that this threshold could reduce the amount of investment capital available to ACOs, we believe it strikes an appropriate balance to incent and empower ACO participants to be accountable for the success of the ACO's operations.

We also clarify that existing entity ACOs, such as a hospital employing ACO professionals, by definition, would have 100 percent control of the governing body, because the existing entity is the only member of the governing body.

Notwithstanding this requirement, we also agree with commenters that we should provide ACOs with flexibility regarding the composition of the ACO's governing body. This flexibility is discussed later in this section of this final rule and provides a means for an ACO to compose its governing body to involve ACO participants in innovative ways in ACO governance. We believe this flexibility obviates the commenters' concerns that the 75 percent threshold would conflict with laws governing the composition of tax-exempt or State-licensed entities.

Comment: In response to our request for comments on whether our requirement that 75 percent control of the governing body be held by ACO participants was an appropriate percentage, commenters suggested a variety of different percentage requirements on the governing body for certain types of ACO physicians and other health care providers. Commenters suggested that physicians occupy at least one-third, one-half, or greater than one-half of governing body seats. Other commenters suggested that primary care physicians comprise at least 50 percent of the ACO governing body and independent practices have representation proportionate to their percentage of ACO physicians, while another commenter suggested that the governing body include an equal number of primary care and specialty physicians to guarantee that ACOs' leadership structures focus on primary care, prevention, care coordination and disease management. Another commenter suggested that 50 percent of the governing body consist of physicians who have their own practice and not physicians who are employed directly or indirectly by a hospital system.

By contrast, some commenters suggested that we require a more balanced composition, with 50 percent ACO participant representation, a majority of which should be primary care providers, and 50 percent key community stakeholders who do not derive livelihood from the ACO or one of its products. Some commenters suggested that the inclusion of employer and/or labor representatives in the community stakeholder portion would also serve as a way to help prevent cost-shifting to the private sector. Another commenter suggested a bare minimum of provider representation, because anything more may bring in members to the board who do not have the requisite skill and experience to function in a leadership role.

Response: For the reasons previously discussed, we will finalize our proposal to require 75 percent control by ACO participants that are Medicare-enrolled TINs. We decline, as previously discussed, to require how the voting control will be apportioned among ACO participants.

Comment: Some commenters supported the requirement that each ACO participant choose an appropriate representative from within its organization to represent them on the governing body. Several commenters sought clarification about the requirement. For example, one commenter sought clarification that an employee of an IPA (which is a member of an ACO) can be the representative on the board. Other commenters sought clarification about the word ''organization'' in the phrase ''from within its organization,'' specifically whether organization meant each and every ACO participant's organization or the ACO as an organization.

Response: Under our proposal, we intended that a representative from each ACO participant would be included on the ACO's governing body. But, as previously discussed, we believe that ACOs should have flexibility to construct their governing bodies in a way that allows them to achieve the three-part aim in the way they see fit. Accordingly, we will eliminate the requirement that each ACO participant choose an appropriate representative from within its organization to represent it on the governing body.

Comment: Several commenters were unclear whether we were requiring that all entities with which an ACO contracts would be considered an ACO participant and therefore have a seat on the governing body. In particular, some commenters sought clarification about the interaction between an ACO and a third party that would develop the technology, systems, processes and administrative functions for the ACO. Other comments sought clarification of whether we will consider a provider system one ACO or multiple ACO participants, because the individuals within the system each have separate TINs that are eligible as ACOs in their own right.

Response: We expect that ACOs, in some instances, will contract with third parties to provide technology, systems, processes, and administrative functions for the ACO. These entities are not ACO participants as that term is defined in § 425.20 of these regulations. Accordingly, we are not requiring these third parties to be represented on the governing body. A provider system made up of multiple Medicare-enrolled TINs will have flexibility to use its existing governing body (assuming it is an existing legal entity with a pre-existing governing body) or to structure a new governing body in a way that meets the requirements for meaningful representation of its ACO participants while also enabling it to accomplish the three-part aim.

Comment: Many commenters strongly supported our proposal to require ACOs to include a beneficiary on the governing body so that the person would advocate for the local community, patient safety issues,

provide a strong, independent voice, and be part of ACO decision making. Other commenters suggested requiring even more consumer or community-based organization representation such as a plurality of the board or proportional representation based on the number of Medicare beneficiaries, such as two Medicare beneficiary representatives for every 5,000 patients assigned to the ACO, but no less than 15 percent beneficiary representation, or three beneficiaries and three local community organization representatives.

Several commenters suggested that one beneficiary on the board is insufficient. Other commenters argued that together beneficiaries and consumer advocates must possess a sufficient number of seats on the governing body to enable them to substantively influence an ACO and its operations, because beneficiary representatives and consumer advocates bring distinct perspectives to the table. Other commenters suggested that the ACO describe in its application how it would have diverse, balanced, and effective consumer representation in the ACO's governance.

Other commenters objected to our proposal to deem ACOs as having met the requirement to partner with community stakeholders simply by including a community stakeholder on the governing board. These comments argue that ACOs will serve a diverse population with a range of needs, preferences, and values and, thus, one representative will not be able to speak for the entire community on all issues. These commenters urged us to require that ACOs develop partnerships with community-based organizations that—(1) operate within a single local or regional community; (2) are representative of a community or significant segments of a community; and (3) provide health, educational, personal growth, and improvement, social welfare, self-help for the disadvantaged or related services to individuals in the community.

Several commenters expressed concern about how the beneficiary representative would be chosen. For example, one commenter sought clarification on how we would know that the chosen beneficiary is truly representative of the beneficiary population served by the ACO. Another commenter expressed concern about the potential influence of this board on the consumer representative. Some commenters stated it would make more sense for the beneficiary representative to have healthcare knowledge or business experience. One commenter suggested that non-medical oriented individuals will likely promote their special projects that they perceive as beneficial to their own goals and aims.

One commenter sought clarification about whether beneficiary and/or community organization is counted toward the 75 percent threshold or if it is in the 25 percent non-participant group.

By contrast, many comments stated our proposed requirement was too prescriptive. Commenters indicated that such a requirement could: (1) Mean that a clinically integrated physician network would have to restructure its bylaws and thus re-contract with its entire physician network; (2) place the beneficiary in an inappropriate position to be voting on decisions of the organization's non-ACO lines of business; (3) conflict with State law which requires only licensed medical professionals to govern the professional corporation; (4) conflict with State and local laws that dictate composition of public hospital/health system boards and/or restrict the authority those boards may be able to delegate (given their authority over taxpayer funds); or (5) result in a potential HIPAA violation.

These commenters suggested that there are more effective ways to obtain beneficiary representation such as through creation of a committee of participants and/or beneficiaries which could accomplish the same purpose without the necessity of a board role. They recommended creating non-voting and ongoing advisory groups of beneficiaries rather than requiring an ACO to include a single beneficiary on the governing body. One commenter suggested that we define lack of a ''conflict of interest.''

Response: We continue to believe that a focus on the beneficiary in all facets of ACO governance will be critical for ACOs to achieve the three-part aim. Therefore, we finalize our proposal to require beneficiary representation on the governing body, with an option (discussed later in this final rule) to allow for flexibility for those ACOs that seek innovative ways to involve beneficiaries in ACO governance.

We decline the suggestions to increase the beneficiary representation requirement, because we believe the proposal achieves our objective but still permits ACOs flexibility to structure their governing bodies appropriately. We encourage all ACOs to consider seriously how to provide other opportunities for beneficiaries to be involved further in ACO governance in addition to the seat on the governing body. We also clarify that, as we proposed, the beneficiary representative (like all members on the governing body as discussed previously) must not have a conflict of interest, such that he or she places his or her own interest, or an interest of an immediate family member, above the ACO's mission. In addition, the beneficiary representative cannot be an ACO provider/supplier within the ACO's network.

We recognize commenters' concerns that requiring a beneficiary on the governing body could conflict with State corporate practice of medicine laws or other local laws regarding, for instance, governing body requirements for public health or higher education institutions. In addition, there could be other reasons that beneficiary representation on an ACO's governing body may not be feasible. For these reasons, we agree with commenters that it is appropriate to provide flexibility regarding the composition of ACO governing bodies. Accordingly, an ACO that seeks to compose its governing body in such a way that it does not meet either the requirement regarding 75 percent ACO participant control or the requirement regarding beneficiary representation on the governing body would be able to describe in its application how the proposed structure of its governing body would involve ACO participants in innovative ways in ACO governance and provide a meaningful opportunity for beneficiaries to participate in the governance of the ACO. For example, this flexibility would allow ACOs that operate in States with Corporate Practice of Medicine restrictions to structure beneficiary representation accordingly and it also would allow for consumer-driven boards that have more than 25 percent consumer representation. This option could also be used by existing entities to explain why they should not be required to reconfigure their board if they have other means of addressing the consumer perspective in governance.

Final Decision: In summary, we will finalize our proposals that at least 75 percent control of the ACO's governing body must be held by the ACO's participants. The governing body of the ACO must be separate and unique to the ACO in the cases where the ACO comprises multiple, otherwise independent entities that are not under common control (for example, several independent physician group practices). However, the members of the governing body may serve in a similar or complementary manner for a participant in the ACO. Each ACO should provide for beneficiary representation on its governing body. In cases in which the composition of an ACO's governing

body does not meet the 75 percent ACO participant control threshold or include the required beneficiary governing body representation, the ACO must describe why it seeks to differ from the established requirements and how the ACO will involve ACO participants in innovative ways in ACO governance and/or provide for meaningful participation in ACO governance by Medicare beneficiaries. (§ 425.106).

4. Leadership and Management Structure

Section 1899(b)(2)(F) of the Act requires an eligible ACO to ''have in place a leadership and management structure that includes clinical and administrative systems.'' In the proposed rule, we stated that we believed an ACO's leadership and management structure should align with and support the goals of the Shared Savings Program and the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

We drew from two sources to develop our proposals for ACO leadership and management structures. We first highlighted those factors that participants in the PGP demonstration identified as critical to improving quality of care and the opportunity to share savings. Second, we discussed the criteria developed by the Antitrust Agencies to assess whether collaborations of otherwise competing health care providers are likely to, or do, enable their collaborators jointly to achieve cost efficiencies and quality improvements. We explained that the intent of the Shared Savings Program and the focus of antitrust enforcement are both aimed at ensuring that collaborations between health care providers result in improved coordination of care, lower costs, and higher quality, including through investment in infrastructure and redesigned care processes for high quality and efficient service delivery. We stated in the proposed rule that the Antitrust Agencies' criteria provide insight into the leadership and management structures, including clinical and administrative systems, necessary for ACOs to achieve the three-part aim of better care for individuals, better health for populations, and lower growth in expenditures.

We stated that it is in the public interest to harmonize the eligibility criteria for ACOs that wish to participate in the Shared Savings Program with the similar antitrust criteria on clinical integration, because competition between ACOs is expected to have significant benefits for Medicare beneficiaries. Further, because ACOs that operate in the Shared Savings Program are likely to use the same organizational structure and clinical care practices to serve both Medicare beneficiaries and consumers covered by commercial insurance, the certainty created by harmonizing our eligibility criteria with antitrust criteria will help to reduce the likelihood that an ACO organization participating in the Shared Savings Program will be challenged as per se illegal under the antitrust laws, which could prevent the ACO from fulfilling the term of its agreement under the Shared Savings Program.

Thus, in order to meet the requirements in section 1899(b)(2)(F) of the Act that an ACO have a leadership and management structure that includes clinical and administrative systems, we proposed that an ACO meet the following criteria:

- The ACO's operations would be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.
- Clinical management and oversight would be managed by a senior-level medical director who is a board-certified physician, licensed in the State in which the ACO operates, and physically present on a regular basis in an established location of the ACO.
- ACO participants and ACO providers/suppliers would have a meaningful commitment to the ACO's clinical integration program to ensure its likely success.
- The ACO would have a physician-directed quality assurance and process improvement committee that would oversee an ongoing quality assurance and improvement program.
- The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures.
- The ACO would have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of service.

In order to determine an ACO's compliance with these requirements, as part of the application process, we proposed that an ACO would submit all of the following:

- ACO documents (for example, participation agreements, employment contracts, and operating policies) that describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO, how the opportunity to receive shared savings will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and the evidenced-based clinical guidelines.
- Documents that describe the scope and scale of the quality assurance and clinical integration program, including documents that describe all relevant clinical integration program systems and processes.
- Supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including the names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders.
- Evidence that the ACO has a board-certified physician as its medical director who is licensed in the State in which the ACO resides and that a principal CMS liaison is identified in its leadership structure.
- Evidence that the governing body includes persons who represent the ACO participants, and that these ACO participants hold at least 75 percent control of the governing body.

Additionally, upon request, the ACO would also be required to provide copies of the following documents:

- Documents effectuating the ACO's formation and operation, including charters, by-laws, articles of incorporation, and partnership, joint venture, management, or asset purchase agreements.
- Descriptions of the remedial processes that will apply when ACO participants and ACO providers/suppliers fail to comply with the ACO's internal procedures and performance standards, including corrective action plans and the circumstances under which expulsion could occur.

We also proposed to allow ACOs with innovative leadership and management structures to describe an alternative mechanism for how their leadership and management structure would conduct the activities noted previously in order to achieve the same goals so that they could be given consideration in the application process. That is, an organization that does not have one or more of the following: An executive, officer, manager, or general partner; senior-level medical director; or

physician-directed quality assurance and process improvement committee, would be required in its application to describe how the ACO will perform these functions without such leadership. Additionally, we sought comment on the requirement for submission of certain documents as noted previously and whether an alternative method could be used to verify compliance with requirements. We also requested comment on the leadership and management structure and whether the compliance burden associated with these requirements would discourage participation, hinder innovative organizational structures, or whether there are other or alternative leadership and management requirements that would enable these organizations to meet the three-part aim.

Comment: Some commenters suggested that we require that a physician or a surgeon licensed in the State in which the ACO is organized serve as either the CEO or president of the ACO and that a physician or a surgeon licensed in the State in which the ACO is organized serve as the Chair of the Board of Directors of the ACO. Other commenters recommended that CMS require that primary care physicians be in executive leadership positions of the ACO. Other commenters suggested that we require personnel with health information management experience to be part of the ACO's leadership.

Response: In light of our decision to allow ACOs flexibility in how they establish their governing bodies, we also believe that ACOs should have flexibility to determine their leadership and management structure. We understand commenters' concerns, but we decline to specify additional requirements as suggested by the commenters for ACO leadership and management.

Comment: Many commenters strongly supported the proposed requirement of senior-level medical director with responsibility for clinical management and oversight. Several commenters suggested removing the full-time requirement, because the ACO may not have the volume to support a full-time position, it is costly and inconsistent with the diverse needs of each ACO, and there is little evidence to suggest that a small to mid-size ACO is likely to need a full time senior-level medical director who is physically present on a regular basis at an established ACO location.

Many commenters supported a part-time requirement, flexible time requirement, or no time requirement. One commenter suggested that the duties of a ''full time medical director'' include the provision of direct clinical care to patients. One commenter suggested eliminating the full time requirement, as long as the medical director devotes sufficient time to fulfilling their ACO related responsibilities. Another commenter suggested that the focus should be on whether the required coordination of care processes are in place and functional at a core level, rather than who is directing them.

Several comments suggested removing the requirement that the medical director be a physician because the Act does not require physician leadership, nor is there evidence suggesting physician leadership is necessary. Several commenters suggested the medical director could be any qualified health care professional.

A few comments suggested strengthening the requirements for clinical oversight and requiring that the director demonstrate an understanding of the core concepts of medical management or have managerial experience, advanced management degree, or certification in medical management and system leadership. One commenter suggested that physician leadership show that it has geriatric competencies, to ensure that patients with dementia and Alzheimer's disease do not receive poorer care.

A few comments suggested that we: (1) Not require the medical director to be licensed in the State because if a medical director has been effective in excelling in services in one State and seeks to expand those services into another State, CMS would be ill-advised to prevent this from occurring; and (2) not require board certification but instead allow a physician who has acquired certification in medical management or quality improvement to be the medical director.

Some commenters sought clarification as to whether the medical director must be licensed in every State in which a multi-State ACO operates and whether the medical director must be on-site at each location at which the ACO provides services (if a multi-site ACO).

Response: We believe physician leadership of clinical management and oversight is important to an ACO's ability to achieve the three-part aim and we will finalize the proposed requirement that an ACO have a senior-level medical director who is a board-certified physician. However, we understand that this requirement may pose an additional financial burden, particularly in small or rural ACOs. Therefore, we are modifying our original proposal to eliminate the full time requirement. Instead, we will require that clinical management and oversight be managed by a senior-level medical director who is one of the ACO's physicians. We decline to require additional qualifications for the medical director, because such qualification may be burdensome for small and rural ACOs. However, we are maintaining the requirement that the medical director be board-certified and licensed in one of the States in which the ACO operates. We believe such certification and licensure are necessary to establish credibility among physicians in the ACO. Further, we clarify that an ''on site'' physician is one who is present at any clinic, office, or other location participating in the ACO.

Comment: Some commenters supported the requirement for a physician-directed quality assurance and process improvement committee. Several comments stated that physician-led quality and clinical process improvement activities are crucial to building trust and credibility with physicians and beneficiaries, as well as necessary ingredients to achieving the quality and beneficiary satisfaction targets set by the program.

By contrast, other commenters believed that such a physician-led committee would be onerous in rural areas and that safety net providers should have some flexibility in meeting these requirements. Several commenters suggested removing the requirement for physician leadership and instead requiring leadership by any qualified healthcare professional. Some comments suggested requiring the director to demonstrate special training or certification in quality improvement.

Response: We acknowledge commenters' concerns that a committee could be burdensome for certain ACOs and that quality improvement activities can be directed by non-physician leadership. In particular, we are persuaded by commenters who suggested that many existing and successful quality improvement efforts are not physician-led. Accordingly, we will eliminate the requirement for ACOs to establish such a committee. Instead, as part of its application, an ACO will be required to describe how it will establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional. We believe these modifications will provide ACOs with greater flexibility to meet this requirement.

Comment: Some commenters supported our proposal to learn from the Antitrust Agencies' clinical integration requirements to help specify

the necessary ''clinical and administrative systems'' that are required to be part of the ACO's leadership and management structure. These commenters recognized that ''success will be determined by the engagement and commitment of practicing physicians.'' Indeed, one commenter explained that unregulated clinical integration was likely to lead to the greater vertical consolidation of provider markets, which in turn will fuel cost growth, making health care less affordable for private payers.

By contrast, several commenters contended that the proposed rule's decision to rely, in part, on the Antitrust Agencies' clinical integration requirements for ''clinical and administrative'' systems was in error. These and other commenters opposed the proposed clinical integration requirements as overly prescriptive, unnecessary, likely to limit innovation in design and implementation of ACOs and unrelated to the three-part aim. However, many of these commenters acknowledge that it is a step forward that the proposed Antitrust Policy Statement states that an ACO that meets CMS criteria will be found to be sufficiently ''integrated'' to meet part of the test for avoiding antitrust enforcement actions. Several commenters also suggested that even if there are changes to the ACO program to make it more attractive financially, these barriers to clinical integration will impede a robust response to the ACO program.

One commenter explained that real clinical integration is evidenced by patient coordination of care across health care settings, providers, and suppliers and is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently. This commenter and others suggested that we focus on the statutorily required processes regarding reporting quality measures, promoting evidence-based patient processes, and coordinating care, thus making separate clinical integration requirements moot.

Several commenters suggested that we eliminate the requirements regarding clinical integration and instead describe, at a very high level, examples of possible ways an ACO could meet the three-part aim. Some commenters suggested that the Antitrust Agencies specify which criteria are related to antitrust issues and which are applicable to all clinically integrated health care organizations. One commenter suggested that CMS, as a purchaser of health care services, should negotiate targets for performance at a higher level and not place requirements on how ACOs achieve these targets. Several commenters suggested we work with the Antitrust Agencies to create more flexibility for physicians to join together to provide services. A commenter argued that participation in the Shared Savings Program, in itself, is an undertaking of meaningful financial integration, thus rendering the need for compliance with clinical integration unnecessary to avoid per se condemnation.

Response: We disagree with the commenters' suggestion that relying, in part, on the Antitrust Agencies' clinical integration requirements for ''clinical and administrative'' systems is overly prescriptive, unnecessary, or likely to limit innovation in ACO design. As we explained in the proposed rule, the purposes of the Shared Savings Program and the Antitrust Agencies' clinical integration requirements are complementary and, indeed, mutually reinforcing. The purposes of the Shared Savings Program are to promote accountability for a patient population, coordinate items and services furnished to beneficiaries under Medicare Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. The Antitrust Agencies' clinical integration criteria require participants to show a degree of interaction and interdependence among providers in their provision of medical services that enables them to jointly achieve cost efficiencies and quality improvements. We do not see how ACO participants and ACO providers/suppliers could achieve the statutory goals of the Shared Savings Program without showing a degree of interaction and interdependence in their joint provision of medical services such that they provide high quality and efficient service delivery. Many commenters agreed with this conclusion and we disagree with the commenters that suggested otherwise.

We also agree with commenters that the four statutorily required processes (section 1899(b)(2)(G) of the Act) to promote evidence-based medicine, report cost and quality metrics, promote patient engagement, and coordinate care overlap and are consistent with our proposed clinical integration criteria. Accordingly, we are aligning our final requirements regarding sufficient ''clinical and administrative systems'' with our final requirements regarding these four required processes. These required processes are discussed later in this section of the final rule.

We disagree with the commenter that participation in the Shared Savings Program is an undertaking of meaningful financial integration. Because ACO participants and ACO providers/suppliers will continue to receive FFS payments and are required only to have a mechanism to receive and distribute shared savings, they will not necessarily be sharing substantial financial risk, which is the hallmark of financial integration.

Comment: Some commenters suggested that we provide concrete standards as to what a meaningful commitment is (especially a meaningful human investment). Another commenter suggested that those ACO providers/suppliers providing a meaningful financial commitment should receive increased shared savings.

A commenter questioned whether it is sufficient to demonstrate a meaningful commitment if a provider agrees to participate contractually in an ACO and to comply with the ACO's clinical, performance, and administrative standards.

A commenter suggested we revise our interpretation of ''meaningful commitment to the ACO's clinical integration,'' because financial and human capital are insufficient to show clinical integration; rather, real clinical integration is evidenced in patient coordination of care across health care settings, providers, and suppliers.

Some commenters queried how a specialist or other health care professional can show ''meaningful commitment'' if they are in more than one ACO. Other commenters suggested that the level of observable commitment is neither a precursor to clinical activity nor the outcome.

Response: We continue to believe that each ACO participant and ACO provider/supplier must demonstrate a meaningful commitment (for example, time, effort, or financial) to the ACO's mission to ensure its likely success so that the ACO participant and/or ACO provider/supplier will have a stake in ensuring the ACO achieves its mission. Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant or ACO provider/supplier to take the actions necessary to help the ACO achieve its mission. A meaningful commitment may be evidenced by, for example—

- Financial investment such as capital contributions for ACO infrastructure information systems, office hardware, computer software,

ACO staff, training program, or any other aspect of the ACO's operations where that investment provides the ACO participant or provider/supplier with a sufficient stake in the successful operation of the ACO such that the potential loss or recoupment of the investment is likely to motivate the participant or provider/supplier to achieve the mission of the ACO; and

• Human investment such as serving on the ACO's governing body; serving on committees relating to the establishment, implementation, monitoring or enforcement of the ACO's evidence-based medical practice or clinical guidelines; or otherwise participating in other aspects of the ACO's operations, such as definition of processes to promote patient engagement, care coordination, or internally reporting on cost and quality metrics, to a degree that evidences a personal investment in ensuring that the ACO achieves its goals.

We also believe that a commitment can be meaningful when ACO participants and ACO providers/suppliers agree to comply with and implement the ACO's required processes and are accountable for meeting the ACO's performance standards. By doing so, we believe that they will be motivated to achieve the ACO's internal performance standards and to comply with the processes required by section 1899(b)(2)(G) of the Act (as discussed later in this section). Indeed, we fail to see how the required processes discussed later in this final rule could be effectuated unless ACO providers/suppliers meaningfully commit to implement, adhere to, and be accountable for the ACO's evidenced-based medical guidelines, care coordination procedures, patient engagement processes, and reporting of cost and quality that are essential to meeting the three-part aim.

We also clarify that an ACO provider/supplier can contractually agree to work with one or more ACOs by agreeing to implement, adhere to, and be accountable for that ACO's statutorily required processes. We disagree with the commenter's suggestion that the level of observable commitment is neither a precursor to clinical activity nor to outcome. We do not see how an ACO could achieve its mission if its providers and suppliers do not agree to comply with and implement the ACO's required processes. Such a commitment is necessary, although insufficient in and of itself, to ensure that an ACO achieves the three-part aim.

Comment: Several commenters suggested that the requirement that ACOs include descriptions in their applications of how they will satisfy certain criteria and make documents available is too burdensome and creates a barrier to participation, especially for safety net providers and many smaller and non-hospital-based applicants. Some commenters asked what we will do with the information (for example, employment contracts).

But several comments suggested we strengthen the application requirement. For example, these commenters stated that an ACO should be required to detail how it plans to partner with community-based organizations, and to detail the kinds of processes it will use to coordinate the care of Medicare beneficiaries with post-acute care providers.

Another commenter suggested self-attestation for the many requested documents to show the leadership and management structures. Other commenters urged us to use NCQA's ACO certification standards to deem an ACO as acceptable and to work with NCQA to eliminate duplicating requirements and aligning accreditations.

Response: We acknowledge commenters' concerns that the proposed documentation requests may be burdensome for certain ACOs. Accordingly, we have aligned our proposed documentation requests regarding clinical and administrative systems with the statutory processes that are described in this section. We believe that this streamlining of document requests addresses the commenters' suggestions for additional detail regarding certain clinical and administrative processes. It also obviates the need to rely NCQA's ACO certification standards. Notwithstanding this alignment, we continue to believe that ACOs should submit certain documentation regarding their clinical and administrative systems to ensure that the ACO meets the eligibility requirements, has the requisite clinical leadership, and has a reasonable chance of achieving the three-part aim. In addition, we will use the documents to assess whether ACO participants and ACO provider/supplier(s) have the requisite meaningful commitment to the mission of the ACO.

Comment: Several commenters applauded our proposal to consider an innovative ACO with a management structure not meeting the proposed leadership and management requirements. As noted previously, many commenters suggested that the leadership and management requirements were overly prescriptive. Thus, many commenters supported the innovative option proposal.

Response: We will finalize our proposal to allow ACO applicants to describe innovative leadership and management structures that do not meet the final rule's leadership and management structures in order to encourage innovation in ACO leadership and management structures.

Final Decision: We will finalize the requirement that the ACO's operations be managed by an executive, officer, manager, or general partner, whose appointment and removal are under the control of the organization's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency, processes, and outcomes. In addition, clinical management and oversight must be managed by a senior-level medical director who is one of the ACO's physicians, who is physically present on a regular basis in an established ACO location, and who is a board-certified physician and licensed in one of the States in which the ACO operates.

As part of its application, an ACO will be required to describe how it will establish and maintain an ongoing quality assurance and improvement program, led by an appropriately qualified health care professional. ACO participants and ACO providers/suppliers must demonstrate a meaningful commitment to the mission of the ACO. A meaningful commitment can be shown when ACO participants and ACO providers/suppliers agree to comply with and implement the ACO's processes required by section 1899(b)(2)(G) of the Act and are held accountable for meeting the ACO's performance standards for each required process as defined later in this section.

As part of their applications, ACOs must submit certain documentation regarding their leadership and management structures, including clinical and administrative systems, to ensure that the ACO meets the eligibility requirements. We are finalizing the following document requests to effectuate our leadership and management structure requirements:

• ACO documents (for example, participation agreements, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers/suppliers' rights and obligations in the ACO.

• Supporting materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job

descriptions for senior administrative and clinical leaders.

Additionally, upon request, the ACO may also be required to provide copies of documents effectuating the ACO's formation and operation, including charters, by-laws, articles of incorporation, and partnership, joint venture, management, or asset purchase agreements.

We also will finalize our proposal to allow ACO applicants to describe innovative leadership and management structures that do not meet the final rule's leadership and management requirements. (§ 425.108, § 425.112, and § 425.204).

5. Processes To Promote Evidence-Based Medicine, Patient Engagement, Reporting, Coordination of Care, and Demonstrating Patient-Centeredness

Section 1899(b)(2) of the Act establishes a number of requirements which ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. Specifically, section 1899(b)(2)(G) of the Act requires an ACO to define processes to: Promote evidence-based medicine and patient engagement; report on quality and cost measures; and coordinate care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies.

We proposed that to meet the requirements under section 1899(b)(2)(G) of the Act, the ACO must document in its application its plans to: (1) Promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. We proposed to allow ACOs the flexibility to choose the tools for meeting these requirements that are most appropriate for their practitioners and patient populations. In addition, we proposed that the required documentation present convincing evidence of concrete and effective plans to satisfy these requirements and that the documentation provide the specific processes and criteria that the ACO intends to use. This documentation was necessary because we wanted to ensure such processes would include provisions for internal assessment of cost and quality of care within the ACO, and that the ACO would employ these assessments in continuous improvement of the ACO's care practices. We explained in the proposed rule that as we learn more about successful strategies in these areas, and as we have more experience assessing specific critical elements for success, the Shared Savings Program eligibility requirements with regard to section 1899(b)(2)(G) of the Act may be revised. We also specifically solicited comment on whether more prescriptive criteria may be appropriate for meeting some or all of these requirements under section 1899(b)(2)(G) of the Act for future rulemaking.

In addition, section 1899(b)(2)(H) of the Act requires an ACO to ''demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.'' We explained that a patient-centered, or person-centered, orientation could be defined as care that incorporates the values of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in health care. We drew from the work of the Institute of Medicine and the principles articulated by the National Partnership for Women and Families to develop our proposals. We explained that the statutory requirement for ''patient-centeredness criteria'' means that patient-centered care must be promoted by the ACO's governing body and integrated into practice by leadership and management working with the organization's health care teams.

We proposed that an ACO would be considered patient-centered if it has all of the following:

- A beneficiary experience of care survey in place and a description in the ACO application of how the survey results will be used to improve care over time.
- Patient involvement in ACO governance. The ACO would be required to have a Medicare beneficiary on the governing board.
- A process for evaluating the health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population. A description of this process must be included in the application, along with a description of how the ACO would consider diversity in its patient population and how it plans to address its population needs.
- Systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations, including integration of community resources to address individual needs.
- A mechanism in place for the coordination of care (for example, via use of enabling technologies or care coordinators). In addition, the ACO should have a process in place (or clear path to develop such a process) to electronically exchange summary of care information when patients transition to another provider or setting of care, both within and outside the ACO, consistent with meaningful use requirements under the Electronic Health Records (EHR) Incentive program.
- A process in place for communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them. This process should allow for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities.
- Written standards in place for beneficiary access and communication and a process in place for beneficiaries to access their medical records.
- Internal processes in place for measuring clinical or service performance by physicians across the practices, and using these results to improve care and service over time.

We explained that this list provides a comprehensive set of criteria for realizing and demonstrating patient-centeredness in the operation of an ACO. We solicited comment on these criteria.

We also noted that there is substantial overlap and alignment between the processes ACOs are required to define under section 1899(b)(2)(G) of the Act and both the proposed patient-centeredness criteria (as defined by the Secretary in accordance with section 1899(b)(2)(H) of the Act) and the clinical and administrative systems that are to be in place in the ACO's leadership and management structure as required by section 1899(b)(2)(F) of the Act. Accordingly the following comment and responses discussion includes a discussion of not only the required process, but also the patient-centeredness criteria and the necessary clinical and administrative systems.

Comment: Commenters suggested that we require a sufficient level of detail on processes that ACOs are required to define. Several commenters suggested that we require ACOs to evaluate their own practices and make adjustments as necessary and hold ACOs accountable for adhering to their stated plans. Other commenters expressed concerns that ACOs will need clear and certain guidance, including technical support, on the processes to promote: Evidence-based medicine, patient engagement, reports on quality and cost measures, and the coordination of care. Other commenters explained that patient coordination of care across health care

settings, providers, and suppliers is best shown when there is a structure in place that is patient-focused and where clinicians collaborate on best practices in an effort to furnish higher quality care that they likely would not achieve if working independently. These commenters suggested that our requirements regarding the four statutorily required processes can help ensure that there is a structure in place to ensure the likelihood that an ACO can achieve the three-part aim.

Response: Although we understand the request by some commenters that we develop a more prescriptive approach to define each of the four processes, we are concerned that such an approach would be premature and potentially impede innovation and the goals of this program. ACOs should retain the flexibility to establish processes that are best suited to their practice and patient population.

Final Decision: We will finalize our proposal requiring that in order to be eligible to participate in the Shared Savings Program, the ACO must provide documentation in its application describing its plans to: (1) Promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. As part of these processes, an ACO shall adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams. These plans must include how the ACO intends to require ACO participants and ACO providers/suppliers to comply with and implement each process (and sub element thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply. In addition, these plans must describe how such processes will include provisions for internal assessment of cost and quality of care within the ACO and how the ACO would employ these assessments in continuous improvement of the ACO's care practices. (§ 425.112).

a. Processes To Promote Evidence-Based Medicine

As stated previously, section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to promote evidence-based medicine * * *.'' We explained in the proposed rule that evidence-based medicine can be generally defined as the application of the best available evidence gained from the scientific method to clinical decision-making. We proposed that as part of the application, the ACO would describe the evidence-based guidelines it intends to establish, implement, and periodically update.

Comment: Nearly all comments received supported processes to promote evidence-based medicine. Some commenters also suggested that the ACO's evidence-based guidelines apply to a broad range of conditions that are found in the beneficiary population served by the ACO. In addition, some commenters suggested that we provide additional guidance on the development and implementation these guidelines and processes by: (1) Requiring sufficient level of detail on processes and tools that will be utilized; (2) requiring ACOs to evaluate the practices and make adjustments as necessary; (3) including measures that assess the intended outcomes of these practices in the quality reporting requirement; and holding ACOs accountable for adhering to their stated plans.

Additionally, several commenters recommended that these processes be more prescriptive and include: Measures for improvement to functional status, suggested tools for monitoring decision support, and specifications for baseline evidence-based guidelines. Other commenters suggested that we establish guidelines for how ACOs should establish their evidence-based medicine. For example, one commenter explained why the organized medical staff of a hospital in which an ACO participates should review and approve all medical protocols and all other quality programs concerning inpatient care at that hospital. Other commenters suggested that we require specialist involvement in the development of these clinical guidelines and processes so that the guidelines reflect appropriate standards of care for their patients and so that new treatments are not discouraged or disadvantaged. Another commenter suggested we require that clinical practice guidelines used by ACOs located in the same geographical area be consistent so that specialists may be able to participate in more than one ACO. One comment suggested that we adopt a similar set of criteria to evaluate the evidence-based approaches of ACOs similar to the one the Institute of Medicine (IOM) recently released in its consensus report, ''Clinical Practice Guidelines We Can Trust,'' that details criteria that all evidence-based guidelines should meet.

One commenter suggested broadening the definition of the term ''evidence-based medicine'' to include best practices regarding evidence-based psychosocial interventions not generally included as medicine. One commenter suggested that we require that the application specify how the leadership structure will assure linkage and involvement with local and State health agencies.

One comment recommended that ACOs that have met requirements for NCQA Medical Home recognition be eligible to use the same ''short form'' of documentation of these capabilities that will be available to the PGP demonstration practices.

Response: As discussed previously, we believe it is important that ACOs retain the flexibility to define processes that are best suited to their own practices and patient populations. Thus, for the requirements under section 1899(b)(2)(G) of the Act, ACOs must provide documentation in their respective applications describing how they plan to define, establish, implement, and periodically update processes to promote evidence-based medicine applicable to ACO participants and ACO providers/suppliers as opposed to the establishment of more prescriptive guidelines regarding the processes of evidence-based medicine. We agree with commenters that for these guidelines to have an impact they must cover diagnoses found in the beneficiary population assigned to the ACO. We believe that the guidelines should address diagnoses with significant potential for the ACO to achieve quality improvements, while also accounting for the circumstances of individual beneficiaries. For the reasons stated previously, we decline, however, to establish the processes by which ACOs should develop these evidence-based medicine guidelines. We would consider an ACO that has met the requirements for NCQA Medical Home recognition well on its way to demonstrating that it has processes in place that support evidence-based guidelines, but we will still need to evaluate them in the context of the Shared Savings Program eligibility requirements.

Final Decision: As previously discussed, to be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement, and periodically update its processes to promote evidence-based medicine. These guidelines must cover diagnoses with significant potential for the ACO to achieve quality improvements, taking into account the circumstances of individual beneficiaries. (§ 425.112).

b. Processes To Promote Patient Engagement

Section 1899(b)(2)(G) of the Act also requires an ACO to ''define processes to promote * * * patient engagement.'' We described in the proposed rule that the term ''patient engagement'' is the active participation of patients and their families in the process of making medical decisions. We explained that measures for promoting patient engagement may include, but are not limited to, the use of decision support tools and shared decision making methods with which the patient can assess the merits of various treatment options in the context of his or her values and convictions. Patient engagement also includes methods for fostering ''health literacy'' in patients and their families. We proposed that as part of its application, the ACO would describe the patient engagement processes it intends to establish, implement, and periodically update.

Related to the process to promote patient engagement, we also proposed that ACOs have a beneficiary experience of care survey in place and that the ACO's application should describe how the ACO will use the survey results to improve care over time. We explained in the proposed rule that surveys are important tools for assessing beneficiary experience of care and outcomes. As part of the requirement to implement a beneficiary experience of care survey, we proposed to require ACOs to collect and report on measures of beneficiaries' experience of care and to submit their plan on how they will promote, assess, and continually improve in weak areas identified by the survey.

Specifically we proposed that ACOs will be required to use the CAHPS survey. We also proposed to require the adoption of an appropriate functional status survey module that may be incorporated into the CAHPS survey. As further discussed in section II.F. of this final rule, scoring on the patient experience of care survey would become part of the assessment of the ACO's quality performance.

Promoting patient engagement would also include a requirement that ACOs provide for patient involvement in their governing processes. We proposed that ACOs would be required to demonstrate a partnership with Medicare FFS beneficiaries by having representation by a Medicare beneficiary serviced by the ACO, in the ACO governing body. In order to safeguard against any conflicts of interest, we proposed that any patient(s) included in an ACO's governing body, or an immediate family member, must not have any conflict of interest, and they may not be an ACO provider/supplier within the ACO's network. Section II.B.3. of this final rule discusses these issues in full.

In addition to these two proposals relating to processes for patient engagement, we proposed four other requirements relating to patient-centeredness that overlap substantially with our proposals regarding patient engagement. These processes include: (1) Evaluating the health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population; (2) communicating clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them; (3) engaging beneficiaries in shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities; and (4) having written standards in place for beneficiary communications and allowing beneficiary access to their medical record.

As part of the application, we proposed that the ACO would describe the patient engagement processes it intends to establish, implement, and periodically update.

Comment: Commenters supported our proposal requiring that an ACO describe, in its application, its process for evaluating the health needs of the population, including consideration of diversity in its patient populations, and a plan to address the needs of its Medicare population. Several comments suggest that certain populations, such as tribal populations, have a disproportionate share of diversity and recommended including specific measures to account for the diversity in their Medicare population.

Response: We agree with the comments received that certain beneficiary populations will be more diverse than others, which is why we proposed to provide ACOs with the flexibility to describe the processes that will be most effective in evaluating their patient population as opposed to prescriptively identifying specific measures for all ACOs.

Comment: Several commenters explained that ACOs must recognize that the needs of a diverse population are based on many factors, such as race, gender, gender identity or expression, sexual orientation, disability, income status, English proficiency, and others. These commenters, and others, suggested that we develop an objective set of criteria for the evaluation of population health needs and consideration of diversity.

Response: We agree with commenters that true patient engagement requires sensitivity to the many diverse factors that can affect a specific patient population and the appropriate care to address the health needs of that population. We explained in the proposed rule that several institutions and associations such as the National Committee for Quality Assurance (NCQA) and AHRQ have made recommendations regarding evaluation of population health and diversity. Establishing partnerships with a State or local health department which performs community health needs assessments and applying these findings to the ACO's population and activities may be another viable option for meeting this criterion. Given this broad range of available resources, we decline to develop a set of evaluation criteria to assess the health needs of an ACO's patient population.

Comment: Commenters supported requiring ACOs to demonstrate processes to promote patient engagement relating to communicating clinical knowledge, shared decision making, and beneficiary access to medical records. Some commenters expressed concern that we were allowing too much latitude in defining these processes. These commenters recommended more guidance in areas where there is evidence of best practices. Comments also recommended that in order for the benefits of adherence to processes to promote patient engagement to be realized, patients and families need to be incentivized to actively participate in their own health care.

Response: We believe it is important that ACOs retain the flexibility to establish processes that are best suited to their own practices and patient populations. Additionally, the very act of educating and engaging patients in the decision making processes associated with their own health care needs should sufficiently incentivize patients to actively engage in prospective treatment approaches in the light of their own values and convictions. Therefore, we decline to impose additional requirements in this area.

Final Decision: To be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement, and periodically update processes to promote patient engagement. In its application an ACO must describe how it intends to address all of the following areas: (a) Evaluating the health needs of the ACO's assigned population; (b) communicating clinical knowledge/evidence-based medicine to

beneficiaries; (c) beneficiary engagement and shared decision-making; and (d) written standards for beneficiary access and communication, and a process in place for beneficiaries to access their medical record. (§ 425.112).

c. Processes To Report on Quality and Cost Measures

Section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to * * * report on quality and cost measures.'' We explained in the proposed rule that processes that may be used for reporting on quality and cost measures may include, but are not limited to, developing a population health data management capability, or implementing practice and physician level data capabilities with point-of-service (POS) reminder systems to drive improvement in quality and cost outcomes. We stated that we expect ACOs to be able to monitor both costs and quality internally and to make appropriate modifications based upon their collection of such information.

In our discussion of required clinical and administrative systems, we proposed that an ACO would have an infrastructure that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of care.

We proposed that as part of the application, the ACO would describe its process to report internally on quality and cost measures, and how it intends to use that process to respond to the needs of its Medicare population and to make modifications in its care delivery.

Comment: Several commenters suggested that we outline quality reporting requirements for the Shared Savings Program. Other commenters suggested that an ACO detail its plans to manage information technology (IT) use and to identify personnel responsible for IT.

Response: As discussed previously, we believe it is important that ACOs retain the flexibility to establish processes that are best suited to their own practices and patient populations. Thus, consistent with the requirements under section 1899(b)(2)(G) of the Act, Shared Savings Program, we will require that ACOs provide documentation in their applications describing their processes to internally report on quality and cost measures in order to be eligible to participate in the Shared Savings Program.

Comment: Some comments expressed concerns that, in rural settings, hospitals will not be able to address, achieve, and implement quality measures for patients with specific chronic conditions and that use of these hospitals will interrupt the relationship between patients and their respective specialty provider that are participating in the Shared Savings Program.

Response: We believe that the Shared Savings Program provides new incentives for providers in rural areas to develop the means to report on cost and quality of their patients with chronic conditions in ways that benefit their patient population.

Final Decision: We will finalize our proposal that to be eligible to participate in the Shared Savings Program, the ACO must define, establish, implement and periodically update its processes and infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics to enable the ACO to monitor, provide feedback, and evaluate ACO participant and ACO provider/supplier performance and to use these results to improve care and service over time. (§ 425.112).

d. Processes To Promote Coordination of Care

Section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to * * * coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.'' We explained in the proposed rule that coordination of care involves strategies to promote, improve, and assess integration and consistency of care across primary care physicians, specialists, and acute and post-acute providers and suppliers, including methods to manage care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist.

We also noted that the strategies employed by an ACO to optimize care coordination should not impede the ability of a beneficiary to seek care from providers that are not participating in the ACO, or place any restrictions that are not legally required on the exchange of medical records with providers who are not part of the ACO. We proposed to prohibit the ACO from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

In addition, the process to promote coordination of care includes the ACOs having systems in place to identify high-risk individuals and processes to develop individualized care plans for targeted patient populations. We proposed that an individualized care plan be tailored to—(1) the beneficiary's health and psychosocial needs; (2) account for beneficiary preferences and values; and (3) identify community and other resources to support the beneficiary in following the plan. This plan would be voluntary for the beneficiary, privacy protected, and would not be shared with Medicare or the ACO governing body; it would solely be used by the patient and ACO providers/suppliers for care coordination. If applicable, and with beneficiary consent, the care plan could be shared with the caregiver, family, and others involved in the beneficiary's care. An ACO would have a process in place for developing, updating, and, as appropriate, sharing the beneficiary care plan with others involved in the beneficiary's care, and providing it in a format that is actionable by the beneficiary.

We requested comments on our proposal that ACOs be required to demonstrate the processes they have in place to use individualized care plans for targeted beneficiary populations in order to be eligible for the Shared Savings Program. We proposed that the individualized care plans should include identification of community and other resources to support the beneficiary in following the plan. We also stated that we believe that a process for integrating community resources into the ACO is an important part of patient-centeredness.

For purposes of the application to participate in the Shared Savings Program, we proposed that an ACO would be required to submit a description of its individualized care program, along with a sample care plan, and explain how this program is used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients. In addition, the ACO should describe additional target populations that would benefit from individualized care plans. We also proposed that ACOs describe how they will partner with community stakeholders as part of their application. ACOs that have a stakeholder organization serving on their governing body would be deemed to have satisfied this requirement. We requested comment on these recommendations.

Comment: Comments received acknowledged that requiring ACOs to define processes to promote coordination of care is vital to the success of the Shared Savings Program. Commenters stressed the importance of health information exchanges in coordination of care activities and recommended that CMS allow ACOs the flexibility to use any standards-based electronic care coordination tools that

meet their needs while other comments suggested that the proposed rule anticipated a level of functional health information exchange and technology adoption that may be too aggressive for deployment in January 2012.

Response: We agree that ACOs should coordinate care between all types of providers and across all services. We also agree that health information exchanges are of the utmost importance for both effective coordination of care activities and the success of the Shared Savings Program. We understand that there will be variable ability among ACOs to adopt the appropriate health information exchange technologies, but underscore the importance of robust health information exchange tools in effective care coordination. Additionally, as discussed in the Agreement section of this regulation, we will allow for two start dates in the first year of the agreement period. These additional start dates will provide an ''on ramp'' for all ACOs to get the appropriate health information exchanges in place before they enter the program.

Comment: Commenters supported our proposal to require an ACO to submit a description of its individualized care program, along with a sample care plan, and explain how this program is used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients. Several comments recommended that CMS make a stronger case for the need to integrate community resources into the individualized care plans by requiring that ACOs have a contractual agreement in place with community-based organizations.

Response: Although we agree with comments that the integration of community resources into the individualized care plans is important to the concept of patient-centeredness, we also believe it is important to afford ACOs the flexibility to accomplish this requirement in a manner that is most suited to their patient population.

Final Decision: We will finalize our proposal requiring ACOs to define their care coordination processes across and among primary care physicians, specialists, and acute and post acute providers. The ACO must also define its methods to manage care throughout an episode of care and during its transitions. The ACO must submit a description of its individualized care program as part of its application along with a sample care plan and explain how this program is used to promote improved outcomes for, at a minimum, their high-risk and multiple chronic condition patients. The ACO should also describe additional target populations that would benefit from individualized care plans. In addition, we will finalize our proposal that ACOs describe how they will partner with community stakeholders as part of their application. ACOs that have stakeholder organizations serving on their governing body will be deemed to have satisfied this requirement. (§ 425.112).

6. Overlap With Other CMS Shared Savings Initiatives

a. Duplication in Participation in Medicare Shared Savings Programs

The statute includes a provision that precludes duplication in participation in initiatives involving shared savings. Section 1899 of the Act states that providers of services or suppliers that participate in certain programs are not eligible to participate in the Shared Savings Program. Section 1899(b)(4) of the Act states these exclusions are ''(A) A model tested or expanded under section 1115A [the Innovation Center] that involves shared savings under this title or any other program or demonstration project that involves such shared savings; (B) The independence at home medical practice pilot program under section 1866E.''

In the proposed rule, we identified several programs or demonstrations that we believed included a shared savings component and would be considered duplicative. Specifically, we identified the Independence at Home Medical Practice Demonstration program, Medicare Health Care Quality (MHCQ) Demonstration Programs, Multipayer Advanced Primary Care Practice (MAPCP) demonstration, and the PGP Transition Demonstration. We also recognized that additional programs, demonstrations, or models with a shared savings component may be introduced in the Medicare program in the future. We recommended that interested parties check our Web site for an updated list.

We further noted that the prohibition against duplication in participation in initiatives involving shared savings applies only to programs that involve shared savings under Medicare. Providers and suppliers wishing to participate in the Shared Savings Program would not be prohibited from participating if they are also participating in demonstrations and initiatives established by the Affordable Care Act that do not involve Medicare patients or do not involve shared savings, such as State initiatives to provide health homes for Medicaid enrollees with chronic conditions as authorized under section 2703 of the Affordable Care Act.

As we explained in the proposed rule, we believe a principal reason underlying the prohibition against participation in multiple initiatives involving shared savings is to prevent a provider or supplier from being rewarded twice for achieving savings in the cost of care provided to the same beneficiary. Therefore, to ensure that a provider or supplier is rewarded only once with shared savings for the care of a beneficiary, an ACO participant may not also participate in another Medicare program or demonstration involving shared savings. However, in order to maintain as much flexibility as possible for ACO providers/suppliers to participate concurrently in multiple CMS initiatives involving shared savings, we do not believe it is appropriate to extend this prohibition to individual providers and suppliers. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program under one ACO participant TIN and another shared savings program under a different non-ACO participant TIN if the patient population is unique to each program.

Finally, we proposed a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings. If such a program assigns beneficiaries based upon the TINs of health care providers from whom they receive care, we proposed to compare the participating TINs in the program or demonstration with those participating in the Shared Savings Program to ensure that TINs used for beneficiary assignment to an ACO participating in the Shared Savings Program are unique and that beneficiaries are assigned to only one shared savings program. If the other program or demonstration involving shared savings does not assign beneficiaries based upon the TINs of the health care providers from whom they receive care, but uses an alternate beneficiary assignment methodology, we proposed working with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. We proposed that applications to the Shared Savings Program that include TINs that are already participating in another program or demonstration involving shared savings would be rejected.

Comment: Commenters generally requested clarification on what programs and demonstrations would be considered overlapping and disqualifying for participating in the Shared Savings Program. Some commenters asked CMS to confirm that initiatives such as the New Jersey gain sharing demonstration are not considered to overlap with the Shared Savings Program. Another commenter asked CMS for an official opinion whether the MHCQ demonstrations, specifically, the Indiana Health Information Exchange (IHIE) demonstration and the North Carolina Community Care Network, and an ACO could coexist and, if so, how CMS would calculate the shared savings.

Several commenters requested that CMS remove the MAPCP demonstration from the initiatives in which ACOs may not participate pointing out that the demonstration is not for shared savings, but rather one that is restricted to explicit payment for care coordination services to medical/health care homes. One commenter stated that it is possible to account for costs and payments in MAPCP and in an ACO so that CMS does not reward the same savings more than once.

Some commenters asked CMS to provide guidance on whether participation in other value-based purchasing initiatives or demonstrations that do not involve shared savings, such as the Community-Based Care Transitions Programs, Hospital Value-Based Purchasing Programs, bundled payment programs, Maryland's all-payer waiver, or other Innovation Center initiatives, would overlap with the Shared Savings Program. Other commenters wondered whether organizations participating in State shared savings initiatives involving Medicaid or dually eligible beneficiaries would be ineligible to participate in the Shared Savings Program. One commenter requested a comprehensive list of initiatives involving shared savings for which there would be overlap.

Response: We have determined there are several ongoing demonstrations involving shared savings that would be considered overlapping. We have determined that currently two of the MHCQ demonstration programs, the IHIE and North Carolina Community Care Network (NCCCN), involve shared savings payments for a Medicare population, therefore, providers and suppliers who participate in the IHIE and NCCCN will not be permitted to also participate in the Medicare Shared Savings Program. However, once a Medicare enrolled TIN completes its participation in the IHIE or NCCCN, it may apply for the Shared Savings Program and would no longer be prohibited from participation because of duplication.

At the time of publication of the proposed rule, the MAPCP demonstration offered several different payment arrangements to participating providers. Since then, we selected the States of Maine, Vermont, New York, Rhode Island, Pennsylvania, North Carolina, Michigan, and Minnesota for the MAPCP Demonstration. To the extent that any of the participating providers have chosen a shared savings arrangement, participation in both MAPCP and the Shared Savings Program will be prohibited. MAPCP participants who do not have shared savings arrangements under the demonstration would not be prohibited from participating in the Shared Savings Program.

Subsequent to publication of the proposed rule, we have determined that the Care Management for High-Cost Beneficiaries Demonstrations authorized by 42 U.S.C. 1395b–1 is also a shared savings program, as well as the Pioneer ACO Model.

After due consideration, we have determined that providers would be able to participate in both the Medicare Shared Savings Program and programs that focus on the integration of the Medicare and Medicaid programs for dually eligible individuals, specifically, State initiatives to integrate care for dually eligible individuals announced recently by the Medicare-Medicaid Coordination Office in partnership with the Innovation Center. Due to the unique design of these demonstrations as well as the relationship of States with providers in the Medicaid program, it is not necessary or reasonable to prohibit involvement in both programs. However, we will work closely with providers and States to prevent duplication of payment. Furthermore, we have also determined that demonstrations that do not involve shared savings, such as the New Jersey gain sharing demonstration and others would not be considered overlapping for purposes of participation in the Shared Savings Program.

Comment: We received several comments regarding transitions from demonstrations to the Shared Savings Program. A member organization of the IHIE thanked CMS for acknowledging the demonstration as a worthwhile project. The commenter wrote that it would be counterproductive to halt the MHCQ demonstration after substantial investment in that program to make it a success, especially since the goals of the program and ACOs are consistent.

One commenter indicated that the potential transition from the IHIE demonstration to the Shared Savings Program may be difficult because of the asynchronous performance years under the two programs. Several other commenters wrote in support of transitioning North Carolina's 646 demonstration program into an ACO and reported that Community Care of North Carolina is already taking steps to establish a North Carolina Accountable Care Collaborative. A commenter suggested that CMS clarify at what point a Medicare-enrolled TIN previously involved in another shared savings would be eligible for participation in an ACO under the Shared Savings Program.

Response: We recognize that our initiatives may have different lengths of agreement periods or different start and end dates. In the Shared Savings Program, we sought to align with many programs that function on a calendar year basis, such as the Physician Quality Reporting System (PQRS). We do not believe this proposal should disrupt ongoing participation in other shared savings initiatives, and we encourage participants in ongoing demonstrations to complete the term of their agreement before entering the Shared Savings Program. We recognize that not all programs and demonstrations operate on a calendar year basis and that, as a result, there may be some providers and suppliers who will have gaps in time from the end of one program or demonstration to the beginning of participation in another. An entity must have terminated its involvement with another shared savings program prior to participation in the ACO Shared Savings Program. After an organization with a Medicare-enrolled TIN concludes an overlapping shared savings demonstration, its application to the Shared Savings Program would not be denied on the basis of duplication.

Comment: Several commenters suggested that the restriction against participation in multiple initiatives involving shared savings would potentially stifle creation of other leading-edge initiatives that are well-aligned with best practices for patient quality of care. One commenter stated that CMS should not deter ACOs from investing in other delivery system innovations such as patient-centered medical homes and healthcare innovation zones that share objectives. One commenter asked if an ACO might not receive all of the potential savings if the organization or the same patients are also participating in another shared savings program. If so, the commenter

believed that this would be a significant deterrent to participation because an organization would have to decide between Shared Savings Program and other Innovation Center initiatives. Another commenter encouraged CMS, if it finds that the statute is creating too many barriers to entry for interested providers and suppliers, to approach Congress to request that the restriction be eased. One commenter suggested that the Secretary should consider a mechanism to provide waivers to organizations that are especially well-suited to innovation in care delivery and that could provide substantial benefit to CMS to permit participation in multiple projects or trials. A commenter questioned if there are multiple TINs in a system, whether one TIN can participate in the Shared Savings Program and another in an Innovation Center program for example, the independence at home project, the State option to provide health homes and the use of community health teams. Several commenters recommended that for groups with multiple companies or subsidiaries, the separate divisions should be permitted to simultaneously seek ACO contracts.

One commenter suggested that to ensure broad participation by Medicare providers and suppliers, CMS should read section 1899(b)(4) of the Act more narrowly than CMS has proposed. At a minimum, CMS should only restrict ACO participants from also participating in a program or demonstration project that is primarily intended to share savings. CMS should not read section 1899(b)(4) of the Act to preclude a provider or supplier's participation in an ACO by virtue of the fact that the provider or supplier is also participating in another program that incidentally makes payments based on cost reductions.

Another commenter stated that if a particular ACO provider/supplier only bills Medicare under one TIN, as is the case for some physician groups and other suppliers, and the TIN is an ACO participant, that individual ACO provider/supplier would be unable to participate in any other initiatives involving shared savings. This commenter suggested the prohibition would prevent such a group from successfully coordinating the care of Medicare beneficiaries who are not assigned to the ACO under the Shared Savings Program but are assigned to an organization under another shared savings model.

Response: We believe there is opportunity for providers and suppliers to participate in multiple complementary initiatives. However, the statute clearly states that a provider that participates in any other program or demonstration project that involves shared savings under Medicare is ineligible to participate in an ACO under the Shared Savings Program. We believe our operational definition of an ACO as a collection of Medicare enrolled TINs, combined with our assignment methodology, discussed in section II.E of this final rule, helps ensure a unique patient population to an ACO on the basis of services billed by the ACO participant TINs. We recognize that health systems may be comprised of multiple TINs that bill Medicare. It may be appropriate for some of those TINs to apply to participate in the Shared Savings Program while others do not. We believe organizations should have flexibility to determine what TINs join together to form an ACO.

To ensure that a provider or supplier is rewarded only once with shared savings for the care of a beneficiary, we proposed that an ACO participant TIN may not also participate in another Medicare program or demonstration involving shared savings. However, in order to maintain as much flexibility as possible for ACO providers/suppliers to participate concurrently in multiple CMS initiatives involving shared savings, we do not believe it is appropriate to extend this prohibition to individual providers and suppliers. Accordingly, an ACO provider/supplier who submits claims under multiple Medicare-enrolled TINs may participate in both the Shared Savings Program and another shared savings program if the patient population is unique to each program and if none of the relevant Medicare-enrolled TINs participate in both programs. For example, an ACO practitioner participating in the Shared Savings Program under an ACO participant practice TIN could also participate in the Independence at Home Demonstration under a non-ACO participant TIN since there would be no duplication in beneficiary assignment; and therefore, no duplication in shared savings.

We believe our proposal identifying ongoing CMS initiatives that involve shared savings meets both the letter and spirit of the statutory prohibition against duplication of participation in initiatives involving shared savings. Furthermore, we do not believe the fact that the stated goal of a particular program is something other than to achieve shared savings lessens the potential for duplication in payment for the same beneficiaries or changes the applicability of the statutory prohibition against duplicative participation when the incentive for participation in the other program is the provision of shared savings. As noted previously, in developing our proposed policy, we carefully considered currently implemented programs and sought to provide as much flexibility as possible to potential Shared Savings Program participants while also ensuring there is no duplication in payments for savings achieved for the same Medicare beneficiaries.

Further, we disagree with the conclusion that the prohibition against participating in duplicative initiatives involving shared savings would prevent a practice or an individual practitioner that bills under a single TIN from successfully coordinating the care of Medicare beneficiaries who are not assigned to the ACO under the Shared Savings Program but are assigned to an organization under another shared savings model. We believe that the Shared Savings Program assignment methodology, described in detail in section II.E of this final rule, provides an incentive for participating providers and suppliers to redesign care delivery to all their Medicare FFS beneficiaries.

Finally, we note, as explained in section II.E of this final rule, that certain Shared Savings Program ACO participants have the opportunity to participate in more than one Medicare Shared Savings Program ACO, as long as assignment of beneficiaries is not dependent on the ACO participant TIN. We believe that participation in more than one ACO within the Shared Savings Program is separate and distinct from participating in multiple Medicare shared savings initiatives, and therefore would not be subject to the statutory prohibition.

Comment: Many commenters suggested that CMS allow participation in multiple initiatives involving shared savings provided that such participation does not result in double counting achieved savings and providing that the same patients are not assigned to both demonstrations, for example, some large health systems suggested they should be able to participate in multiple programs so long as CMS ensures they are not being paid twice for the same care to the same patient. A commenter encouraged CMS to consider ways to prevent duplicative payments based on the beneficiary identification so that a provider or supplier to whom a particular beneficiary is assigned is only rewarded once for that beneficiary.

Response: We believe our proposed methodology ensures no duplication in payment while adequately allowing provider flexibility. Further, the law states that a provider may not

participate in this program if they are already participating in another shared savings program, so for purposes of determining eligibility to participate in the Shared Savings Program, we will review the ACO participant TINs submitted on the application of a prospective ACO and determine whether or not those TINs are already participating in another shared savings program. Applications that have such an overlap will be rejected. Furthermore, despite this precaution, because assignment methodologies may differ from program to program, as noted previously in the case of the Pioneer ACO Model, we will work with other initiatives involving shared savings and demonstrations to prevent duplicative payments based on beneficiary identification where necessary. We would note that while participation in some demonstrations, for example, the Bundled Payment for Care Improvement Initiative, would not exclude ACO participants from participating in the Shared Savings Program, it is our intention to ensure duplicative payments are not being made within the design of the demonstration.

Comment: A few commenters requested clarification that this prohibition does not apply to providers and suppliers upon whom assignment cannot be based or to non-Medicare enrolled participants.

Response: We disagree that ACO participants upon whom assignment is not based may participate in multiple initiatives involving shared savings. We read section 1899(b)(4) of the Act to direct us to ensure that ACO participants are not also participating in another initiative involving shared savings. Furthermore, such an interpretation would be inconsistent with the intent of the law, which is to avoid duplicate incentive payments across initiatives. However, within the Shared Savings Program itself, we are able to prevent duplicate payments by ensuring unique assignment to each ACO. As described in section II.E of this final rule, ACO participants upon whom assignment is not based would have the opportunity to participate in more than one Medicare Shared Savings Program ACO, that is, they would not be required to be exclusive to a single Medicare Shared Savings Program ACO. In response to specific requests for clarification, we note that these final rules apply only to Medicare enrolled ACO participants and ACO providers/suppliers. They do not apply to providers and suppliers that are not enrolled in Medicare.

Comment: A commenter questioned whether a provider or supplier, for example, a pharmacy, could fill prescriptions and provide health screenings for more than one ACO.

Response: We appreciate this question; however, we are unclear exactly what the commenter is asking. That is, it is unclear whether the commenter is wondering whether they can participate in more than one Medicare ACO or whether they are asking if, once in an ACO, the services they render would be limited to ACO assigned beneficiaries. We stress that the Medicare Shared Savings Program is not a managed care program and as such does not require lock in of beneficiaries nor does it require a participating provider or supplier to reassign their billing to the ACO or render services only on behalf of the ACO or only to beneficiaries assigned to the ACO. Medicare enrolled providers and suppliers that are participating in an ACO or whose beneficiaries are assigned to an ACO would continue to care for their beneficiaries and bill Medicare for services rendered under FFS as usual.

However, for purposes of participation in the program, as described in more detail in section II.E of this final rule, ACO participants upon whom assignment is based must be exclusive to a single ACO. So providers and suppliers who do not bill for primary care services and upon whom assignment is not based, including pharmacies, would have the opportunity to participate in multiple ACOs in the Shared Savings Program.

Final Decision: We have identified several current initiatives in which ACO participants receive shared savings such that they would be prohibited from participation in the Shared Savings Program: Independence at Home, the MHCQ IHIE and NCCCN demonstrations, MAPCP arrangements involving shared savings, PGP Transition demonstration, the Care Management for High-Cost Beneficiaries Demonstrations, and the Pioneer ACO Model through the Innovation Center. We recognize, however, that there may be other demonstrations or programs that will be implemented or expanded as a result of the Affordable Care Act, some in the near future. We will update our list of duplicative shared savings efforts periodically to inform prospective Shared Savings Program participants and as part of the application.

Additionally, we are finalizing our proposal to implement a process for ensuring that savings associated with beneficiaries assigned to an ACO participating in the Shared Savings Program are not duplicated by savings earned in another Medicare program or demonstration involving shared savings. Specifically, applications for participation in the Shared Savings Program will be reviewed carefully to assess for overlapping TINs. TINs that are already participating in another Medicare program or demonstration involving shared savings will be prohibited from participating in the Medicare Shared Savings Program. An ACO application that contains TINs that are already participating in another Medicare program or demonstration involving shared savings will be rejected.

If the other program or demonstration involving shared savings does not assign beneficiaries based upon the TINs of the health care providers from whom they receive care, but uses an alternate beneficiary assignment methodology, we will work with the developers of the respective demonstrations and initiatives to devise an appropriate method to ensure no duplication in shared savings payment. For example, billing TINs who are participating in the Pioneer ACO Model would be prohibited from also participating in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and assigns beneficiaries prospectively, we will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§ 425.114).

b. Transition of the Physician Group Practice (PGP) Demonstration Sites Into the Shared Savings Program

The PGP demonstration, authorized under section 1866A of the Act, serves as a model for many aspects of the Shared Savings Program. The Affordable Care Act provided authority for the Secretary to extend the PGP demonstration. On August 8, 2011 we announced the PGP Transition Demonstration which will follow many of the same parameters from the original PGP Demonstration, with some modifications. The modifications include: shifting spending benchmarks to the national rather than regional level, aligning beneficiaries first with primary care physicians (PCPs) and then specialists, and implementing a patient experience of care survey. All 10 PGP demonstration participants have agreed to participate in the PGP Transition Demonstration.

As discussed previously, consistent with section 1899(b)(4) of the Act, to be eligible to participate in the Shared Savings Program, a provider of services or supplier may not also be participating in a demonstration project that involves shared savings, such as the PGP

demonstration. Thus, the PGP sites will not be permitted to participate concurrently in the Shared Savings Program. Since assignment methodologies are similar between the Shared Savings Program and the PGP demonstration, we will provide for unique assignment of beneficiaries by ensuring there is no overlap in participating Medicare-enrolled TINs as mentioned previously.

In the proposed rule, we discussed an appropriate transition in the event that a PGP site decides to apply for participation to the Shared Savings Program. We proposed to give the site the opportunity to complete a condensed application form. The condensed application form would require the applicant to provide the information that is required for the standard Shared Savings Program application but that was not already obtained through its application for or via its participation in the PGP demonstration and, if necessary, to update any information contained in its application for the PGP demonstration that is also required on the standard Shared Savings Program application.

Comment: One commenter noted they thought that several innovative health care systems such as PGP demo sites have indicated that they will forego applying to the Shared Savings Program but would instead ''apply for funding'' through the Innovation Center.

Response: We recognize there are many opportunities for organizations to participate in our programs involving shared savings as well as other Affordable Care Act demonstrations. We are pleased that all 10 of the original PGP demonstration sites have contracted to participate in the PGP Transition Demonstration which implements many of the same policies as the Shared Savings Program.

Final Decision: We are finalizing our proposals without change (§ 425.202).

c. Overlap With the Center for Medicare & Medicaid Innovation (Innovation Center) Shared Savings Models

Section 1899(i) of the Act gives the Secretary the authority under the Shared Savings Program to use other payment models determined to be appropriate, including partial capitation and any additional payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under Medicare. The purpose of the Innovation Center, established in section 1115A of the Act, is to test innovative payment and service delivery models to reduce expenditures under Medicare, Medicaid, and the CHIP, while preserving or enhancing the quality of care furnished to individuals under these programs. Preparations are currently underway to develop this capability. Within the Innovation Center, it may be possible to test different payment models, provide assistance to groups of providers and suppliers that wish to develop into an ACO, or enhance our understanding of different benchmarking methods. As the Innovation Center gains experience with different ACO payment models, we can use proven methods to enhance and improve the Shared Savings Program over time.

The Innovation Center has recently implemented or is exploring several ACO-related initiatives:

- Pioneer ACO Model—announced in a May 17, 2011 Request for Application.
- Accelerated development learning sessions (ADLS)—to provide the executive leadership teams from existing or emerging ACO entities the opportunity to learn about essential ACO functions and ways to build capacity needed to achieve better care, better health, and lower costs through improvement.
- Advance Payment Model—Subsequent to the publication of the proposed rule, the Innovation Center sought comment on providing an advance on the shared savings ACOs are expected to earn as a monthly payment for each preliminarily prospectively assigned Medicare beneficiary.

As discussed previously, section 1899(b)(4) of the Act restricts providers of services and suppliers from participating in both the Shared Savings Program and other Medicare shared savings programs and demonstrations. We intend to coordinate our efforts to ensure that there is no duplication of participation in shared savings programs through provider or supplier participation in both the Shared Savings Program and any Medicare shared savings models tested by the Innovation Center. Similarly, we will also take steps to ensure there is a methodology to avoid duplication of shared savings payments for beneficiaries aligned with providers and suppliers in both the Shared Savings Program and any current or future models tested by the Innovation Center.

Further, we are looking forward to applying lessons learned in the Pioneer ACO Model that can help inform changes to the Shared Savings Program over time.

Comment: Many commenters were supportive of the purpose of the Innovation Center, the concept of the Advance Payment Model, and the Pioneer Model ACO demonstration. Commenters applauded the use of lessons learned in the Pioneer program to inform the Shared Savings Program and noted that the Pioneer model may effectively test innovative models that may be more effective for certain types of providers. Some commenters made specific suggestions for improvement of the Pioneer model.

Response: We appreciate the feedback, and have passed specific suggestions for improvements to the Pioneer ACO Model on to the Innovation Center.

Comment: A number of commenters expressed concerns about the upfront costs to participate and urged CMS to address the need for startup funding in the final rule.

Many commenters were generally supportive of providing advanced payments to ACOs through the Innovation Center. These commenters suggested that advance payments would make program participation more attractive to many ACOs, particularly those comprised of networks of smaller practices, providers that operate on small margins, or hospitals in specific regions of the country. Several commenters suggested that financial support from a program such as the Advance Payment Models alone may be insufficient to allay the very high startup costs for ACOs. Some suggested direct capital support was necessary and suggested alternatives to the Advance Payment Model. Some commenters asked for clarification or offered suggestions on specific aspects of the initiative, such as the structure of the incentive or eligibility criteria.

Many urged CMS to provide upfront capital support to ACOs to defray start-up and operational expenses and to encourage participation, and some suggested that based on PGP data, ACOs may require more than three years to recoup their start up investment. Several commenters concurred with the need for robust health information technology (HIT) in ACOs but stated that acquisition costs create a substantial barrier to physician ACOs. Numerous commenters urged CMS to create additional ways to help finance physicians' acquisition of HIT. Several explained that shared savings alone will not assist practices with upfront costs nor provide assurance that they will recover their initial investments and that, as a result, transitional models are needed. A few commenters noted that providers should not have to divert resources to two similar initiatives (for example, electronic health records incentives and shared savings) with only technical differences. Groups identified by commenters that may be

especially challenged by the upfront costs of ACO formation and operations include: Private primary care practitioners, small to medium sized physician practices, small ACOs, MAPCP demonstration programs, minority physicians and physicians who see minority patients, safety net providers (that is, RHCs, CAHs, FQHCs, community-funded safety net clinics (CSNCs)), rural providers (that is, Method II CAHs, rural PPS hospitals designated as rural referral centers, sole community hospitals or Medicare dependent hospitals), and rural primary care providers. A few commenters suggested that CMS offer special funding or access to capital through grants or no-interest loans for ACOs formed by rural and safety-net providers, or other providers, such as home health or hospice providers, to enhance participation of these groups in the Shared Savings Program. A commenter suggested that CMS offer a rural primary care provider incentive, such as an enhanced FFS payment or other payment methods (for example, partial capitation), for joining a Medicare ACO to help fund the infrastructure requirements of a Medicare ACO, buffer risk, and stimulate further participation.

Some commenters made specific suggestions for offsetting costs to the ACO, for example, a number of comments recommended that the final rule provide an additional financial incentive for the collection and reporting of patient satisfaction data or other quality data.

On the other hand, some commenters noted that many high quality organizations are likely to have already made the capital investments to achieve high quality and efficient care delivery, and are therefore poised to become ACOs.

Response: We recognize that a real commitment to improving care processes for Medicare beneficiaries will require financial investment on the part of the ACO, ACO participants, and ACO providers/suppliers. The Shared Savings Program is designed to provide an incentive for ACOs demonstrating high quality and improved efficiencies. We have passed along comments related to Advance Payment to our colleagues in the Innovation Center.

In this final rule, we have made significant changes to reduce burden on participants and improve the opportunity to share in savings. In section II.F. of this final rule, we note our intent to provide funding for the patient experience of care survey for 2012 and 2013, providing early adopters with additional upfront assistance. In section II.G (shared savings/losses) of this final rule, we describe changes to the financial model that benefit Shared Savings Program participants such as removal of the 25 percent withhold, removal of the net 2 percent requirement so that ACOs may share from first dollar savings once the MSR is overcome, and an increase to the shared savings cap. Additionally, in response to comments, we are reducing the claims run out period from 6 to 3 months, allowing for earlier payment of shared savings. Finally, in section II.C. (Agreement) of this final rule, we discuss lengthening the agreement period for early adopters. Moreover, as noted, the Innovation Center is considering an Advance Payment model for certain ACOs, which would test whether pre-paying a portion of future shared savings could increase participation in the Shared Savings Program.

Finally, we note there are also other public and private options to offset start up costs such as financing arrangements, grants from non-profit and existing government sources, as well as savings from non-Medicare patient populations. Other CMS initiatives, such as the EHR Incentive Program, provide incentives for HIT adoption. Potential participants will want to consider all options available.

Comment: Several commenters suggested that CMS provide technical assistance to certain ACOs such as those comprised of safety net providers, or physician-only ACOs, or to ACOs in general.

Response: In addition to ongoing technical assistance provided for specific program activities, such as quality measures reporting, we will consider ways in which additional assistance can be provided to Shared Savings Program ACOs. We note that the Innovation Center has held several well-received ADLS sessions designed to provide the executive leadership teams from existing or emerging ACO entities the opportunity to learn about essential ACO functions and ways to build capacity needed to achieve better care, better health, and lower costs through improvement. We will also explore other opportunities to assist Shared Savings Program ACOs.

Final Decision: We are finalizing our proposal to exclude Pioneer ACO Model participants from participation in the Shared Savings Program. Additionally, since the Pioneer ACO Model may begin before the Shared Savings Program and will and assign beneficiaries prospectively, we will work with the Innovation Center to ensure no beneficiaries used to determine shared savings are assigned to both (§ 425.114).

C. Establishing the Agreement With the Secretary

1. Options for Start Date of the Performance Year

Section 1899(a)(1) of the Act requires the Shared Savings Program to be established ''not later than January 1, 2012''. This final rule establishes the Shared Savings Program. We will start accepting applications from prospective ACOs shortly after January 1, 2012. For information on the application process, please see our Notice of Intent which will appear shortly after publication of this final rule at *https://www.cms.gov/sharedsavingsprogram/*.

Section 1899(b)(2)(B) of the Act provides that an ''ACO shall enter into an agreement with the Secretary to participate in the [Shared Savings Program] for no less than a 3-year period * * *'' Section 1899(d)(1) of the Act provides that an ACO shall be eligible to receive shared savings payments for each ''year of the agreement period,'' if the ACO has met applicable quality performance standards and achieved the requisite savings. In establishing the requirement for a minimum 3-year agreement period, the statute does not prescribe a particular application period or specify a start date for ACO agreement periods.

In the proposed rule we considered several options for establishing the start date of the agreement period: annual start dates; semiannual start dates; rolling start dates; and delayed start dates. Adopting an annual application period and start date would create cohorts of ACO applicants, which would allow for more streamlined processes related to evaluation of applications, agreement renewals, and performance analysis, evaluation, and monitoring. However, given the short timeframe for implementation of the program and our desire to permit as many qualified ACOs as possible to participate in the first year, we also gave a great deal of consideration to alternative approaches that would provide flexibility to program applicants. For instance, we considered allowing applicants to apply throughout the course of the year as they become ready and we could review and approve applications and begin agreement periods on a rolling basis. We noted however that, if ACO agreements begin more often than once a year, beneficiaries could be assigned to two ACOs for an overlapping period. As discussed in section II.E.3. of this final rule, we proposed that beneficiaries

would be assigned to ACOs based upon where they receive the plurality of their primary care services. Since the physician associated with the plurality of a beneficiary's primary care services could vary from year to year, having multiple start dates could result in a beneficiary being assigned to multiple ACOs for an overlapping period. This scenario would result in confusion for beneficiaries and the potential for duplicate shared savings payments for care provided to a single beneficiary. Additionally, problems with patient assignment may cause unintended consequences for per capita costs, making it difficult to make comparisons of one ACO's performance to another that has a different start date.

After evaluating various options for start dates, we proposed to establish an application process with an annual application period during which a cohort of ACOs would be evaluated for eligibility to participate in the Shared Savings Program. We further proposed that the performance years would be based on the calendar year to be consistent with most CMS payment and quality incentive program cycles. Specifically, we proposed that: (1) ACO applications must be submitted by a deadline established by us; (2) we would review the applications and approve those from eligible organizations prior to the end of the calendar year; (3) the term of the participation agreement (''agreement period'') would begin on the January 1 following approval of an application; and (4) the ACO's performance years under the agreement would begin on January 1 of each year during the agreement period. Given our concern regarding the short time frame for implementing the Shared Savings Program in the first year of the program, we solicited comment on any alternatives to a January 1 start date for the first year of the Shared Savings Program, such as an additional start date of July 1, and allowing the term of the agreement for ACOs with a July 1, 2012 start date to be increased to 3.5 years. Under this example, the first performance ''year'' of the agreement would be defined as 18 months in order that all of the agreement periods would synchronize with ACOs entering the program on January 1, 2013. We proposed that if adopted, this alternative would only be available in the first year of the program and for all subsequent years applications would be reviewed and accepted prior to the beginning of the applicable calendar year and the term of all subsequent agreements would be for 3 years.

Comment: We received several comments that expressed concerns about the feasibility of a January 1, 2012 start date. Commenters were concerned about the ability of potential ACOs to organize, complete, and submit an application in time to be accepted into the first cohort as well as our ability to effectively review applications by January 1, 2012. Comments suggested that only well organized and larger integrated health care systems would be able to meet the January 1, 2012 start date. Alternatively, comments suggested that the January 1 start date would preclude most small and rural health care systems from being able to participate in the Shared Savings Program. The majority of comments requested a delayed start date or offered support for a July 1 start date for the first year of the program. There were also some comments that requested a 1 or 2 year delay in the start date of the program to allow prospective ACOs the opportunity to build their infrastructure. There were a few comments that requested that we accept applications on a ''rolling'' basis, allowing greater flexibility for the first year.

Response: We agree with the comments requesting additional flexibility in the start date of the Shared Savings Program. Therefore, based upon public comment, we will provide for two application periods for the first year of the Shared Savings Program whereby we will accept applications for an April 1, 2012 or July 1, 2012 start date. All ACOs that start in 2012 will have agreement periods that terminate at the end of 2015. We will provide sub-regulatory guidance to ACOs on the deadlines by which applications must be received in order to be considered for each respective start date.

We summarize the application of our final policy as follows:

ACO starts April 1, 2012: First performance year is 21 months, ending on December 31, 2013. Agreement period is 3 performance years, ending on December 31, 2015.

ACO starts July 1, 2012: First performance year is 18 months, ending on December 31, 2013. Agreement period is 3 performance years, ending on December 31, 2015.

Under this final rule, ACOs will begin receiving data immediately upon entry to the program (historical and quarterly aggregate reports along with rolling information on their preliminary prospective assigned beneficiary population as described in section II.D. of this final rule). After completing its first performance year, the ACO will be evaluated on its performance on the ACO quality metrics and a shared savings payment will be calculated. All ACOs will be eligible to receive the PQRS incentive payments for each calendar year in which they fully and completely report the Group Practice Reporting Option (GPRO) measures, regardless of their start date. This will provide ACOs that join the program in April or July 2012 with some working capital in advance of the completion of the first ACO performance year, regardless of their ability to generate shared savings.

We believe this approach fulfills several desirable goals for the program including: (1) Establishment of the program by January 1, 2012; (2) flexibility for newly formed ACOs to apply when ready; (3) a partial year on-ramp for ACOs to gain experience with understanding the assigned population through receipt of data reports and to gain experience in reporting measures using the PQRS GPRO tool before entering into a period of performance assessment; and (4) assurance that no beneficiary will be double-counted for purposes of establishing ACO performance when there is more than one ACO in a geographic region.

Comment: We received several comments requesting that we expand the agreement period. The majority of the comments surrounding the agreement period specifically requested that the agreement period be expanded to 5 years. The general consensus among comments was that a 3-year agreement period is too short and highlights the fact that the significant capital costs and the need to marshal necessary resources (for example, information technology infrastructure and appropriate management and leadership personnel) make success, in terms of savings, difficult in the early years, if not the entire proposed 3 year term. Comments suggested a 3-year agreement period, combined with our proposal to prohibit future participation of underperforming ACOs or participants after the original term of the agreement has lapsed, works against the small and rural markets that do not have the necessary basics in place to the same extent as larger more integrated health care systems. Commenters stated that the proposed 3-year agreement period increases the risk of loss before any chance of reward is available.

Even those few comments that offered support for a 3-year agreement period recommended that ACOs should be able to withdraw from that agreement without penalty due to the challenges associated with realizing savings in a 3-year agreement.

Response: As discussed previously, and based upon the review of public

comments, we will extend the agreement period to include an extended agreement for those ACOs beginning on April 1, 2012 and July 1, 2012. We believe that extending the agreement period allows for those ACOs that are ready to begin their agreement on April 1, 2012 and July 1, 2012 will provide an on-ramp for organizations to gain experience with measures reporting and data evaluation in the early part of the program. As discussed in Section II.G. of this final rule, we are not finalizing our proposal to require a 25 percent withhold of any shared savings realized to offset any future losses or to be forfeited if an ACO fails to complete the terms of its agreement.

Final Decision: As specified in § 425.200, for the first year of the Shared Savings Program (CY 2012), ACOs will be afforded the flexibility to submit to begin participation in the program on April 1 (resulting in an agreement period of 3 performance years with the first performance year of the agreement consisting of 21 months) or July 1 (resulting in an agreement period of 3 years with the first performance year of the agreement consisting of 18 months). During all calendar years of the agreement period, including the partial year associated with both the April 1, 2012 and July 1, 2012 start dates, the eligible providers participating in an ACO that meets the quality performance standard but does not generate shareable savings will qualify for a PQRS incentive payment (as described in sections II.F. of this final rule and § 425.504).

2. Timing and Process for Evaluating Shared Savings

Section 1899(d)(1) of the Act provides that an ACO shall be eligible to receive shared savings payments for each year of the agreement period, if the ACO has met the quality performance standards established under section 1899(b)(3) of the Act and has achieved the required percent of savings below its benchmark. However, the statute is silent with respect to when the shared savings determination should be made. Potential ACOs have indicated that they need timely feedback on their performance in order to develop and implement improvements in care delivery. In developing our proposals, we were attentive to the importance of determining shared savings payments and providing feedback to ACOs on their performance in a timely manner while at the same time not sacrificing the accuracy needed to calculate per capita expenditures.

Our determination of an ACO's eligibility to receive a payment for shared savings will be based upon an analysis of the claims submitted by providers and suppliers for services and supplies furnished to beneficiaries assigned to the ACO. There is an inherent lag between when a service is performed and when a claim is submitted to us for payment. Additionally, there is also a time lag between when the claim is received by us and when the claim is paid.

From the perspective of the utilization and expenditure data that would be needed in order to determine an ACO's eligibility to receive shared savings and to provide performance feedback reports, the longer the claims run-out period, the more complete and accurate the utilization and expenditure data would be for any given year. Higher completion percentages are associated with longer run-out periods and thus would necessitate a longer delay before we could determine whether an ACO is eligible to receive shared savings and provide performance feedback. Conversely, a lower completion percentage would be associated with a shorter run-out period and thus a quicker turnaround for the shared savings determination and for the provision of performance feedback. Based upon historical trends, a 3-month run-out would result in a completion percentage of approximately 98.5 percent for physician services and 98 percent for Part A services. A 6-month run-out of claims data results in a completion percentage of approximately 99.5 percent for physician services and 99 percent for Part A services. Since neither a 3-month nor a 6-month run-out of claims data would offer complete calendar year utilization and expenditure data, we proposed to work with our Office of the Actuary to determine if the calculation of a completion percentage would be warranted. We proposed that if determined necessary, the completion percentage would be applied to ensure that the shared savings determination reflects the full costs of care furnished to assigned beneficiaries during a given calendar year. Thus, we must balance the need to use the most accurate and complete claims data as possible to determine shared savings with the need to provide timely feedback to ACOs participating in the Shared Savings Program. Additionally, regardless of whether we use a 3-month or 6-month claims run-out period, we are concerned that some claims (for example, high cost claims) may be filed after the claims run-out period which would affect the accuracy of the amount of the shared savings payment. We considered and sought comment on ways to address this issue, including applying an adjustment factor determined by CMS actuaries to account for incomplete claims, termination of the ACO's agreement in cases where the ACO has been found to be holding claims back, or attributing claims submitted after the run-out period to the following performance year.

We proposed using a 6-month claims run-out period to calculate the benchmark and per capita expenditures for the performance year. A 6-month claims run-out would allow for a slightly more accurate determination of the per capita expenditures associated with each respective ACO; however, it would also delay the computation of shared savings payments and the provision of feedback to participating ACOs. We also sought comment on whether there are additional considerations that might make a 3-month claims run-out more appropriate.

Comment: Most of the comments received on this proposal supported a 3-month claims run-out period. Several other comments focused on the fact that ACOs will require significant start up investments to provide adequate infrastructure. These comments suggest that the shorter the turnaround period for feedback on both quality metrics and shared savings reconciliation, the more likely that cash flow distortions would not be created and the better the opportunity that ACOs will be able to continue to operate. We received no comments that supported a 6-month claims run-out.

Response: As discussed previously, our initial analysis of this policy focused on balancing the need for timely feedback and the benefits of utilizing the most complete data in calculating both the quality metrics and the shared savings reconciliation. Based upon our review of the proposal and the input of public comments, we feel that the minimal increased accuracy associated with 6 months of claims run-out does not justify the additional delay in the provision of quality metrics feedback and shared savings reconciliation. We agree that ACOs should receive quality metric feedback as soon as possible so they can focus their activities on potential problem areas. Additionally, public comments have made it clear that a 3-month run-out of claims data, especially in the first year of the agreement, would aid in ensuring success for ACOs by allowing ACOs to offset the initial start up costs which would in turn allow the ACOs to remain financially viable. We agree with the comments that the decrease in the accuracy of the actual data between 6-

months of claims run-out and 3-months of claims run-out can be mitigated by the application of a completion percentage and should not delay the delivery of either the feedback on quality metrics or the reconciliation of any shared savings realized.

Final Decision: Based upon our review of the public comments received on the proposed policy, we are finalizing a policy, under § 425.602, § 425.604, and § 425.606 of using 3-months of claims run-out data, with the application of an appropriate completion percentage, to calculate the benchmark and per capita expenditures for the performance year. We will monitor ACO providers and suppliers for any deliberate delay in submission of claims that would result in an unusual increase in the claims incurred during the performance year, but submitted after, the 3 month run-out period immediately following each performance year, and as discussed in section II.H. of this final rule, will consider such deliberate behavior grounds for termination.

3. New Program Standards Established During the Agreement Period

In the proposed rule, we stated that as we continue to work with the stakeholder community and learn what methods and measures work most effectively for the Shared Savings Program, we would likely make changes and improvements to the Shared Savings Program over time. For example, we expect to integrate lessons learned from Innovation Center initiatives to shape and change the Shared Savings Program. Because we expect that these changes may occur on an ongoing basis, the question arises as to whether an ACO that has already committed to an agreement to participate in the Shared Savings Program should be subject to regulatory changes that become effective after the start of its agreement period.

In the proposed rule, we weighed the pros and cons of requiring an ACO to comply with changes in regulations that become effective before the expiration of its agreement period. We recognized that creating an environment in which the continued eligibility of existing program participants is uncertain could be detrimental to the success of the program and could deter program participation. Conversely, the ability to incorporate regulatory changes into the agreements with ACOs would facilitate the administration of the program because all ACOs would be subject to the requirements imposed under the current regulations, rather than different sets of requirements, depending upon what regulations were in effect in the year in which the ACO entered the program. Additionally, requiring ACOs to adhere to certain regulatory changes related to quality measures, program integrity issues, processes for quality management and patient engagement, and patient-centeredness criteria that are up to date with current clinical practice ensures that ACO activities keep pace with changes in clinical practices and developments in evidence-based medicine. We noted that it is not unprecedented for Medicare agreements to include a provision requiring that the agreement is subject to changes in laws and regulations. For example, the contracts with Medicare Advantage organizations contain such a clause. However, these contracts are for a term of 1 year, as opposed to 3 or more years. As a result, there are more frequent opportunities for these organizations to reassess whether they wish to continue to participate in the program in light of changes to the laws and regulations governing the program.

We proposed that ACOs would be subject to future changes in regulation with the exception of all of the following:

- Eligibility requirements concerning the structure and governance of ACOs.
- Calculation of sharing rate.
- Beneficiary assignment.

Thus, for example, ACOs would be subject to changes in regulation related to the quality performance standard. The language of the ACO agreement would be explicit to ensure that ACOs understand the dynamic nature of this part of the program and what specific programmatic changes would be incorporated into the agreement. We further proposed that in those instances where regulatory modifications effectuate changes in the processes associated with an ACO pertaining to design, delivery, quality of care, or planned shared savings distribution the ACO would be required to submit to us for review and approval, as a supplement to their original application, an explanation of how it will address key changes in processes resulting from these modifications. If an ACO failed to effectuate the changes needed to adhere to the regulatory modifications, we proposed that the ACO would be placed on a corrective action plan, and if after being given an opportunity to act upon the corrective action plan, the ACO still failed to come into compliance, it would be terminated from the program. For a more detailed discussion of the process for requiring and implementing a corrective action plan, please refer to the section II.H.5 of this final rule. We proposed that ACO participants would continue to be subject to all requirements applicable to FFS Medicare, such as routine CMS business operations updates and changes in FFS coverage criteria, as they may be amended from time to time.

Comment: The commenters did not support establishing new standards during the agreement period. Many comments suggested that in order to create the certainty required prior to ACOs making investments in population health management infrastructure, CMS should withdraw any proposals that will afford the agency the ability to alter the terms or requirements to participate in the program during an agreement period. Commenters requested that if standards are established during the agreement period, ACOs should be allowed to either voluntarily terminate their agreements without penalty or should be afforded protections against any changes that negatively affect the ACOs' ability to achieve their obligations under the agreement or that substantially alter the financial terms of their agreement. Other commenters specified that in those instances where standards are established during an agreement period, ACOs be afforded the opportunity to develop a real-time understanding of the new standards via a standard comment and response period. Finally, one commenter recommended that any program changes be introduced only at the start of a new agreement period.

Response: To ensure that ACO activities keep pace with the ever evolving developments in clinical practices and evidence-based medicine, it is important to retain the ability to make changes to the Shared Savings Program on an on-going basis. However, based upon our review of the public comments received on this policy, we agree with allowing an ACO the choice of whether to terminate its agreement without penalty when there are regulatory changes to the Shared Savings Program that impact the ability of the ACO to continue to participate. We believe this policy allows the program flexibility to improve over time while also providing a mechanism for ACOs to evaluate how regulatory changes impact their ability to continue participation in the program and to terminate their agreement without penalty if regulatory changes occur that will negatively impact the ACO.

Final Decision: Under § 425.212 we will finalize our proposal that ACOs be held responsible for all regulatory changes in policy, with the exception of: eligibility requirements concerning the structure and governance of ACOs, calculation of sharing rate, and

beneficiary assignment. However, we will modify our proposal to allow ACOs the flexibility to voluntarily terminate their agreement in those instances where regulatory standards are established during the agreement period which the ACO believes will impact the ability of the ACO to continue to participate in the Shared Savings Program.

4. Managing Significant Changes to the ACO During the Agreement Period

Aside from changes that may result from regulatory changes, the ACO itself may also experience significant changes within the course of its agreement period due to a variety of events, including the following:

- Deviations from the structure approved in the ACO's application, such as, if an ACO participant upon which assignment is based drops out of the program; changes in overall governing body composition or leadership; changes in ACO's eligibility to participate in the program, including changes to the key processes pertaining to the design, delivery and quality of care (such as processes for quality management and patient engagement and patient centeredness) as outlined in the ACO's application for acceptance into the program; or changes in planned distribution of shared savings.
- A material change, as defined in the proposed rule [76 FR 19527], in the ACO's provider/supplier composition, including the addition of ACO providers/suppliers.
- Government- or court-ordered ACO reorganization, OIG exclusion of the ACO, an ACO participant, or an ACO provider/supplier for any reason authorized by law; CMS revoking an ACO, ACO participant or ACO provider/supplier's Medicare billing privileges under 42 CFR § 424.535, for noncompliance with billing requirements or other prohibited conduct; or reorganization or conduct restrictions to resolve antitrust concerns.

Whenever an ACO reorganizes its structure, we must determine if the ACO remains eligible to participate in the Shared Savings Program. Under our proposal, we noted that since an ACO is admitted to the program based on the information contained in its application, adding ACO participants during the course of the agreement period may result in the ACO deviating from its approved application and could jeopardize its eligibility to participate in the program. We therefore proposed that the ACO may not add ACO participants during the course of the agreement. In order to maintain flexibility, however, we proposed that the ACO may remove ACO participants (TINs) or add or remove ACO providers/suppliers (NPIs). We requested comment on this proposal and how it might impact small or rural ACOs.

In addition, we proposed that ACOs must notify us at least 30 days prior to any ''significant change,'' which we defined as an event that causes the ACO to be unable to comply with the terms of the participation agreement due to (1) deviation from its approved application, such as a reorganization of the ACO's legal structure or other changes in eligibility; (2) a material change, which was defined in proposed § 425.14 to include ''significant changes'' as well as other changes that may affect ACO eligibility to participate in the program, including changes in governing body composition and the imposition of sanctions or other actions taken against the ACO by an accrediting organization or government organization, or (3) government or court-ordered reorganization as a result of fraud or antitrust concerns. We proposed that, in response to such a notification, we would make one of the following determinations:

- The ACO may continue to operate under the new structure with savings calculations for the performance year based upon the updated list of ACO participants and ACO providers/suppliers.
- The remaining ACO structure qualifies as an ACO but is so different from the initially approved ACO structure that the ACO must start over as a new ACO with a new agreement.
- The remaining ACO structure qualifies as an ACO but is materially different from the initially approved ACO structure because of the inclusion of additional ACO providers/suppliers that the ACO must obtain approval from a reviewing Antitrust Agency before it can continue in the program.
- The remaining ACO structure no longer meets the eligibility criteria for the program, and the ACO would no longer be able to participate in the program, for example, if the ACO's assigned population falls below 5,000 during an performance year as discussed in section II.B. of this final rule.
- CMS and the ACO may mutually decide to terminate the agreement.

Comment: The proposals surrounding the management of significant changes to the ACO during the agreement period were the most commented upon proposals in section II.C. of the proposed rule. All comments received suggested that not being able to add ACO participants during the agreement period runs counter to the idea of encouraging more integrated models and thus greater coordination of care.

Commenters offered a variety of alternatives to this proposal including the following:

- Removal of this proposal altogether.
- Allowing ACOs to add TINs on an monthly, quarterly, or annual basis as long as they notify CMS of the modifications to their structure.
- One commenter recommended a ''slot'' approach in rural areas whereby if a TIN leaves the system the ''slot'' may be filled with another TIN.
- Allowing changes in ACO participants of up to 10 percent annually with additional changes in excess of 10 percent to be negotiated as an amendment to the ACO participation agreement.

Response: Although it is imperative that we ensure that ACOs do not make changes to their approved structure that would affect their eligibility to participate in the program, we agree with those comments suggesting that there must be some mechanism to add ACO participants during an agreement period. Accordingly, we will finalize a policy that affords ACOs greater flexibility to deviate from the structure approved in their application. Specifically, we will modify this proposal such that ACO participants and ACO providers/suppliers may be added and subtracted over the course of the agreement period. ACOs must notify us of any additions/subtractions within 30 days. Additionally, ACOs must notify us within 30 days of any significant changes, defined as an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program. Such a change may cause the ACO to no longer meet the eligibility criteria, for example, losing a large primary care practice could cause the ACOs assigned patient population to fall below 5,000. Furthermore, such changes may necessitate adjustments to the ACO's benchmark, or cause changes to risk scores and preliminary prospective assignment as described in sections II.G and II.E. of this final rule respectively, of this final rule.

Comment: Some commenters also stated that our definitions of significant change and material change were circular.

Response: In this final rule, we have removed the reference to ''material change'' and its accompanying definition. In response to general comments regarding the need to strengthen program requirements, we are finalizing our proposal to require ACOs to notify us within 30 days of any

''significant change,'' which is defined as an event that could cause an ACO to be unable to meet the eligibility or program requirements of the Shared Savings Program. For example, a significant change that affects compliance with eligibility requirements would include losing a large primary care practice that causes the ACO's assigned patient population to fall below 5,000.

Final Decision: Under § 425.214, we are modifying our proposal so that ACO participants and ACO providers/suppliers may be added and subtracted over the course of the agreement period. ACOs must notify us of the change within 30 days of these additions/subtractions of ACO participants or providers/suppliers. Additionally, in the event of ''significant changes'', which is defined as an event that occurs resulting in an ACO being unable to meet the eligibility or program requirements of the Shared Savings Program, the ACO must also notify us within 30 days. Such changes may necessitate, for example, adjustments to the ACO's benchmark, but allow the ACO to continue participating in the Shared Savings Program. Such changes may also cause the ACO to no longer meet eligibility, for example, losing a large primary care practice could cause the ACO assignment to fall below 5,000, and result in termination of the agreement.

5. Coordination With Other Agencies

As mentioned previously, in developing our proposals for the Shared Savings Program, and in response to stakeholder concerns, we worked closely with agencies across the Federal Government to facilitate participation in the Shared Savings Program and to ensure a coordinated and aligned inter- and intra-agency effort in connection with the program. The result of this effort was the release of three documents, concurrently with the Notice of Proposed Rulemaking, including: (1) A joint CMS and DHHS Office of Inspector General (OIG) Notice with Comment Period on Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center addressing proposed waivers of the civil monetary penalties (CMP) law, Federal anti-kickback statute, and the physician self-referral law; (2) an Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations, including tax-exempt hospitals, participating in the Shared Savings Program; (3) a proposed Statement of Antitrust Enforcement Policy Regarding Organizations Participating in the Medicare Shared Savings Program issued by the FTC and DOJ (collectively, the Antitrust Agencies). The comment periods for all of these documents have now closed. Some comments received on this proposed rule were in response to these concurrently released documents, and thus outside the scope of this final rule. We have shared relevant comments with the appropriate agencies.

We have continued working with these agencies while drafting this final rule. As a result a joint CMS and OIG interim final rule with comment period will also be published in the **Federal Register** concurrently with this final rule. The Antitrust Agencies also will publish in the **Federal Register** a final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program.

a. Waivers of CMP, Anti-Kickback, and Physician Self-Referral Laws

Certain arrangements between and among ACOs, ACO participants, other owners, ACO providers/suppliers, and third parties may implicate the CMP law (section 1128A(b)(1) and (2) of the Act), the Federal Anti-kickback statute (section 1128B(b)(1) and (2) of the Act), and/or the physician self-referral prohibition (section 1877 of the Act). Section 1899(f) of the Act authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of the Shared Savings Program. Accordingly, pursuant to section 1899(f) of the Act, CMS and OIG are jointly publishing an interim final rule with comment period describing waivers applicable to ACOs, ACO participants, and ACO providers/suppliers in the Shared Savings Program. The interim final rule with comment period can be found elsewhere in this issue of the **Federal Register**. The waivers described in the interim final rule with comment period will also apply to the Innovation Center's Advance Payment Model demonstration because ACOs participating in that model will also be participating in the Shared Savings Program.

Comments received in response to the April 2011 proposed rule directed toward the joint CMS and DHHS OIG solicitation will be responded to in the interim final rule with comment period. We encourage reader review of the interim final rule.

b. IRS Guidance Relating to Tax-Exempt Organizations Participating in ACOs

Nonprofit hospitals and other health care organizations recognized by the IRS as tax-exempt organizations are likely to participate in the development and operation of ACOs in the Shared Savings Program. Accordingly, the IRS issued Notice 2011–20 soliciting public comment on whether existing guidance relating to the Internal Revenue Code provisions governing tax exempt organizations is sufficient for those tax-exempt organizations planning to participate in the Shared Savings Program through ACOs and, if not, what additional guidance is needed. For additional information, tax-exempt organizations and ACOs should refer to Notice 2011–20 and other applicable IRS guidance available on *www.irs.gov.*

We also received comments relating to the tax treatment of ACOs. Tax issues are within the jurisdiction of IRS, not CMS. Accordingly, those issues are not addressed in this Final Rule but we have shared the relevant comments with IRS.

c. Antitrust Policy Statement

Concurrently with the issuance of the Shared Savings Program proposed rule, the Antitrust Agencies issued a proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (proposed Antitrust Policy Statement). The proposed Antitrust Policy Statement had several features relevant to the Shared Savings Program, including—

- An antitrust ''safety zone.'' The Antitrust Agencies, absent extraordinary circumstances, would not challenge as anticompetitive ACOs that were within the safety zone. The safety zone also included a rural exception for ACOs operating in rural areas.
- For ACOs outside the safety zone, guidance on the types of conduct to avoid that could present competitive concerns.
- A mandatory Antitrust Agency review procedure for ACOs that met certain thresholds. The mandatory review would be triggered if two or more ACO participants that provide a common service (as defined in the proposed Antitrust Policy Statement) to patients from the same Primary Service Area (''PSA'') have a combined share of greater than 50 percent for that service in each ACO participant's PSA.

The proposed Antitrust Policy Statement described the methodology that ACO participants could use to determine whether the ACO was required to obtain an Antitrust Agency review. Some of the data to be used in this methodology are available at *http://www.cms.gov/sharesavingsprogram/*

35_Calculations.asp. The proposed Antitrust Policy Statement applied to collaborations among otherwise independent providers and provider groups, formed after March 23, 2010 (the date on which the Affordable Care Act was enacted) and that have otherwise been approved to participate, or seek to participate, as ACOs in the Shared Savings Program.

The Antitrust Agencies solicited and received comments on the proposed Antitrust Policy Statement. The Antitrust Agencies are releasing concurrently with this final rule a final Antitrust Policy Statement in response to the comments. Nothing in this final rule shall be construed to modify, impair, or supersede the applicability of any of the Federal antitrust laws. For further guidance on antitrust enforcement policy with respect to ACOs, ACOs should review the final Antitrust Policy Statement.

Comment: Numerous commenters appreciated our work with the Antitrust Agencies to facilitate participation in the Shared Savings Program. However, several commenters suggested we provide additional flexibility to potential ACO applicants and modify the scope of the mandatory antitrust review.

Response: The next section of this final rule discusses our proposals, and addresses all comments, relating to the proposed mandatory antitrust review.

d. Coordinating the Shared Savings Program Application With the Antitrust Agencies

We proposed to require that certain ACOs be subject to mandatory review by the Antitrust Agencies before we would approve their participation in the Shared Savings Program. Specifically, we proposed this mandatory review requirement would apply to any newly formed ACO with a PSA share above 50 percent for any common service that two or more ACO participants provide to patients from the same PSA, and that did not qualify for the rural exception articulated in the proposed Antitrust Policy Statement. Those ACOs would be required to submit to us, as part of their Shared Savings Program applications, a letter from the reviewing Antitrust Agency confirming that it had no present intent to challenge or recommend challenging the proposed ACO. Absent such a letter, the proposed ACO would not be eligible to participate in the Shared Savings Program.

In addition, the proposed Antitrust Policy Statement explained that ACOs that are outside the safety zone and below the 50 percent mandatory review threshold frequently may be pro-competitive. The proposed Antitrust Policy Statement identified five types of conduct that an ACO could avoid to reduce significantly the likelihood of an antitrust investigation. An ACO in this category that desired further certainty regarding the application of the antitrust laws to its formation and planned operation also could seek an expedited review from the Antitrust Agencies, similar to the mandatory review described previously, and similarly would not be eligible to participate in the Shared Savings Program if the reviewing Antitrust Agency reviews the ACO and determines that it is likely to challenge or recommend challenging the ACO as anticompetitive. Finally, we proposed that an ACO that falls within the safety zone would not be required to obtain an Antitrust Agency review as a condition of participation.

Additionally, we recognized in the proposed rule there may be instances during the agreement period where there is a material change (as discussed in section II.C.4. of this final rule) in the composition of an ACO. We proposed that when a material change occurred, the ACO must notify us of the change within 30 days and that the ACO must recalculate and report at that time its PSA shares for common services that two or more independent ACO participants provide to patients from the same PSA. We proposed that if any revised PSA share is calculated to be greater than 50 percent, the ACO would be subject to mandatory review or re-review by the Antitrust Agencies. If the ACO failed to obtain a letter from the reviewing Antitrust Agency confirming that it has no present intent to challenge or recommend challenging the ACO, we proposed that the ACO would be terminated from the Shared Savings Program.

We explained in the proposed rule that the purpose of requiring Antitrust Agency confirmation that it had no present intent to challenge or recommend challenging the ACO as a condition of participation is two-fold. First, it would ensure that ACOs participating in the Shared Savings Program would not present competitive problems that could subject them to antitrust challenge that may prevent them from completing the term of their agreement with us. Second, it would maintain competition for the benefit of Medicare beneficiaries by reducing the potential for the creation of ACOs with market power. In this context market power refers to the ability of an ACO to reduce the quality of care furnished to Medicare beneficiaries and/or to raise prices or reduce the quality for commercial health plans and enrollees, thereby potentially increasing providers' incentives to provide care for private enrollees of higher-paying health plans rather than for Medicare beneficiaries. We stated that competition in the marketplace benefits Medicare and the Shared Savings Program because it promotes quality of care for Medicare beneficiaries and protects beneficiary access to care. Furthermore, competition benefits the Shared Savings Program by allowing the opportunity for the formation of two or more ACOs in an area. Competition among ACOs can accelerate advancements in quality and efficiency. All of these benefits to Medicare patients would be reduced or eliminated if we were to allow ACOs to participate in the Shared Savings Program when their formation and participation would create market power.

Comment: A significant number of commenters opposed mandatory review of ACOs, because an ACO is a new business model designed to encourage collaboration and coordination of care while still providing beneficiaries the freedom of choice of providers under FFS Medicare. The commenters made the following points:

- The Social Security Act, as amended by the Affordable Care Act, does not authorize us either to issue regulations governing the application of the antitrust laws or to delegate to the Antitrust Agencies the authority to block participation in the Shared Savings Program by certain ACOs. These commenters cited a recent article suggesting that the proposed mandatory review confers unreviewable authority on the Antitrust Agencies to disqualify entities from participating in the Shared Savings Program and therefore violates the subdelegation doctrine.[1]
- It is bad public policy to change the nature of antitrust enforcement from law enforcement to a regulatory regime by requiring a mandatory review for ACO applicants with PSA shares greater than 50 percent for common services.
- The mandatory review should be modified such that an ACO's actions, not its size, should be monitored, because if an ACO produces savings while maintaining quality and patient centeredness, market share is not an appropriate measure of anticompetitive behavior.
- Require mandatory notice of the PSA shares, but do not require those ACOs with greater than a 50 percent PSA share to obtain a mandatory review.

[1] Richard D. Raskin, Ben J. Keith, & Brenna E. Jenny, ''Delegation Dilemma: Can HHS Required Medicare ACOs to Undergo Pre-Clearance by the Antitrust Agencies?,'' 20 Health L. Rep. 961 (2011).

• The mandatory review imposes substantial costs on every ACO applicant by requiring them to build their PSA calculations, with a larger burden falling on smaller physician or other physician groups that may not have the tools to do so, thus discouraging their participation. Commenters suggested that we calculate each ACO's PSA shares.

• The proposed antitrust review and CMS application review should occur simultaneously given the tight timeframes to get the program up and running.

• The proposed rule and the proposed Antitrust Policy Statement are inconsistent because the proposed rule does not carve out entities formed before March 23, 2010 from the mandatory review (meaning all entities need a review), whereas the proposed Antitrust Policy Statement does not apply to entities formed before that date.

By contrast, numerous commenters supported the mandatory review to ensure the Shared Savings Program does not become a vehicle for ACOs to obtain market power. Several commenters explained that the consolidation of ACO providers/suppliers into ACOs could have a significant impact on the commercial market. One commenter noted it was important for us to consider ''the impact of competition (or the lack thereof) on quality of care and access to care.'' Several commenters suggested that we lower the threshold for mandatory antitrust review to 40 percent to ensure that there are sufficient providers to allow the formation of competing ACOs to serve Medicare beneficiaries. Another commenter suggested that we carefully consider favoring ACO applications from provider groups without market power while we calibrate and refine the Shared Savings Program.

Response: Based on the comments received, we have reconsidered our approach to coordinating with the Antitrust Agencies. We believe that we can achieve the same two objectives identified in the proposed rule using a less burdensome approach that is consistent with antitrust law enforcement norms and does not raise subdelegation concerns.

Accordingly, in this final rule we are adopting an approach that relies on three prongs to maintain competition among ACOs. First, the Antitrust Agencies will offer a voluntary expedited antitrust review to any newly formed ACO (as defined in the final Antitrust Policy Statement) before it is approved to participate in the Shared Savings Program. We strongly encourage newly formed ACOs that may present competitive issues or are uncertain about their legality under the antitrust laws to take advantage of this opportunity to obtain expedited antitrust review before participating in the Shared Savings Program. This voluntary review will enable ACOs to assess whether they are likely to present competitive concerns that could subject them to an antitrust challenge and prevent them from completing the term of their agreement with us. As noted in the final rule, CMS may terminate an ACO's participation in the Shared Savings Program for, among other reasons, violation of the antitrust laws.

Second, we will provide the Antitrust Agencies with aggregate claims data regarding allowable charges and fee-for-service payments, which will assist the Antitrust Agencies in calculating PSA shares for ACOs participating in the Shared Savings Program. We will share these data with the Antitrust Agencies as soon as the data become available. In addition, we will require ACOs formed after March 23, 2010, to agree, as part of their application to participate in the Shared Savings Program, to permit us to share a copy of their application with the Antitrust Agencies. Both the aggregate data and the information contained in these applications will help the Antitrust Agencies to assess and monitor ACOs' effects on competition and take enforcement action, if appropriate. Third, the Antitrust Agencies will rely on their existing enforcement processes for evaluating concerns raised about an ACO's formation or conduct and filing antitrust complaints when appropriate.

Thus, we are not finalizing our proposal to require mandatory antitrust review and the submission of a letter from a reviewing Antitrust Agency confirming that it has no present intent to challenge, or recommend challenging, an ACO formed after March 23, 2010, that does not qualify for the rural exception articulated in the final Antitrust Policy Statement, and that has a PSA share above 50 percent for any common service that two or more ACO participants provide to patients from the same PSA. In other words, we will not condition Shared Savings Program eligibility on whether an ACO has obtained the requisite letter from the Antitrust Agencies. Rather, we will accept such an ACO into the Shared Savings Program regardless of whether it voluntarily obtains a letter from the Antitrust Agencies and regardless of the contents of any letter it may have voluntarily obtained from the Antitrust Agencies, assuming that the ACO meets the other eligibility requirements set forth in this final rule. We emphasize that the acceptance of an ACO into the Shared Savings Program represents no judgment by CMS about the ACO's compliance with the antitrust laws or the ACO's competitive impact in a commercial market. Moreover, we do not believe that allowing anticompetitive ACOs to operate in commercial markets is necessary for the Shared Savings Program to function effectively.

Again, as noted previously, we encourage newly formed ACOs that desire greater antitrust guidance to seek a voluntary expedited review from the Antitrust Agencies before applying to the Shared Savings Program. All participants in the Shared Savings Program will remain subject to the antitrust laws. In addition, as discussed previously, we released in June 2011 some of the information necessary for ACO applicants to identify common services and to help calculate the relevant PSA shares. The final Antirust Policy Statement describes the procedures for obtaining the voluntary expedited antitrust review.

Although we are eliminating the proposed mandatory review requirement, we still intend to coordinate closely with the Antitrust Agencies throughout the application process and the operation of the Shared Savings Program to ensure that the implementation of the program does not have a detrimental impact upon competition. As discussed in the proposed rule, competition among ACOs participating in the Shared Savings Program will foster improvements in quality, innovation, and choice for Medicare FFS beneficiaries. Section 1899(a)(1)(A) of the Act, which states that ''groups of providers and suppliers meeting criteria specified by the Secretary may work together * * * through an accountable care organization,'' authorizes us to specify eligibility criteria for the ACOs that participate in the Shared Savings Program. As discussed previously, we are using that authority to specify that to be eligible to participate in the Shared Savings Program, an ACO newly formed after March 23, 2010 (as defined in the final Antitrust Policy Statement), must agree to permit us to share its Shared Savings Program application with the Antitrust Agencies. We believe this action is necessary to ensure appropriate monitoring of the competitive effects of ACOs that participate in the Shared Savings Program.

Comment: Several comments recommended we monitor an ACO's per capita health care cost, for both Medicare beneficiaries and commercial

patients. For example, several comments explained that the consolidation of providers to form ACOs could have a significant impact on the commercial market. These commenters explained that through the aggregation of market power, ACOs could have an enhanced incentive and ability to obtain shared savings payments by reducing Medicare expenditures to achieve ''savings'' under the Shared Savings Program, while compensating for the reduced Medicare payments by charging higher rates and possibly reducing quality of care in the private market. This cost shifting could have the effect of raising premiums for enrollees of private and employer-based health plans.

Many of these comments strongly urged us to collaborate with the Antitrust Agencies on data collection and analysis to detect any patterns of anti-competitive practices, including consolidation, that could harm Medicare beneficiaries and enrollees in private markets and threaten the viability of the Shared Savings Program. Other commenters urged us to implement requirements for ACOs to report publicly on the cost and price of care.

Some comments urged us to add requirements to the Shared Savings Program to build a more robust monitoring system for costs. In particular, these comments suggested that we could do the following:

- Require that all participating ACOs have a mechanism for assessing performance on private sector per capita costs by the second year of the program.
- Gather data regarding current market shares, market entries and exits, and pricing trends for the ACOs during the agreement period.
- Set expectations for resource stewardship and waste reduction, including public reporting of quality and cost metrics.
- Specify a standardized set of measures for costs, with input from consumers, purchasers, and other stakeholders.
- Hold ACOs in the Shared Savings Program to a maximum threshold of price increase with their commercial market clients.
- Move to requiring ACOs to take part in all-payer claims databases (APCD) for added transparency.

Response: We agree with commenters that suggested we provide the Antitrust Agencies the data and information to help identify potentially anticompetitive conduct, including consolidation, which could be related to implementation of the Shared Savings Program. Accordingly, we will provide the Antitrust Agencies aggregate claims data regarding allowable charges and fee-for-service payments for ACOs participating in the Shared Savings Program. In addition, we will share copies of applications submitted by ACOs formed after March 23, 2010, with the Antitrust Agencies.

In addition, we have requested that the Antitrust Agencies conduct a study examining how ACOs participating in the Shared Savings Program have affected the quality and price of health care in private markets. We anticipate using the results of this study to evaluate whether we should, in the future, expand our eligibility criteria so that we consider competition concerns more explicitly in the Shared Savings Program application review process.

Comment: Commenters stated that the proposed Antitrust Policy Statement does not mention a process for re-review of the ACO by the Antitrust Agencies for material changes in the ACO's composition. Commenters also stated that the proposed rule's language is circular about the conditions that trigger a ''material'' or ''significant'' change in composition, thus requiring a re-review by the Antitrust Agencies.

Response: As discussed previously, we will no longer require an Antitrust Agency review, such that the commenters' concerns about re-review based on antitrust issues are moot.

Comment: Several commenters suggested that the Shared Savings Program will lead to increased hospital employment of physicians or it will lead to hospital purchases of physician practices, because start-up costs are so great only large entities will be able to afford to participate. As a result, there will be no competition and prices will increase in the commercial sector. Other commenters suggested that hospitals will employ specialist physicians so that they can have patient referrals to related facilities, regardless of price and quality.

Other commenters indicated that hospital employment of physicians will exacerbate the inefficiency problem of physicians being paid a higher rate for performing the same procedures in certain settings. As a result, hospitals will use any market power they have to form hospital-based provider departments and obtain higher rates, through their continued fee-for-service payments, for the same services that could be provided in a less-expensive setting. These comments suggested we adopt policies to safeguard against these practices.

Response: As we discussed in the proposed rule, we do not believe that mergers and acquisitions by ACO providers and suppliers are the only way for an entity to become an ACO. The statute permits ACO participants that form an ACO to use a variety of collaborative organizational structures, including collaborations short of merger. Indeed, we are also finalizing our proposal that entities that on their own are not eligible to form an ACO can participate in the Shared Savings Program by forming joint ventures with eligible entities. We reject the proposition that an entity under single control, that is an entity formed through a merger, would be more likely to achieve the three-part aim. Moreover, the increased flexibility regarding governing body composition and the leadership and management of an ACO that we are adopting in this final rule demonstrates our belief that different types of entities can be successful in this program.

Comment: Multiple comments discussed the competitive aspects of ACO membership. For example, one commenter suggested that if an urban ACO wants to partner with providers in rural communities, it should be required to allow all providers in the rural community to participate in the ACO if they so choose. Other commenters suggested that an ACO should not be able to use its market power to require smaller providers or suppliers to participate in the ACO (or to prohibit them from participating in the Shared Savings Program as part of a competing ACO) and that we should coordinate with the FTC and DOJ to thwart anti-competitive behavior in the formation of ACOs.

Some commenters requested that we monitor whether ACOs are using information technology requirements to prevent various allied health professionals from participating in an ACO.

Response: We acknowledge the commenters' concerns and remind them that the antitrust laws will continue to apply to the operations and conduct of all ACOs participating in the Shared Savings Program. In other words, if an entity believes that an ACO is engaging in anticompetitive conduct, it can pursue an appropriate private action or bring the conduct to the attention of the Antitrust Agencies.

Final Decision: In sum, we are modifying our proposal. We believe that the voluntary expedited review approach discussed previously, coupled with the Antitrust Agencies' traditional law enforcement authority and our collaborative efforts to share data and information with the Antitrust Agencies, will allow ACOs a reasonable opportunity to obtain guidance

regarding their antitrust risk in an expedited fashion, while also providing appropriate safeguards so that potential or actual anticompetitive harm can be identified and remedied. We are finalizing these policies at § 425.202. However, we will continue to review these policies and adjust them accordingly as we gain more experience with the Shared Savings Program.

D. Provision of Aggregate and Beneficiary Identifiable Data

1. Data Sharing

Under section 1899(b)(2)(A) of the Act an ACO must ''be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.'' Further, in order to be eligible to participate in the Shared Savings Program, section 1899(b)(2)(G) of the Act states an ''ACO shall define processes to * * * report on quality and cost measures, and coordinate care * * *.'' Section 1899 of the Act does not address what data, if any, we should make available to ACOs on their assigned beneficiary populations to support them in evaluating the performance of ACO participants and ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health. In agreeing to become accountable for a group of Medicare beneficiaries, and as a condition of participation in the Shared Savings Program, we expect that ACOs will have, or are working towards having, processes in place to independently identify and produce the data they believe are necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care, and produce efficiencies in utilization of services. Moreover, this ability to self-manage is a critical skill for each ACO to develop, leading to an understanding of the unique patient population that it serves.

However, as we discussed in the proposed rule, although an ACO typically should have, or is moving towards having complete information for the services it provides to its assigned beneficiaries, we also recognize that the ACO may not have access to complete information about all of the services that are provided to its assigned beneficiaries by providers outside the ACO—information that would be key to its coordinating care for its beneficiary population. Therefore, we proposed to generate aggregate data reports, to provide limited identifying information about beneficiaries whose information serves as the basis for the aggregate reports (and who are preliminarily prospectively assigned), and to share beneficiary identifiable claims data with the ACO unless the beneficiary chooses to decline to share their data. As we stated in the proposed rule, we believe that access to this information would provide ACOs with a more complete picture about the care their assigned beneficiaries receive both within and outside the ACO. It would also enable the ACOs to ascertain their ACO participants and ACO providers'/suppliers' patterns of care, and could be used to assess their performance relative to their prior years' performance.

As noted in the proposed rule, the disclosure of this information in accordance with applicable privacy and security requirements would enable an ACO to be better able to identify how its ACO participants and ACO providers/suppliers measure up to benchmarks and targets, how they perform in relation to peers internally, and to identify and develop a plan for addressing the specific health needs of its assigned beneficiary population.

2. Sharing Aggregate Data

In the proposed rule, we discussed supplementing the information ACOs will be gathering as part of their internal processes for monitoring and improving care furnished to its assigned beneficiary population with aggregated (de-identified) data on beneficiary use of health care services.

We proposed to provide aggregate data reports at the start of the agreement period that would be based on data for those beneficiaries historically assigned (hereafter referred to as preliminary prospectively assigned beneficiaries), and included in the calculation of the ACO's benchmark. These reports would include, when available, aggregated metrics on the beneficiary population and beneficiary utilization data at the start of the agreement period, based on the historical data used to calculate the benchmark. We further proposed to include these data in conjunction with the yearly financial and quality performance reports. Additionally, we proposed to provide quarterly aggregate data reports to ACOs based upon the most recent 12 months of data from potentially assigned beneficiaries. We requested comments on these proposals. For a comprehensive review of our proposals and rationale, see section II.C.4. of the proposed rule (76 FR 19555).

Comment: The comments received were supportive of the proposal to provide aggregate data to ACOs but suggested that this data would not be useful unless it was delivered in a timely manner. Recommendations included providing the aggregate data set prior to the submission of an application, quarterly, immediately following the reporting period, or in real time. A few commenters expressed concerns that aggregate reports based upon a historical population may not provide the ACO with sufficient information to make appropriate changes for its future fee-for-service population.

Response: Although we intend to provide these aggregate data reports in a timely manner, it will not be possible to provide these reports to ACOs in ''real time.'' The aggregate reports would be derived from provider and supplier claims data. Claims data are only available after they have been submitted and processed. As such, there is an inherent delay between when a service is performed and when a claim is processed. This process delay is in addition to the time it takes to prepare this claims level data to an aggregate level data set. Both of these factors make it impossible to provide aggregate data reports to ACOs in ''real time.''

It is also not possible to provide aggregate data reports prior to the submission and approval of an ACO application and the ACO signing its participation agreement. The aggregate data report is based upon the ACO application itself and the TINs and NPIs that enter into an agreement with the ACO. Until we have received and reviewed the applications, determined the eligibility of the ACO participants and ACO providers/suppliers to participate, and received a signed DUA from the ACO, we cannot begin to construct the aggregate data reports. Finally, in response to those who expressed concern about the utility of historic data, we note that we proposed to supply the aggregate data report historically for the benchmark, quarterly and in conjunction with the yearly financial and quality performance reports, the provision of this data in subsequent years of the agreement period is already a component of our proposed policy.

Additionally, our experience with the PGP demonstration and modeling of our proposed methodology for identifying beneficiaries associated with the ACO suggests that a high percentage of patients who chose ACO participants and ACO providers/suppliers in the benchmark period will continue to receive care from these ACO participants and ACO providers/suppliers. We believe knowing

individuals who would have been assigned in the past will help the ACO participants identify the kinds of interventions that are likely to improve care for their fee-for-service population going forward.

Comment: Several commenters were concerned about the delivery, format, and content of the aggregate data report. Several commenters questioned the ability of CMS to deliver accurate, relevant, and comprehensive data to ACOs and suggested that CMS outline a detailed plan to improve its data delivery system. Commenters felt that the data should be standardized by CMS as aggregate data would be too complex for many organizations to analyze. Commenters also suggested that the aggregate data reports must include: Links to the beneficiary identifiable data and health quality indicators, comparative regional and national claims data, and separate aggregate data on patients that have chosen to ''opt-out of the shared savings program.'' A few comments suggested that we provide customized reports to each ACO. Finally, one commenter suggested that CMS should also supply aggregate savings/losses reports to ACOs quarterly.

Response: We proposed to deliver aggregate data reports to ACOs at the start of the agreement period, quarterly, and in conjunction with the annual quality and financial reports. These data extractions would be standardized reports for all ACOs. It would not be administratively feasible to offer customized reports for each ACO. We expect that ACOs would be able to incorporate the aggregated data reports into their own data processing systems for use in developing population health management capabilities. By its nature, aggregate data cannot be linked to individual beneficiary identifiable data as the purpose of the aggregate data is to offer a broad view of the overall population of assigned beneficiaries and potential areas for improvement. Additionally, the aggregate data will not be linked to specific quality indicators as this is not the purpose of providing the standardized aggregate data reports. The ability to receive lists of beneficiaries whose data were used to compile the aggregate data reports and monthly beneficiary identifiable claims data, as discussed later in this final rule, in conjunction with the aggregate data reports, will afford ACOs the opportunity to use the lessons learned from the aggregate data reports to implement delivery system reforms appropriate for their own beneficiary populations. While we did not propose to offer regional or national aggregate data reports or include a report on beneficiaries that have declined to share their protected health information (PHI), we think these suggestions merit consideration and we will keep them in mind during future rulemaking cycles. For now, aggregate data reports will be provided on the assigned beneficiary population, including beneficiaries who may have declined to share their PHI data.

Finally, due to the inherent delay in receiving and processing claims level data, it would not be feasible or accurate to supply shared savings/loss reports to ACOs quarterly. However, the quarterly reports will include information on per capita expenditures for assigned beneficiaries that ACOs can use to monitor and improve their performance.

Final Decision: We will finalize without change our proposals related to sharing of aggregate data (see part 425 subpart H in regulatory text of this final rule).

3. Identification of Historically Assigned Beneficiaries

Based on feedback from the PGP demonstration, the RFI comments on the Shared Savings Program, and the Shared Savings Program Open Door Forums, we proposed to make certain limited beneficiary identifiable information available to ACOs at the beginning of the first performance year. We believed ACOs would benefit from understanding which of their FFS beneficiaries were used to generate the aggregated data reports. Accordingly, we proposed to disclose the name, date of birth (DOB), sex and Health Insurance Claim Number (HICN) of the preliminary prospective assigned beneficiary population. We believed that knowing these data elements would be useful to the ACO in two ways: First, the ACO participants and ACO providers/suppliers could use the information to identify the preliminary prospective assigned beneficiaries, review their records, and identify care processes that may need to change. Second, experience with the PGP demonstration has suggested that a high percentage of preliminary prospective assigned beneficiaries will continue to receive care from the ACO participants and ACO providers/suppliers.

We recognized that there are a number of issues and sensitivities surrounding the disclosure of individually-identifiable (patient-specific) health information, and noted that a number of laws place constraints on the sharing of individually identifiable health information. We analyzed these issues and legal constraints and concluded that the proposed disclosure of the four identifiers would be permitted under the applicable laws and address the issues raised, subject to the conditions described in detail in the proposed rule (76 FR 19555), and we sought comment on this proposal.

Comment: Although the majority of comments supported our proposal to supply ACOs with the name, DOB, sex and HICN of the preliminary prospective assigned beneficiary population, we did receive a few comments that objected to this proposal. Of those comments that disagreed with our proposal, the concerns were related to the confusion that could result for ACO participants and ACO providers/suppliers related to the provision of data on the preliminary prospective assigned beneficiaries who may not choose to see ACO participants or ACO providers/suppliers going forward, the potential for ACOs to use the proposed data elements to avoid at-risk and/or high cost beneficiaries, and the legality of disclosing this type of data. Others suggested the four data points be expanded to include other beneficiary identifiable information.

Response: We proposed providing limited beneficiary identifiable information to ACOs at the start of the agreement period in order to assist the ACO in conducting population-based activities related to improving health or reducing costs, protocol development, case management and care coordination. We believed that the ACO could use the information to identify the preliminary prospective assigned beneficiaries, review their records, and identify care processes within its organization that may need to change. Since a high percentage of beneficiaries who choose ACO participants and ACO providers/suppliers in the benchmark period will continue to receive care from these ACO participants and ACO providers/suppliers, we do not believe this data set will generate any confusion for ACOs. As we outlined in the proposed rule, we believe the agency has legal authority to provide this data to ACOs. As also discussed in the proposed rule, we believe these particular data elements will be useful to the ACO for two reasons: (1) The ACO participants and ACO providers/suppliers could use the information to identify the preliminary prospectively assigned beneficiaries, review their records, and identify care processes that may need to change, and (2) experience with the PGP demonstration has suggested that a high percentage of preliminary prospective assigned beneficiaries will continue to receive care from the ACO participants and ACO providers/suppliers. We

believe that the proposed four data points will be sufficient to aid ACOs in focusing their initial care redesign efforts going forward. We also believe these four data points are the minimum data necessary for providers to begin the process of developing care plans in an effort to provide better care for individuals and better health for populations. As described in section II.D.4 of this final rule, the ACO would have the additional opportunity to request claims data for these individuals after having given these beneficiaries the opportunity to decline such data sharing. Finally, we agree with the comment that while providing such information may be a benefit to both the beneficiary and the ACO, concerns remain that ACOs could use it to avoid at-risk beneficiaries or to stint on care. For this reason we have included in section II.H. of this final rule a detailed discussion of the safeguards and sanctions that have been incorporated into the program to guard against avoidance of at-risk beneficiaries.

Comment: Several comments suggested that we provide the limited beneficiary identifiable data set in advance of ACOs signing agreements.

Response: The limited beneficiary identifiable data set is constructed based upon the content of the ACO's application, including the associated TINs that have been verified as part of the application process. The data would be comprised of information regarding the beneficiaries who would have met the criteria for assignment to the ACO during the benchmark period. Without a verified list of eligible TINs that will be associated with the ACO, we cannot construct this data set. Additionally, as discussed later in this final rule, we will require ACOs to enter into a Data Use Agreement (DUA) prior to receipt of any beneficiary identifiable claims data, and this agreement can only be executed after an applicant has been approved to participate in the Shared Savings Program as an ACO.

Under HIPAA and the required business associate agreements, the ACO and its participants will not be able to use or disclose any individually identifiable health information it receives from us in a manner in which a HIPAA covered entity would be barred from doing. Furthermore, under the DUA, the ACO would be prohibited from sharing the Medicare claims data that we provide through the Shared Savings Program with anyone outside the ACO that has not co-signed the DUA as a contractor to the ACO. In addition, ACOs must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the ACO program's statutory and regulatory requirements. Compliance with the DUA will be a condition of the ACO's participation in the Shared Savings Program—non-compliance with this requirement would result in the ACO no longer being eligible to receive data, and could lead to termination from the Shared Savings Program or additional sanctions and penalties available under the law.

For these reasons, we cannot disclose beneficiary identifiable information to an ACO until such time as any necessary Business Associate Agreements (BAAs) between an ACO and its ACO participants and ACO providers/suppliers are established in accordance with HIPAA and there is a signed DUA in place with us.

Comment: Several comments requested that at the start of the agreement period, we provide more detailed and robust beneficiary identifiable data than the four data points identified and that we update and provide to ACOs the list of the potentially assigned beneficiary population monthly or quarterly.

Response: Although we understand that ACOs would prefer to have more detailed beneficiary identifiable data at the start of the agreement period, in the proposed rule (76 FR 19555) we described the minimum necessary data elements we believed were essential to accomplish the health care operations described in the NPRM. As discussed in response to a previous comment, we believe that the proposed four data points will be sufficient to aid ACOs in focusing their care redesign efforts initially. As noted in section II.D.4. of this final rule, however, the ACO will have the opportunity to request additional claims data for these beneficiaries once the ACO has given them the opportunity to decline data sharing.

As described in section II.E. of this final rule, we are modifying our proposed assignment methodology to provide ACOs preliminary prospective assignment of beneficiaries with retrospective reconciliation based on actual beneficiary utilization. We agree with commenters that providing quarterly aggregate reports on the preliminarily prospective assigned population would assist ACOs in conducting population-based activities relating to improving health or reducing costs, protocol development, case management and care coordination. Therefore, we will be providing ACOs with quarterly listings of preliminarily prospective assigned beneficiary names, DOB, sex, and HCINs that were to generate each quarterly aggregate data report. We believe that the provision of the quarterly aggregate reports and the limited identifiable information on beneficiaries used to generate the reports, combined with the opportunity to request monthly beneficiary identifiable claims data as discussed later in this final rule, and our modification to allow ACOs to request claims data of beneficiaries that appear on these reports, will provide sufficient information for treatment and health care operations activities with the Medicare FFS population for which it is accountable.

Final Decision: We are finalizing our proposal to provide the ACO with a list of beneficiary names, dates of birth, sex, and HICN derived from the beneficiaries whose data was used to generate the preliminary prospective aggregate reports (Subsection H). We are modifying our proposal to provide similar information in conjunction with each quarterly aggregated data report, based upon the most recent 12 months of data, consistent with the time frame listed in the proposed rule.

4. Sharing Beneficiary Identifiable Claims Data

While the availability of aggregate beneficiary information and the identification of the beneficiaries used to determine the benchmark will assist ACOs in the overall redesign of care processes and coordination of care for their assigned beneficiary populations, we believe that more complete beneficiary-identifiable information would enable practitioners in an ACO to better coordinate and target care strategies towards the individual beneficiaries who may ultimately be assigned to them. There are recognized limits to our data, however, and to our ability to disclose it.

After consideration of the legal limitations and policy considerations that would be applicable to disclosure of these data, which are discussed in detail in the proposed rule (76 FR 19557 through 19559), we proposed to give the ACO the opportunity to request certain beneficiary identifiable claims data on a monthly basis, in compliance with applicable laws. We proposed to limit the available claims to those of beneficiaries who received a primary care service from a primary care physician participating in the ACO during the performance year, and who have been given the opportunity to decline to have their claims data shared with the ACO but have declined to do so. Furthermore, we proposed that beneficiary information that is subject to the regulations governing the confidentiality of alcohol and drug

abuse patient records (42 CFR Part 2) would only be made available if the beneficiary provided his or her prior written consent. Finally, we proposed to limit the content of the claims data to the minimum data necessary for the ACO to effectively coordinate care of its patient population.

As a condition of receiving the data, the ACO would be required to submit a formal data request, either at the time of application or later in the agreement period, and explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population.

Additionally, we proposed to require ACOs to enter into a DUA prior to receipt of any beneficiary-identifiable claims data. Under the DUA, the ACO would be prohibited from sharing the Medicare claims data that we provide through the Shared Savings Program with anyone outside the ACO. In addition, we proposed to require in the DUA that the ACO agree not to use or disclose the claims data, obtained under the DUA, in a manner in which a HIPAA covered entity could not without violating the HIPAA Privacy Rule. We proposed to make compliance with the DUA a condition of the ACO's participation in the Shared Savings Program—non-compliance with this requirement would result in the ACO no longer being eligible to receive data, and could lead to its termination from the Shared Savings Program or additional sanctions and penalties available under the law. ACOs would be required to certify to their willingness to comply with the terms of the DUA in their application to participate in the program or at the time they request the claims data, we solicited comments on our analysis and proposals described previously. For a complete discussion of our analysis of our legal authority to disclose beneficiary-identifiable parts A, B, and D claims data to ACOs (see 76 FR 19556 through 19559).

Comment: The majority of comments supported the provision regarding beneficiary-identifiable data. However, some expressed concern about the ability of CMS to provide timely data to ACOs. The majority of comments supported the provision of this data on a monthly basis but some comments requested a more streamlined approach that would enable the provision of this data ''real time'' or weekly.

One commenter believed that claim-based data simply cannot be timely, stating that by the time a claim for a service is submitted, processed and adjudicated, and compiled and extracted, significant time will have elapsed. Additionally, the commenter also contended that by the time the monthly transfer is received and properly ''loaded'' on an ACO's system, and analyzed by the ACO's or their consultant's staff, several more months will have elapsed, rendering the data less than useful. Another commenter suggested these data would be useful on a quarterly basis.

Response: Although we understand that ACOs would like to obtain data on a real time, or nearly real time basis, as we explained in the proposed rule, there is an inherent lag between when a service is performed and when the service is submitted for payment, for this reason it is not feasible to provide data in real time. As noted previously, however, we expect that ACOs will have, or will be working towards having, processes in place to independently identify and produce the data they believe are necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care, and produce efficiencies in utilization of services. A robust health information exchange infrastructure and improving communication among ACO participants and the ACO's neighboring health care providers could assist in accessing data that is closer to ''real time''.

In keeping with the ''minimum necessary'' provisions of the HIPAA Privacy Rule, ACOs are expected only to request data from us that will be useful to them for conducting the kinds of activities that are described in the proposed rule. ACOs may request data as frequently as each month but are not required to submit a request monthly. ACOs may submit requests less frequently if monthly reports are not necessary to suit their needs.

Comment: Several comments were concerned about the ability of ACOs to convert a large volume of claims data into actionable information. Some requested that CMS standardize the monthly information in a way that is actionable for the ACO.

Response: We agree that not all ACOs may have the capability, desire, or need to handle large volumes of claims data in a way that will complement the ACO's activities to improve care processes. For that reason, we are not requiring all ACOs to submit DUAs or request monthly beneficiary identifiable claims data, as noted previously. Accordingly, as described previously, before receiving any data, the ACO will be required to explain how it intends to use these data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population.

Comment: A few comments requested that the data elements contained in the monthly beneficiary identifiable data be expanded. Commenters additionally suggested that the data elements should include detailed information on all services received by beneficiaries who have been treated by an ACO participant. One comment specifically requested that the claims data include both the NPI and TIN so they can drill their quality and cost containment efforts down to the individual provider level while another comment specifically requested that for suppliers, such as laboratories, the minimum necessary data set must include the Place of Service (POS) code as the supplier ID serves no real purpose for laboratories.

Response: In the proposed rule, we stated that we believed the minimum necessary Parts A and B data elements would include data elements such as: Procedure code, diagnosis code, beneficiary ID, date of birth, gender, and, if applicable, date of death, claim ID, the form and thru dates of service, the provider or supplier type, and the claim payment type. (76 FR 19558). Similarly, we stated that the minimum necessary Part D data elements could include data elements such as: Beneficiary ID, prescriber ID, drug service date, drug product service ID, and indication if the drug is on the formulary. (76 FR 19559). We would like to clarify that these lists of data elements were provided in order to offer examples of the types of data elements that might be the minimum data necessary to permit an ACO to undertake evaluation of the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities with and on behalf of the ACO participants and ACO providers/suppliers, and conduct population-based activities relating to improved health for Medicare beneficiaries who have a primary care visit with a primary care physician used to assign patients to the ACO during a performance year. We did not, however, intend that these data elements would be the only data elements that an ACO could request. Rather, we intended that an ACO could request additional data elements provided it could demonstrate how the additional requested information would

be necessary to performing the functions and activities of the ACO, such that they would be the minimum necessary data for these purposes. Accordingly, in this final rule, we are clarifying that the minimum necessary data elements may include, but are not limited to, the list of Parts A and B data elements and the list of Part D data elements that were specifically included in the proposed rule.

Furthermore, we agree with the request to include the provider's identity, such as through the NPI or TIN. One of the important functions of the ACO is to coordinate care, and without the provider's identity, the ACO would not able to make full use of the claims data to determine which other providers it will need to work with in order to better coordinate the beneficiary's care. For the same reasons, the POS code will be useful. We do agree that in order to effectively evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities, and conduct population-based activities to improve the health of its assigned beneficiary population the minimum necessary data set should be expanded to include TIN, NPI, and POS codes.

Comment: Several commenters requested that beneficiary identifiable data be supplied to ACOs 6 months prior to their initial agreement start date while other comments did not specify a specific timeframe but generally requested that beneficiary identifiable data be provided to ACOs in advance of signing their agreements.

Response: Similar to the response provided previously related to the provision of the four beneficiary identifiable data points associated with the aggregate data reports, the legal bases for the disclosure of beneficiary-identifiable information would not be applicable prior to the start of the ACO's participation in the Shared Savings Program.

Comment: Several comments requested that we make Medicare claims data available to Regional Health Improvement Collaboratives as soon as possible so that they can help providers in their community identify successful strategies for forming ACOs and also develop other innovative payment and delivery reforms that the Innovation Center can support.

Response: This comment is outside the scope of this rule. In the proposed rule, we proposed to share beneficiary-identifiable claims data with the ACOs under the terms specified. We did not propose to make these data available to other entities. However, we note that under section 10332 of the Affordable Care Act certain qualified entities, which may include existing community collaboratives, that meet certain requirements for performance measurement and reporting can access beneficiary identifiable claims data for the purposes of evaluating the performance of providers and suppliers on measures of quality, efficiency, effectiveness and resource use.

Comment: One comment recommended that ACOs should be required to assure that health data is bi-directional with State health agency registries. This bi-directional sharing of data is an important resource to draw on the expertise of governmental public health in using data to identify high risk populations. State health agencies can provide improvements in individual and population care, resulting in better health and reduced expenditures.

Response: We recognize the importance of encouraging health information exchange with State health agency registries. Two of the objectives of our Medicare EHR Incentive Program for eligible professionals are related to sharing information with State health agencies, such as immunization data and syndromic surveillance data. More information about the Medicare EHR Incentive Program is available at *https://www.cms.gov/ehrincentiveprograms/30_Meaningful_Use.asp.* As discussed in section II.F. of this final rule, we have adopted a quality measure requiring ACOs to report the percentage of primary care providers who successfully qualify for an EHR Incentive Program payment.

We anticipate that ACOs will participate in active health information exchange with their State health agencies as appropriate; however, we decline to require ACOs to send information to their State health agencies as a condition of participation in the Shared Savings Program. We are finalizing our proposal to share beneficiary identifiable data with ACOs that are qualified to participate in the program.

Comment: Several commenters were concerned that the integrated design of ACOs could result in DUA and privacy law violations without appropriate monitoring and safeguards in place, and would request that CMS be more prescriptive in those policies addressing its sharing of data, the ACOs sharing of data internally, and the ACO's suppression of inappropriate data flowing to sources (that is adolescent/minor data to a parent/guardian, beneficiary data to an ex-spouse, etc.).

Response: As discussed previously, we believe we have the legal authority to share beneficiary identifiable claims data under the conditions specified. While not required to do so under the applicable laws, we have also elected to bar redisclosure of any CMS claims data that are received by an ACO through the Shared Savings Program. Furthermore, the recipients of CMS claims data under this program are either HIPAA covered entities or business associates of HIPAA covered entities. The HIPAA Privacy and Security rules will provide added protections (and enforcement mechanisms) outside of the ACO program requirements. Additionally, we have proposed, and are finalizing robust monitoring protocols (described in section II.H. of this final rule) that will protect beneficiary privacy interests and penalize ACOs that misuse data.

Comment: A comment stated that CMS must assure that all ACO participants have equal access to beneficiary identifiable data. Another commenter recommended that pharmacists specifically be allowed to be active partners in data sharing.

Response: We believe it is in the best interest of all ACO participants to have a voice in the decision making and function of the ACO. As such, we have proposed that ACO participants (defined as any Medicare enrolled provider or supplier, including pharmacists) have a mechanism of shared governance. Shared governance ensures all ACO participants have the ability to jointly make decisions on how best to use and disseminate information derived from beneficiary identifiable claims in accordance with all applicable laws for purposes of the health care operations of the ACO participants, and/or effectively treating the assigned patient population of the ACO.

Comment: Several comments expressed concerns regarding how the data for those patients that are ultimately not assigned to the ACO will be handled. One comment specifically requests that no beneficiary identifiable data be shared with any program until after the Medicare Advantage open season has concluded as this would ensure that a Medicare beneficiary has the option of electing a different health care delivery method without having their personal information shared with an organization through which they are not receiving health services.

Response: We recognize that some beneficiaries will not continue to see the ACO participants because they may move or change providers. Some beneficiaries may change providers because they have enrolled in a Medicare Advantage plan that does not

include their existing provider. When beneficiaries stop receiving care from ACO participants, for whatever reason, the ACO no longer needs to receive claims data for these beneficiaries because the ACO would no longer be responsible for coordinating their care. Accordingly, consistent with § 425.704(b), ACOs should not continue to request claims data from us for beneficiaries that the ACO knows are no longer being treated by ACO participants.

We are finalizing our proposal to share these data with the ACO once the beneficiary has been notified and has not declined to have their data shared. We will also monitor the ACO's compliance with the terms of the DUA.

Comment: Several commenters recommended that we specify in the regulation that an ACO may transmit data to a vendor or designate a vendor to receive data from CMS on their behalf, and that this vendor may use this data in a manner that complies with HIPAA and their business associate agreements.

Response: In the proposed rule, we discussed the ability under HIPAA for covered entities to share beneficiary identifiable data with business associates. We believe based on its work on behalf of covered entity ACO participants and ACO providers/suppliers in conducting quality assessment and improvement activities, a vendor could qualify as a business associate or subcontractor of a business associate. Therefore, we believe an ACO may allow a vendor to receive claims information on its behalf, but it must assume responsibility for that vendor's use and disclosures of the data.

Comment: One comment suggested that the provision of beneficiary identifiable data on a monthly basis could undermine the movement to EHRs if ACOs instead invest in free-standing programs to analyze claims data. Other comments state that the ability to facilitate health information exchange among affiliated and unaffiliated providers through the use of both EHR and HIT interoperability standards is an important ingredient to the success of ACOs.

Response: We disagree that the movement toward adopting EHRs will be somehow undermined by our provision of beneficiary identifiable claims data to the ACOs. As we have explained, the beneficiary identifiable claims data that will be furnished by us, although useful, is not ''real time'' and is not expected to supplant the expectation that ACOs are growing in their capability for internal analysis of data to improve quality as well as improving coordination of care by better communication between ACO participants and non-participant providers. Additionally, because the ACO will be held accountable for an assigned population of FFS Medicare beneficiaries, we expect that beneficiary identifiable claims data will be useful in identifying services and goods obtained from non-ACO providers and suppliers and in developing processes to improve communication with those practitioners to improve overall care delivery. The development of interoperable EHR and HIT among both affiliated and unaffiliated providers would be one way to facilitate communication with practitioners.

5. Giving Beneficiaries the Opportunity To Decline Data Sharing

Although we have the legal authority, within the limits described previously, to share Medicare claims data with ACOs without the consent of beneficiaries, we nevertheless believe that beneficiaries should be notified of, and have control over, who has access to their personal health information for purposes of the Shared Savings Program. Thus, we proposed to require that, as part of its broader activities to notify patients that its ACO provider/supplier is participating in an ACO, the ACO must also inform beneficiaries of its ability to request claims data about them if they do not object.

Specifically, we proposed that when a beneficiary has a visit with their primary care physician, their physician would inform them at this visit that he or she is an ACO participant or an ACO provider/supplier and that the ACO would like to be able to request claims information from us in order to better coordinate the beneficiary's care. If the beneficiary objects to sharing their data, he or she would be given a form stating that they have been informed of their physician's participation in the ACO and explaining how to decline having their personal data shared. The form could include a phone number and/or email address for beneficiaries to call and request that their data not be shared. Thus, we proposed that ACOs would only be allowed to request beneficiary identifiable claims data for beneficiaries who have: (1) Visited a primary care participating provider during the performance year; and (2) have not chosen to decline claims data sharing. We noted that it is possible that a beneficiary would choose not to have their data shared with the ACO but would want to continue to receive care from ACO participants or providers/suppliers. We further noted that in such a case, the ACO would still be responsible for that beneficiary's care, and as such, the beneficiary's data would continue to be used to assess the performance of the ACO. To ensure a beneficiary's preference is honored, we proposed to maintain a running list of all beneficiaries who have declined to share their data. We proposed to monitor whether ACOs request data on beneficiaries who have declined data sharing, and proposed to take appropriate actions against any ACO that has been to make such a request. For a complete discussion of our policy rationale for these proposals (see (76 FR 19559 and 19560)).

Comment: Some comments suggested that this proposal to permit beneficiaries to decline data sharing runs counter to the goal of coordinated care and will make it nearly impossible for ACOs to succeed. These comments offered various alternatives ranging from: Eliminating the opportunity for beneficiaries to decline data sharing, removing those beneficiaries who elect to decline to have their data shared from ACO performance assessment, requiring beneficiaries who choose to decline to participate in data sharing from continuing to seek care from an ACO participant, allowing ACOs to refuse care to beneficiaries who choose to decline data sharing, and making the beneficiary's choice to receive care from an ACO provider/supplier an automatic opt-in for data sharing.

Response: Although we have the legal authority, within the limits described previously, to share Medicare claims data with ACOs without the consent of the Medicare beneficiaries, we believe that beneficiaries should be notified of their provider's participation in an ACO and have some control over who has access to their personal health information for purposes of the shared savings program. Furthermore, we believe that a beneficiary should not be subject to any penalties, such as being required to change their healthcare provider, if they decide that they do not want their information shared. The requirement that an ACO provider/supplier engage patients in a discussion about the inherent benefits, as well as the potential risks, of data sharing provides an opportunity for true patient-centered care and will create incentives for ACOs, ACO participants, and ACO providers/suppliers to develop positive relationships with each beneficiary under their care. Additionally, this proposal will provide ACO participants and ACO providers/suppliers the opportunity to engage with beneficiaries by explaining the shared savings program and its potential benefits to both the beneficiaries and the health

care system as a whole. FFS beneficiaries will retain their right to seek care from any provider, including those participating in an ACO, even if they decline to share their data. Additionally, requiring that ACOs be accountable to all assigned beneficiaries will allow us to compare the quality metrics and costs between those beneficiaries who have declined to share their data and those beneficiaries who have allowed their data to be shared in order to evaluate the effectiveness of the data sharing provisions. We will monitor for any actions taken on the part of the ACO to steer patients away that have declined data sharing.

Comment: A few comments recommend that for the elderly, less literate or tribal populations, that an opt-in approach would be more conducive to offering beneficiaries meaningful control over their personal health information. Commenters believe the advantage of an opt-in approach is that consent must be sought before which time any sharing of health information can occur. Obtaining affirmative written permission would also provide documentation of the beneficiary's choice. A few other comments supported our policy to afford meaningful choice over their personal health information to beneficiaries but recommended that we make this less burdensome on the beneficiary.

Response: We disagree that an opt-in approach would offer beneficiaries more control over their personal health information then an opt-out approach. We believe either approach, done well, offers equivalent control. As discussed previously, our opt-out approach coupled with notification of how protected health information will be shared and used affords beneficiaries choice and will offer ACOs, ACO participants, and ACO providers/suppliers the opportunity to develop positive relationships with each beneficiary under their care. Additionally, our notification and opt out approach will provide ACOs, ACO participants, and ACO providers/suppliers the opportunity to explain the shared savings program and its inherent benefits to both the beneficiaries and the health care system as a whole. We recognize that obtaining affirmative written permission would provide documentation of the beneficiary's choice in an opt-in model. However, we believe that under this approach significant paperwork burdens arise as providers must track consents for the majority of their patient population.

Comment: One comment stated that requiring beneficiaries to change their health care delivery in order to avoid having their personal health information shared among ACO providers is contrary to the message delivered during the health care debate that if a beneficiary was happy with their health care, nothing would change. Another comment was concerned that patients may be skeptical of or not understand the opt-out proposal and for this reason seek care outside the ACO, even if the beneficiary has an established relationship with the ACO participant.

Response: We disagree with this comment and contend that the transparency provided by this proposal ensures the beneficiary may decline data sharing while also allowing the beneficiary to continue to receive care from an ACO provider if they are happy with the care he/she is providing. In this way, beneficiaries retain freedom under traditional FFS Medicare to choose their own health care providers while also affording them the option of whether or not to share their data.

Comment: Several comments approved of our proposal to offer all beneficiaries the opportunity to decline to share their health data and especially liked that it would afford providers the opportunity to engage with patients to promote trust. Many of these comments also suggested that this policy would allow CMS to evaluate whether or not the sharing of beneficiary identifiable claims data is an important factor in improving health care delivery by comparing outcomes for beneficiaries who decline data sharing against those who do not.

Response: We agree that evaluating the outcomes of beneficiaries who have declined data sharing versus those who have not could provide valuable information, and will investigate the possibility of conducting such a study. We believe comparative evaluations like this are important for identifying potential improvements to improving the Medicare program. We intend to study the effects of the Shared Savings Program over time, and expect to improve the program through lessons learned by participants and evaluations of similar initiatives, such as those undertaken through the Innovation Center.

Comment: A few commenters recommended that CMS maintain the list of beneficiaries who have declined to share their data, and that CMS report to the ACOs the percentage of attributed beneficiaries who decline data sharing to the ACO since this will directly impact data integrity, risk assessment, validation, and potentially performance.

Response: We agree that knowing the percentage of beneficiaries that have declined data sharing could be useful to ACOs. However, because the ACO will be compiling and submitting the list of beneficiaries who have not declined data sharing on a monthly basis, the ACO will already have sufficient data to assess the percentage of beneficiaries who decline data sharing.

Comment: A few comments suggest that CMS explore alternative assignment methodologies that will facilitate a greater willingness by beneficiaries to share data. Additionally, one commenter recommended that the data sharing process proposed in the Pioneer ACO Model should be adopted for the general Shared Savings Program.

Response: We appreciate these comments and are looking forward to lessons learned from testing different approaches in the Pioneer ACO Model.

Comment: Several commenters were concerned that allowing ACOs access to beneficiary identifiable data only after: (1) The beneficiary has visited a primary care participating provider during the performance year; and (2) does not elect to decline to participate in data sharing, will result in a delay in the provision of claims data to ACOs, and may generate unnecessary office visits for the beneficiary population as providers might attempt to pull beneficiaries into the office for needless visits just in order to explain the Shared Savings Program to the beneficiaries.

Response: We have considered these comments in light of our goal to promote better physician-patient relationships, program transparency and reduce administrative burden. We are modifying our proposed approach to providing beneficiary identifiable data to ACOs. We will continue to require ACOs to notify patients at the point of care that they are participating in an ACO, that they will be requesting PHI data, and that the beneficiary has the right to decline to share this data with the ACO. In addition, we will also provide a mechanism by which ACOs can notify beneficiaries and request beneficiary identifiable data in advance of the point of care visit using the lists of preliminary prospectively assigned patients provided to the ACO at the start of the agreement period and quarterly during the performance year.

As discussed previously, upon signing participation agreements and a DUA, ACOs will be provided with a list of preliminary prospectively assigned set of beneficiaries that would have historically been assigned and who are likely to be assigned to the ACO in future performance years. ACOs may utilize this initial preliminary

prospectively assigned list along with the quarterly lists to provide beneficiaries with advance notification prior to a primary care service visit of their participation in the shared savings program and their intention to request their beneficiary identifiable data. Beneficiaries will be given the opportunity to decline this data sharing as part of this notification. After a period of 30 days from the date the ACO provides such notification, ACOs will be able to request beneficiary identifiable data from us absent an opt-out request from the beneficiary. Although we would expect providers/suppliers to still actively engage beneficiaries in conversation about the Shared Savings Program and their ability to decline to share their own health data at the beneficiaries' first primary care visit.

We believe this modification will continue to afford beneficiaries with a meaningful choice about the sharing of their claims data, while also allowing practitioners to have more timely access to beneficiaries' claims data in order to begin coordinating care for those beneficiaries as soon as possible. This additional flexibility may be particularly important in the case of beneficiaries who do not schedule an appointment with a primary care practitioner until later in the year or not at all in a given year. As noted previously, under § 425.704(b) ACOs should not continue to request claims data for beneficiaries that the ACO knows are no longer being treated by ACO participants or who have not been assigned to the ACO during the retrospective reconciliation.

Final Decision: We will finalize our proposal in § 425.704, to allow ACOs to request beneficiary identifiable data on a monthly basis.

Additionally, we are modifying this proposal in § 425.708 to allow the ACO the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data. If, after a period of 30 days from the date the ACO provides such notification, neither the ACO nor CMS has received notification from the beneficiary to decline data sharing, the ACOs would be able to request beneficiary identifiable data. The ACO would be responsible for repeating the notification and opportunity to decline sharing information during the next face-to-face encounter with the beneficiary in order to ensure transparency, beneficiary engagement, and meaningful choice.

We note that if a beneficiary declines to have their claims data shared with the ACO, this does not preclude physicians from sharing medical record information as allowed under HIPAA amongst themselves, for example, a referring primary care physician providing medical record information to a specialist.

E. Assignment of Medicare Fee-for-Service Beneficiaries

Section 1899(c) of the Act requires the Secretary to ''determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A). Subsection 1899(h)(1)(A) constitutes one element of the definition of the term ''ACO professional.'' Specifically, this subsection establishes that ''a physician (as defined in section 1861(r)(1))'' is an ''ACO professional'' for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term physician as ''* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action''. In addition, section 1899(h)(1)(B) of the Act defines an ACO professional to include practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs.

Assigning Medicare beneficiaries to ACOs also requires several other elements: (1) An operational definition of an ACO (as distinguished from the formal definition of an ACO and the eligibility requirements that we discuss in section II.B. of this final rule) so that ACOs can be efficiently identified, distinguished, and associated with the beneficiaries for whom they are providing services; (2) a definition of primary care services for purposes of determining the appropriate assignment of beneficiaries; (3) a determination concerning whether to assign beneficiaries to ACOs prospectively, at the beginning of a performance year on the basis of services rendered prior to the performance year, or retrospectively, on the basis of services actually rendered by the ACO during the performance year; and (4) a determination concerning the proportion of primary care services that is necessary for a beneficiary to receive from an ACO in order to be assigned to that ACO for purposes of this program.

The term ''assignment'' in this context refers only to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from physicians associated with a specific ACO so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care. Consistent with section 1899(b)(2)(A) of the Act, the ACO will then be held accountable ''for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.'' The ACO may also qualify to receive a share of any savings that are realized in the care of these assigned beneficiaries due to appropriate efficiencies and quality improvements that the ACO may be able to implement. It is important to note that the term ''assignment'' for purposes of this provision in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise complete freedom of choice in the physicians and other health care practitioners and suppliers from whom they receive their services.

Thus, while the statute refers to the assignment of beneficiaries to an ACO, we would characterize the process more as an ''alignment'' of beneficiaries with an ACO, that is, the exercise of free choice by beneficiaries in the physicians and other health care providers and suppliers from whom they receive their services is a presupposition of the Shared Savings Program. Therefore, an important component of the Shared Savings Program will be timely and effective communication with beneficiaries concerning the Shared Savings Program, their possible assignment to an ACO, and their retention of freedom of choice under the Medicare FFS program. The issues of beneficiary information and communications are further discussed in section II.H.2.a. of this final rule.

Comment: A commenter noted that CMS experiences savings on Medicare Cost Contract products when admissions are avoided, but the value this generates is not currently shared by providers. The commenter noted that, in a Medicare Cost Contract, health plans assume risk for Part B services while CMS retains the risk for Part A services. In the PGP demonstration, the commenter's organization created savings for both Medicare FFS and Cost Contract patients, and CMS received the benefit of reduced hospital admissions. These savings were not calculated into the gain sharing arrangement within the PGP demonstration program nor could they be recognized in cost plan contracts since the value accrued solely to CMS. The commenter believed that this disconnect makes it cost prohibitive to invest in technologies to improve care across our senior patient population. CMS should include these patients in

the performance calculations for ACOs with a significant Cost Contract population''

Response: We assume that the commenter is referring to cost contracts which exist under section 1876 of the Act. Section 1899(h)(3) of the Act defines a ''Medicare fee-for-service beneficiary'' for purposes of the Shared Savings Program as ''an individual who is enrolled in the original Medicare fee-for-service program under parts A and B and is not enrolled in an MA plan under part C, an eligible organization under section 1876, or a PACE program under section 1894.'' Therefore, the statute precludes assignment of cost contract beneficiaries to ACOs under the Shared Savings Program.

Comment: Another commenter cited the definition of ''Medicare fee-for-service beneficiary'' under section 1899(h)(3) of the Act, but then requested that Medicare beneficiaries that can participate in the ACO should include Seniorcare enrollees. The commenter describes ''Seniorcare'' as a product for Medicare beneficiaries which falls under section 1876 of the Act, and contends that their participation in an ACO should be permitted because they represent a small population that is ''important in rural areas.'' Finally, the commenter contends that dual eligibles should be included in the program, observing that their participation in the Shared Savings Program would require coordination with the States, and suggesting that we gather data on the dual eligibles who participate during the first years of the MSSP in order to determine whether any issues arise with their participation.

Response: As we have discussed previously, section 1899(h)(3) of the Act specifically excludes individuals ''enrolled in an eligible organization under section 1876'' from the definition of ''Medicare fee-for-service beneficiary'' for purposes of the Shared Savings Program. The commenter stated that Seniorcare is a Medicare product offered under section 1876 of the Act. Seniorcare enrollees therefore may not be assigned to an ACO. Nothing in section 1899 of the Act, however, precludes assignment of dual eligibles enrolled in the original Medicare FFS program to ACOs participating in the Shared Savings Program. CMS' goal is to promote complete integration of care provided and align incentives for all individuals whether under Medicare, Medicaid, or both. We agree with the commenter's suggestion that we carefully monitor ACO care coordination, quality of care, and costs for dual eligibles including the impact on Medicaid and will implement this within our monitoring plans. In addition, we intend to study the effect of assignment of dually eligible individuals to ACOs in the MSSP on Medicaid expenditures, and may use this information in the development of future models for testing by the Innovation Center.

Final Decision: We are finalizing our proposed policies concerning the eligibility of Medicare FFS beneficiaries for assignment to an ACO under the Shared Savings Program. Specifically, as required by the statute, and consistent with the definition of Medicare fee-for-service beneficiary in § 425.20, under § 425.400(a) only individuals enrolled in the original Medicare fee-for-service program under parts A and B, and not enrolled in an MA plan under Part C, an eligible organization under section 1876 of the Act, or a PACE program under section 1894 of the Act, can be assigned to an ACO.

1. Definition of Primary Care Services

Section 1899(c) of the Act requires the Secretary to assign beneficiaries to an ACO ''based on their utilization of primary care services'' provided by a physician. However, the statute does not specify which kinds of services should be considered ''primary care services'' for this purpose, nor the amount of those services that would be an appropriate basis for making assignments. We discuss issues concerning the appropriate proportion of such services later in the final rule. In this section of this final rule, we discuss how to identify the appropriate primary care services on which to base the assignment and our final policy for defining primary care services for this purpose.

In the proposed rule, we proposed to define ''primary care services'' as a set of services identified by these HCPCS codes: 99201 through 99215; 99304 through 99340; and 99341 through 99350. Additionally, we proposed to consider the Welcome to Medicare visit (G0402) and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program.

Comment: One commenter expressed concern that an assignment methodology based on primary care services could lead to an unintended negative consequence: ''An attribution model based on primary care utilization could result in a disproportionate number of high-risk beneficiaries, as compared to low-risk beneficiaries, being assigned to the ACO. Low-risk beneficiaries may be less likely to have visited a PCP or other physician, resulting in that patient not being assigned to an ACO. Therefore, the commenter encourages CMS to consider ways in which these beneficiaries can be encouraged to seek preventive care and become involved in an ACO.

Response: We disagree that an attribution model based on primary care utilization could result in a disproportionate number of high-risk beneficiaries being assigned to the ACO. Many low risk beneficiaries still visit a PCP or other physician once or twice a year for routine check-ups and assessments. Furthermore, we are bound by the statutory requirement that assignment be based upon the utilization of primary care services rendered by a physician. Nevertheless, we will keep this concern in mind as we implement the Shared Savings Program and gain experience in its operation during its first few years.

Comment: One commenter requested that the code sets used to determine assignment include inpatient evaluation and management (E&M) code: ''Observation—99218–99220/Initial, 99224–99226/Subsequent; Hospital Inpatient—99221- 99223/Initial, 99231–99233/Subsequent; and Hospital Inpatient Consultation—99251–99255.'' Another recommended excluding hospital emergency visits and urgent care visits. Another commenter noted that the proposed rule narrowly defines ''primary care services,'' and expressed uncertainty about how we envision the organization of care such as occupational therapy within the proposed ACO framework. Specifically, the commenter asked whether only E&M codes will be used to determine the plurality of care, or whether the provision of other services will also be considered. Or will these other services only be considered in terms of savings?

A national association recommended that certain CPT codes for remote monitoring and care coordination be used in the assignment process without being tied to a physician office visit. Another association expressed concern that the method for assigning beneficiaries should account for the patients receiving care in post-acute settings, where the providers may not fall within the proposed definition of primary care physician. One commenter argued that the inclusion of skilled nursing facility (SNF) and home visit CPT codes would be problematic for some systems because an ACO could potentially provide the plurality of outpatient care in an office setting to a beneficiary and yet the beneficiary still might not be assigned to that ACO. The commenter noted that this would happen in the case where a beneficiary is hospitalized and then discharged to a

nursing home not affiliated with the ACO physicians. In the view of the commenter, this method would not result in the alignment of the beneficiary with the correct provider. Another commenter noted that groups that have providers practicing in skilled nursing facilities are often assigned patients who have many visits over a short period of time in those facilities, but who are not their primary care patients.

Response: We proposed the list of codes that would constitute primary services for two reasons. First, we believed the proposed list represented a reasonable approximation of the kinds of services that are described by the statutory language (which refers to assignment of ''Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services''). In addition, we selected this list to be largely consistent with the definition of ''primary care services'' in section 5501 of the Affordable Care Act. That section establishes an incentive program to expand access to primary care services, and thus its definition of ''primary care services'' provides a compelling precedent for adopting a similar list of codes for purposes of the Shared Savings Program. We have slightly expanded the list in section 5501 of the Affordable Care Act to include the Welcome to Medicare visit (HCPCS code G0402) and the annual wellness visits (HCPCS codes G0438 and G0439) as primary care services for purposes of the Shared Savings Program. These codes clearly represent primary care services frequently received by Medicare beneficiaries, and in the absence of the special G codes they would be described by one or more of the regular office visit codes that we have adopted from section 5501 of the Affordable Care Act. Finally, the statute requires that assignment be based upon the utilization of primary care services by physicians. For this reason, only primary care services can be considered in the assignment process. Other services can, as one commenter noted, only be considered in terms of determining shared savings, if any.

With regard to the comments about the inclusion or exclusion of certain codes, we would observe first that the codes for hospital emergency visits (99281 through 99288) and urgent care visits (we assume the commenter refers to 99291 and 99292, which represent critical care services) were not included in our proposed list of codes representing primary care services. We believe that the inclusion of the codes for SNF visits is appropriate because beneficiaries often stay for long periods of time in SNFs, and it is reasonable to conclude that these codes represent basic evaluation and management services that would ordinarily be provided in physician offices if the beneficiaries were not residing in nursing homes. Inpatient hospital visit codes (99221 through 99223), in contrast, are intrinsically related to the acute care treatment of the specific condition or conditions that required the inpatient hospital stay, and we therefore do not believe that these codes represent the kind of general evaluation and management of a patient that would constitute primary care. Finally, we would observe in general that it would be impossible to establish a list of primary care codes by considering all of the ways in which the inclusion, or exclusion, of certain codes or sets of codes would advantage or disadvantage different types of potential ACOs. The code set that we are adopting in this final rule represents the best approximation of primary care services based upon relevant precedents and the information we currently have available. However, we intend to monitor this issue and will consider making changes to add (or delete) codes, if there is sufficient evidence that revisions are warranted.

Final Decision: We are finalizing our proposal to define ''primary care services'' in § 425.20 as the set of services identified by the following HCPCS codes: 99201 through 99215, 99304 through 99340, 99341 through 99350, the Welcome to Medicare visit (G0402), and the annual wellness visits (G0438 and G0439) as primary care services for purposes of the Shared Savings Program. In addition, as we will discuss later in this final rule, in this final rule we will establish a cross-walk for these codes to certain revenue center codes used by FQHCs (prior to January 1, 2011) and RHCs so that their services can be included in the ACO assignment process.

a. Consideration of Physician Specialties in the Assignment Process

Primary care services can generally be defined based on the type of service provided, the type of provider specialty that provides the service, or both.

In developing our proposal, we considered three options with respect to defining ''primary care services'' for the purposes of assigning beneficiaries under the Shared Savings Program: (1) Assignment of beneficiaries based upon a predefined set of ''primary care services;'' (2) assignment of beneficiaries based upon both a predefined set of ''primary care services'' and a predefined group of ''primary care providers;'' and (3) assignment of beneficiaries in a step-wise fashion. Under the third option, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family practice, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care physician.

We proposed to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries. As discussed previously, we proposed to define ''primary care services'' on the basis of the select set of HCPCS codes identified in the section 5501 of the Affordable Care Act, including G-codes associated with the annual wellness visit and Welcome to Medicare visit. We made this proposal in the belief that this option best aligned with other Affordable Care Act provisions related to primary care by placing an appropriate level of emphasis on a primary care core in the Shared Savings Program. That is, we believed that the proposed option placed priority on the services of designated primary care physicians (for example, internal medicine, general practice, family practice, and geriatric medicine) in the assignment process. The option is also relatively straightforward administratively.

However, we expressed our concern that this proposal might not adequately account for primary care services delivered by specialists, especially in certain areas with shortages of primary care physicians, and that it may make it difficult to obtain the minimum number of beneficiaries to form an ACO in geographic regions with such primary care shortages. Therefore, while we proposed to assign beneficiaries to physicians designated as primary care providers (internal medicine, general practice, family practice, and geriatric medicine) who are providing the appropriate primary care services to beneficiaries, we invited comment on this proposal and other options that might better address the delivery of primary care services by specialists, including a ''step-wise approach'' under which beneficiaries could be assigned to an ACO based upon primary care services furnished by a specialist if they do not have any visits with a primary care physician.

Comment: We received some very strong comments supporting our exclusion of services provided by

specialists in the assignment process, especially from organizations representing primary care physicians and from individual primary care physicians. Some endorsed our proposal because it ''supports the intent of the ACA for primary care practitioners to reduce the fragmentation of care and improve overall quality. Many specialists are not providing the primary, preventive services that are the building blocks for ACOs. Rather, specialists may tend to be quicker to refer patients to other specialists for problems outside the scope of their practice.'' Several other comments even urged CMS to tighten the definition of primary care services by specifying ''general internal medicine'' rather than ''internal medicine'' to ensure that Medicare ACOs are truly based on primary care physicians. One commenter also noted the absence of ''measures of physician competence or capability'' in a rule with an abundance of requirements in many areas. Another commenter urged that we include preventive medicine physicians under the definition of primary care or the definition of general practice. Another recommended that, rather than list ''primary care services,'' CMS go further to state that the primary care professionals be limited to those eligible for Primary Care Incentive Payments under section 5501 of the Affordable Care Act as a matter of consistency and specificity across CMS policy. This commenter maintained that specialists are not providing continuing and comprehensive primary healthcare to their patients, and the commenter thus opposed any further expansion of the definition of ''primary care professional'' for purposes of assigning patients to ACOs.

However, many commenters, including specialty societies, major medical centers, and others, strongly advocated inclusion of primary care codes from specialist physicians in the assignment process. Among other points, these commenters cited the shortages of primary care physicians in some areas. Others cited the fact that patients with certain chronic conditions (for example, diabetes, cardiac conditions, persons with disabilities, etc.) do receive most of their primary care from the specialist treating their conditions. One commenter raised the concern that the proposed definition of primary care services may not adequately represent services provided in post-acute care settings such as long-term care hospitals (LTCHs). The commenter noted that many LTCH patients are seen by teams of specialists who provide the bulk of the actual primary care services to these patients who often do not have a primary care physician. Other commenters also advocated including specialists in order to allow the formation of condition-specific ACOs, such as ''renal-focused ACOs.'' One physician society advocated expanding the definition of primary care, but retaining some limitations related to the specialty of the physicians providing services designated by the HCPCS basic office visit codes, on the grounds that subspecialty physicians often fulfill the primary care needs of their patients. This commenter and others cited subspecialty areas such as nephrology, oncology, rheumatology, endocrinology, pulmonology, and cardiology that might frequently be providing primary care to their patients.

Another commenter recommended that the specialties designated as providing primary care services be expanded to include certain specialties, but only if the ACO demonstrates, based on its own data of the assigned beneficiaries, that those specified specialist physicians are indeed providing primary care services on a regular and coordinated basis and the ACO is primary care focused and comprised of at least 30 percent primary care physicians and a maximum of 70 percent specialists. The commenter also argued that specialist-only group practices should not be eligible to become an ACO.

One commenter argued that the exclusion of specialists from the assignment process is contrary to the intent of the statute by noting that subsection 1899(h)(1)(A) of the Act defines an ''ACO professional'' for purposes of assignment as a physician as that term is defined in 1861(r)(1) of the Act—in other words, as an M.D. or a D.O. The commenter maintains that it is not an oversight that neither section 1861(r)(1) or 1899(c) of the Act mention physician specialty. The commenter also cites the Ways & Means report on section 1301 of H.R. 3200, the House predecessor to section 3022 of the Affordable Care Act, which codified the Shared Saving Program at section 1899 of the Act, which states: ''The Committee believes that physicians, regardless of specialty, who play a central role in managing the care of their patient populations, and who are willing and able to be held accountable for the overall quality and costs of care for their patients across all care settings, should be allowed to form ACOs.''

In order to account for the provision of many primary care services by specialists to chronically ill and other patients, one commenter suggested that the more appropriate method would be for the ACO to notify CMS who their ''Primary Care Providers'' are for an intended population within the ACO. In this way CMS can understand how to assign a beneficiary and a patient can know who their primary care' physician is within the ACO. Another commenter recommended allowing assignment to certain specialists (nephrology, rheumatology, endocrinology, pulmonology, neurology, and cardiology) provided the Medicare beneficiary has other primary care services for E&M Codes of less than 10 percent. One specialty society offered this alternative definition of primary care in support of considering pediatricians as primary care physicians for purposes of assignment: ''Primary health care is described as accessible and affordable, first contact, continuous and comprehensive, and coordinated to meet the health needs of the individual and the family being served.''

But one commenter maintained that the definition of primary care services should be less focused on the specialty of the provider, recommending that we should define primary care services by the services themselves, and then define primary care practitioners as those practitioners who primarily bill those services.

Of the commenters advocating inclusion of specialists in the assignment methodology, most recommend the option which assigns beneficiaries based on the plurality of primary care services regardless of specialty, although some would accept a variation that excludes those specialties that rarely provide primary care. One comment said that, while they do not believe it is ideal, they could also accept the hybrid model, in which the beneficiary is assigned to a specialist if not otherwise assigned to a primary care physician. The commenter emphasized that, if this option is selected, it would be important to ensure the primary care physician is in fact serving as the beneficiary's principal care provider. A number of other commenters, including MedPAC, recommended that, in the final rule, we adopt the step-wise approach that we discussed as an option in the proposed rule. Another commenter agreed that beneficiaries with at least one visit with a primary care physician (general practice, internists, family medicine or geriatrician as defined by CMS) should be assigned to an ACO based on their utilization of primary care services.

Response: We agree with the commenters who supported our proposal that the Shared Savings

Program should place a strong emphasis on primary care, which is consistent with the statutory requirement that assignment be based on the utilization of primary care services furnished by a physician. However, we cannot agree with those commenters who recommended that we tighten the definition of primary care services for purposes of the Shared Savings Program. For example, we do not agree with the recommendation of a few commenters that we include only ''general internal medicine'' rather than ''internal medicine'' under the proposed definition of primary care physician because the Medicare enrollment and billing systems contain a specialty code (specialty code 11) only for ''internal medicine,'' and we thus have no way to differentiate ''internal medicine'' from ''general internal medicine.'' On the merits, we also doubt that the specialty designations of ''internal medicine'' and ''general internal medicine'' selected by physicians reflect an adequate distinction between internal medicine specialists who primarily deliver primary care services and those who do not. (In addition, as we discuss later in this final rule, we have decided to include the primary care services provided by specialist physicians in the assignment process as part of the step-wise approach that we described in the proposed rule. As a result, to some degree, at least, the distinction between ''general internal medicine'' and ''internal medicine'' has become less significant, since both would be included in our new assignment methodology in any case.) We do not agree with the suggestion to add the designation of ''preventive care specialist'' to our list of primary care physicians, because as much as possible we are following the designations of primary care physicians established under section 5501 of the Affordable Care Act, which does not include this specialty. We also believe that it would be operationally complex, and perhaps overly onerous and restrictive to potential participants in the Shared Savings Program, to incorporate special competency standards into the definition of primary care physician.

We do not agree with commenters who argued that our proposed restriction of primary care services to those provided by primary care physicians was contrary to the statute. Section 1899 of the Act does not specifically define the term ''primary care services.'' Furthermore, section 1899(c) of the Act gives the Secretary discretion to determine ''an appropriate method'' to assign beneficiaries based on their utilization of primary care services furnished by a physician affiliated with the ACO, and thus allows the Secretary broad discretion in defining the term ''primary care.'' We would also note that our proposed definition largely followed the precedent established by section 5501(a) of the Affordable Care Act, the provision governing primary care incentive payments, and is thus clearly consistent with the overall intent of that Act, which also establishes the Shared Savings Program.

However, in the proposed rule we also expressed some concerns about the possible effects of the proposed policy in eliminating certain genuine primary care services from consideration in the assignment process. In particular, we noted our concern about possibly excluding primary care services delivered by specialists, especially in some areas with shortages of primary care physicians, where specialists necessarily deliver the bulk of primary care services. We also noted that, especially for beneficiaries with certain conditions (for example, heart conditions and diabetes), specialist physicians often take the role of primary care physicians in the overall treatment of the beneficiaries. The commenters have confirmed these concerns, and persuaded us that, in the end, the Shared Savings Program should not restrict assignment purely to a defined set of primary care services provided only by the specialties that can be appropriately considered primary care physicians. We agree that our proposed assignment methodology would be unduly restrictive in areas with shortages of primary care physicians. We also agree that specialists do necessarily and appropriately provide primary care services for many beneficiaries with serious and/or chronic conditions.

Therefore, in this final rule we are adopting a more balanced assignment process that simultaneously maintains the primary care-centric approach of our proposed approach to beneficiary assignment, while recognizing the necessary and appropriate role of specialists in providing primary care services. As we previously noted, in the proposed rule we discussed a step-wise approach to beneficiary assignment. Under this approach, after identifying all patients who had a primary care service with a physician at the ACO, beneficiary assignment would proceed by first identifying primary care physicians (internal medicine, family practice, general practice, geriatric medicine) who are providing primary care services, and then identifying specialists who are providing these same services for patients who are not seeing any primary care physician. We hesitated to propose this option because we were concerned that it would introduce a greater level of operational complexity compared to the two other options we considered. In addition, we were concerned that it could undermine our goal of ensuring competition among ACOs by reducing the number of specialists that can participate in more than one ACO, since the TINs of specialists to whom beneficiaries are assigned would be required to be exclusive to one ACO. (As noted in section II.B.1.d of this final rule, the TINs upon which assignment is based must be exclusive to one ACO for purposes of participation in the Medicare Shared Savings Program. However, exclusivity of an ACO participant to one ACO is not necessarily the same as exclusivity of individual practitioners to one ACO. For example, exclusivity of ACO participants leaves individual NPIs free to participate in multiple ACOs if they bill under several different TINs. The ability of individual specialists to participate in more than one ACO is especially important in certain areas of the country that might not have many specialists.) On the other hand, we acknowledged that a ''step-wise approach'' would reflect many of the advantages of the other two approaches we discussed in the proposed rule (including the option we proposed), balancing the need for emphasis on a primary care core with a need for increased assignment numbers in areas with primary care shortages. Despite our initial misgivings regarding this approach, we have come to agree with MedPAC and the other commenters who endorsed such an approach that it provides the best available balance of maintaining a strong emphasis on primary care while ultimately allowing for assignment of beneficiaries on the basis of how they actually receive their primary care services.

Final Decision: Under § 425.402, after identifying all patients that had a primary care service with a physician who is an ACO provider/supplier in an ACO, we will employ a step-wise approach as the basic assignment methodology. Under this approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians. This final policy thus

allows consideration of all physician specialties in the assignment process. We describe this step-wise approach in greater detail later in this final rule, after further addressing other related issues, including consideration of primary care services furnished by non-physician practitioners, such as NPs and PAs. As also discussed later in this final rule, we will also consider only the specific procedure and revenue codes designated in this final rule in the assignment process.

b. Consideration of Services Furnished By Non-Physician Practitioners in the Assignment Process

In the proposed rule we observed that, although the statute defines the term ''ACO professional'' to include both physicians and non-physician practitioners, such as physician assistants (PAs), and nurse practitioners (NPs), for purposes of beneficiary assignment to an ACO, the statute also requires that we base assignment on beneficiaries' utilization of primary care services provided by ACO professionals who are physicians. As we discussed previously, section 1899(c) of the Act requires the Secretary to ''determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in subsection (h)(1)(A).'' Section 1899(h)(1)(A) of the Act constitutes one element of the definition of the term ''ACO professional.'' Specifically, this subsection establishes that ''a physician (as defined in section 1861(r)(1))'' is an ''ACO professional'' for purposes of the Shared Savings Program. Section 1861(r)(1) of the Act in turn defines the term physician as ''* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action''. Therefore, for purposes of the Shared Savings Program, the inclusion of practitioners described in section 1842(b)(18)(C)(i) of the Act, such as PAs and NPs, in the statutory definition of the term ''ACO professional'' is a factor in determining the entities that are eligible for participation in the program (for example, ''ACO professionals in group practice arrangements'' under section 1899(b)(1)(A) of the Act). However, we proposed that the assignment of beneficiaries to ACOs would be determined only on the basis of primary care services provided by ACO professionals who are physicians.

Comment: We received numerous comments, especially from individual practitioners and organizations representing nurses, PAs, and others, objecting to the exclusion of primary care services provided by NPs, certified nurse midwives, other nursing practitioners, PAs and other non-physician practitioners from the assignment process. Many NPs and nurse associations commented that the ''limitation will significantly impair the ability of patients to access primary care services. It will negatively affect not only access, but the cost and quality of the care provided by the ACOs.'' The commenters emphasized that NPs have a long history of providing high quality, cost effective care and that their skills in the area of care coordination, chronic disease management, health promotion, and disease prevention could contribute significantly to the quality and cost savings of any shared saving program. Some commenters urged that CMS should take any opportunity it has to encourage the use of non-physician providers in the care of Medicare beneficiaries.

Commenters advocated several approaches to dealing with the statutory language under which assignment turns on primary care services provided by ''an ACO professional described in subsection (h)(1)(A),'' which specifies ''* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action.'' Some commenters argued that the reference to ''subsection (h)(1)(A)'' represents a drafting error, and that that we should proceed on the assumption that the reference should have been to ''subsection (h)(1),'' which includes not only physicians, but also CNSs, NPs, and PAs. Other commenters argued that it is not necessary to interpret the requirement that beneficiaries be assigned based on primary care services ''provided'' by a physician to mean that Medicare beneficiaries are to be assigned to ACOs solely based on services ''directly provided'' by a physician. These commenters maintained that the statute does not require that services be ''directly provided'' by a physician, but only that physicians provided care, which can be done directly or indirectly.

A national nurses' association and several other commenters acknowledged that the correct statutory reference concerning assignment is to ''subsection (h)(1)(A),'' which allows assignment only on the basis of physician services, but also argued that ''CMS can abide by the statutory requirement by basing assignment on utilization of primary care services provided by an ACO physician without requiring a plurality. Any primary care service provided by an ACO primary care physician should be enough to trigger assignment, as long as some other ACO participant has provided the plurality of primary care services to that beneficiary.''

PAs, their representative organizations, and some other commenters disagreed with the exclusion of PAs from the assignment process. One commenter was ''extremely disappointed'' that PAs are not included in the definition of primary care professional. Some commenters suggest that the discretionary authority provided to the Secretary of Health and Human Services under section 1899(i) of the Act allowing for the utilization of other payment models under the Shared Savings Program could provide the means to include non-physician practitioners such as PAs and NPs. Another commenter recommended that the care provided by a PA, pursuant to the criteria outlined in the proposed rule, be used to determine assignment to an ACO. Since PAs practice in a collaborative nature with physicians, the commenter believed it appropriate that beneficiaries who receive a plurality of primary care services from a PA be assigned based upon these services. However, they would also restrict recognition of care provided by non-physician providers only to those who have a collaborative or supervisory agreement with physicians, excluding some NPs who practice independently.

Response: We cannot agree with those commenters who maintained that the wording of section 1899(c) of the Act with respect to considering primary care services provided by physicians should be treated as a ''drafting error.'' We are unaware of any direct or indirect evidence that the reference to ''an ACO professional described in subsection (h)(1)(A)'' rather than to ''an ACO professional described in subsection (h)(1)'' was made in error. Even if there were convincing evidence to that effect, given the clarity of the plain language of the statute, it would not fall within our authority to correct that error. Therefore, in implementing the Shared Savings Program, the assignment methodology will be based on utilization of primary care services provided by physicians. At the same time, we agree with the many commenters who emphasized that NPs, PAs, and clinical nurse specialists (CNSs) have a well-established record of providing high quality and cost-effective care. We also agree that these practitioners can be significant assets to the ACO in the areas of quality and cost saving, and indeed that the appropriate use of NPs, PAs, and CNSs could be an important element in the success of an

ACO participating in the Shared Savings Program. As many commenters noted, the skills of these practitioners, especially in care coordination, chronic disease management, health promotion, and disease prevention certainly can contribute significantly to the quality and cost savings of any shared saving program. (We would note in this context that nothing in the statute precludes an ACO from sharing savings with NPs and other practitioners, whether or not their services are included in the assignment process.)

We also cannot agree with the commenters who suggested that the statutory language may be read to allow assignment to be based on services provided ''indirectly'' by a physician. Although the statute does not include the word ''directly,'' it does require that assignment be based on services ''provided'' by physicians. The statutory requirement that assignment be based on physician services, not services furnished by ACO professionals more generally, would be rendered meaningless if we were to adopt a reading of the statute that permits physician services to be furnished ''indirectly.'' For example, under this reading, a beneficiary could be assigned to an ACO without ever having seen a physician in the ACO. We believe that such an interpretation is directly contrary to the intent of section 1899(c) of the Act, and in particular, contrary to the express statutory requirement that assignment be based on physician services rather than ACO professional services, more generally.

However, we took special note of one comment cited previously, specifically the comment that: ''Any primary care service provided by an ACO primary care physician should be enough to trigger assignment, as long as some other ACO participant has provided the plurality of primary care services to that beneficiary.'' This commenter suggested that it may be possible to employ the discretion that is afforded to the Secretary under the statute to determine ''an appropriate method'' for assigning beneficiaries to an ACO based on the utilization of primary care services furnished by a physician by considering the receipt of physician primary care services as a triggering factor in the assignment process, prior to considering where the beneficiary has received a plurality of primary care services provided by the full range of ACO professionals, so that the beneficiary is appropriately assigned to the ACO which bears the primary responsibility for his or her primary care. Specifically, we could implement the statutory requirement that assignment be based on physician services, by assigning a beneficiary to an ACO if, and only if, the beneficiary has received at least one primary care service from a physician who is an ACO provider/supplier in the ACO. Therefore, as required by the statute, we would be assigning beneficiaries to an ACO based upon the receipt of primary care from a physician in the ACO. However, we would apply this policy in the step-wise fashion that we have discussed previously, that is, basing assignment in a first step on the primary care services provided by primary care physicians (measured in terms of allowed charges) alone. Then, in a second step, we would assign patients who are not seeing any primary care physician either inside or outside the ACO if they have received at least one primary care service from an ACO physician (of any specialty) in the ACO, and taking into account the allowed charges for primary care services provided by all ACO professionals in the ACO. The beneficiary will be assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers in any other ACO and allowed charges for primary care services furnished by physicians, NPs, PAs, and CNSs, who are not affiliated with an ACO. This method would avoid, for example, assignment of beneficiaries on the basis of receiving a few primary care services from specialist physicians, even though the beneficiary may be receiving the plurality of primary care services from specialist physicians, NPs or PAs who are ACO providers/suppliers in a different ACO.

In adopting this policy, we are also extending the policy regarding exclusivity of TINs on which assignment is based to one ACO: that is, the TINs under which the services of specialists, PAs, and NPs are included in the assignment process subsequent to the identification of the ''triggering'' physician primary care services would have to be exclusive to one ACO for purposes of the Shared Savings Program. (We emphasize that we are establishing this policy for purposes of Shared Savings Program ACOs only: commercial ACOs may or may not wish to adopt a similar policy.)

Comment: We received many comments from chiropractors and chiropractor associations recommending that the definition of ACO professional for purposes of the Shared Savings Program should be expanded to include chiropractors. These commenters cited the quality and cost efficiency of chiropractic services, and many also cited other statutory definitions of ''physician'' as precedents for including chiropractors within the definition of ''physician'' under the Shared Savings Program.

Response: We recognize that some other Federal and State laws include chiropractors within the definition of physician for various purposes. However, we are unable to consider services furnished by chiropractors in the assignment process under the Shared Savings Program. As previously explained, section 1899(c) of the Act requires that assignment be based upon ''utilization of primary care services provided * * * by an ACO professional described in subsection (h)(1)(A).'' Section 1899(h)(1)(A) of the Act defines an ''ACO professional'' as a physician (as defined in section 1861(r)(1) of the Act), which includes ''* * * a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action,'' but does not include chiropractors. Therefore, because chiropractors are not ACO professionals under section 1899(h)(1)(A) of the Act, we are unable to consider their services in the assignment process under the Shared Savings Program. However, it is important to note that this restriction certainly does not preclude Medicare-enrolled chiropractors from participating in ACOs, or from sharing in the savings that an ACO may realize in part because of the quality and cost-effective services they may be able to provide.

Final Decision: Therefore, under § 425.402 of this final regulation we are adopting the following step-wise process for beneficiary assignment. Our final step-wise assignment process takes into account the two decisions that we have just described: (1) Our decision to base assignment on the primary care services of specialist physicians in the second step of the assignment process; and (2) our decision also to take into account the plurality of all primary care services provided by ACO professionals in determining which ACO is truly responsible for a beneficiary's primary care in second step of the assignment process. Our final step-wise assignment process will thus occur in the following two steps, after identifying all patients that received a primary care service from a physician who is a provider/supplier in the ACO (and who are thus eligible for assignment to the ACO under the statutory requirement to base

assignment on ''utilization of primary care services''):

Step 1: We will identify beneficiaries who had received at least one physician primary care service from a primary care physician who is a provider/supplier in an ACO. In this step, a beneficiary can be assigned to an ACO only if he or she has received at least one primary care service from a primary care physician who is an ACO provider/supplier in the ACO during the most recent year (for purposes of preliminary prospective assignment, as discussed later in this final rule), or the performance year (for purposes of final retrospective assignment). If this condition is met, the beneficiary will be assigned to the ACO if the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of that ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are providers/suppliers of other ACOs, and greater than the allowed charges for primary care services provided by primary care physicians who are unaffiliated with any ACO (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate).

Step 2: This step would consider only beneficiaries who have not received any primary care services from a primary care physician either inside or outside the ACO. Under this step a beneficiary will be assigned to an ACO only if he or she has received at least one primary care service from any physician (regardless of specialty) in the ACO during the most recent year (for purposes of preliminary prospective assignment), or the performance year (for purposes of final retrospective assignment). If this condition is met, the beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers of that ACO (including specialist physicians, NPs, PAs, and CNSs), are greater than the allowed charges for primary care services furnished by ACO professionals who are ACO providers/suppliers of each other ACO, and greater than the allowed charges for primary care services furnished by any other physician, NP, PA, or CNS, (identified by Medicare-enrolled TINs or other unique identifiers, as appropriate) who is unaffiliated with any ACO.

c. Assignment of Beneficiaries to ACOs That Include FQHCs and/or RHCs

In the proposed rule, we also considered the special circumstances of FQHCs and RHCs in relation to their possible participation in the Shared Savings Program. (For purposes of this discussion, all references to FQHCs include both section 330 grantees and so-called ''look-alikes,'' as defined under § 405.2401 of the regulations.) Our proposed methodology was to assign beneficiaries to an ACO if they receive a plurality of their primary care services (which we proposed to identify by a select set of E&M services defined as ''primary care services'' for other purposes in section 5501 of the Affordable Care Act, and including the G-codes associated with the annual wellness visit and Welcome to Medicare visit) from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) affiliated with the ACO. Thus, under the proposal, we would need data that identify the precise services rendered (that is, primary care HCPCS codes), type of practitioner providing the service (that is, a physician as opposed to NP or PA), and the physician specialty in order to be able to assign beneficiaries to the entities that wish to participate in the Shared Savings Program.

In general, FQHCs and RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate. These claims distinguish general classes of services (for example, clinic visit, home visit, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining whether the all-inclusive rate can be paid for the service. The claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, or NP) who provided the service. (Starting in 2011, FQHC claims are required to include HCPCS codes that identify the specific service provided, in order for us to develop a statutorily required prospective payment system for FQHCs.) In the proposed rule, we indicated that we did not believe we had sufficient data in order to assign patients to ACOs on the basis of services furnished by FQHCs or RHCs. Instead, recognizing the important primary care role played by these entities, we proposed to provide an opportunity for an ACO to share in a greater percentage of any savings if FQHCs/RHCs are included as ACO participants.

Comment: Many commenters disagreed with our interpretation of the statute's assignment provision (section 1899(c) of the Act) to require a patient to be assigned to an ACO based solely on that beneficiary's use of services furnished by specific categories of primary care physicians. These commenters encouraged CMS to explore other approaches that would allow FQHCs and/or RHCs to independently form ACOs and to take on a more active role in the ACO by allowing assignment of beneficiaries and establishment of benchmarks to be based upon services furnished by these entities.

MedPAC commented that it would be more straightforward to allow assignment of patients to RHCs and FQHCs and encourage their use directly rather than to introduce special provisions for the savings share and thresholds as the proposed rule does. They indicated that ''these are primary care provider teams often associated with a physician and usually providing primary care services. Logically they should be allowed to participate in ACOs and patients should be assigned to them. In many rural areas, RHCs function as primary care physicians' offices and, although they are paid differently under Medicare, they are still fulfilling the same function''. MedPAC suggested that ''CMS posit that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim.''

Similarly, other commenters requested that CMS simply deem all FQHC services as primary care services. Other commenters believed it is more than reasonable to—and detrimental to the program's goals not to—interpret 1899(c) of the Act to find that the ''provided under'' language means not only services provided by the physician personally but also services provided by additional members of the health care team of an FQHC, with whom physicians supervise and collaborate. In short, they believed that the Secretary has the discretion to determine for purposes of patient assignment that patients who receive care from FQHCs can be treated as patients whose care is furnished by physicians since physician services are an integral part of the FQHC service definition, FQHC practice, and FQHC reimbursement.

Other commenters suggested that CMS could assign FQHC beneficiaries to ACOs in other ways. Specifically, a commenter indicated that the UB–04 billing form that FQHCs use to submit their claims contains sufficient information (for example, patient information, revenue codes, and ''attending physician'' information) to establish a reasonable process for assigning FQHC beneficiaries to ACOs. This commenter also noted that these health centers have a limited set of services that are considered ''FQHC

services'' and that virtually all such services would be considered primary care services.

Another commenter indicated that all FQHCs and RHCs should have the capability to provide additional information about their services beyond the information available on their claims. The commenter stated that to be covered for a malpractice claim, a health care center must be able to demonstrate (through appropriate documentation) that the services at issue were within the center's scope of services, provided at a location that was in the scope of services, were delivered to an established patient of the health center, were documented in a permanent medical record and were properly billed. This commenter categorically stated that the necessary information is available, that it is electronic, and that it can be correlated with contemporaneous claims data.

Other commenters suggested that CMS consider other assignment approaches, such as the methodology it is using to attribute Medicare patients to FQHCs in the Adirondack Regional Medical Home Pilot, an all-payer medical home demonstration project in upstate New York.

Yet other commenters suggested that assignment could be made by an FQHC providing a list of patients for whom it considers itself accountable. CMS could then analyze the claims history for the identified patients and exclude those with a plurality of primary care services associated with a provider other than the FQHC.

Regarding RHCs, a number of commenters agreed that when a clinic submits the claim form, it is not required to identify the specific provider who rendered the service. They conceded that the RHC service could have been provided by a physician, a PA or an NP (and in some circumstances, a nurse midwife). These commenters suggested various ways to address this: (1) Require RHCs that are part of an ACO to identify the rendering provider on their claim form using the NPI of the rendering provider, and provide any other information needed through various means (similar to how quality data are submitted; and/or (2) use a patient attestation method for attributing/assigning RHC patients to the ACO.

Response: We agree with the many comments that FQHCs and RHCs should be allowed to participate in ACOs and have their patients assigned to such ACOs, provided that patients can be assigned in a manner that is consistent with the statute.

We indicated in the proposed rule that we would continue to assess the possibilities for collecting the requisite data from FQHCs and RHCs, and consider whether it would be possible for Medicare beneficiaries to be assigned to an ACO on the basis of services furnished by an FQHC or RHC, thereby allowing these entities to have their Medicare beneficiaries included in the ACO's assigned population.

As indicated previously, MedPAC and some other commenters suggested that CMS posit or deem that all claims in RHCs and FQHCs are for primary care services and use them for assignment as it would any other primary care claim. We have not accepted these comments because they do not address the specific requirement in section 1899(c) of the Act which requires assignment of beneficiaries to an ACO based ''on their utilization of primary care services * * * by an ACO professional described in subsection (h)(1)(A).'' As discussed previously, section 1899(h)(1)(A) of the Act establishes that for the purposes of beneficiary assignment, an ''ACO professional'' is defined as a physician as defined in section 1861(r)(1) of the Act.

Likewise, we have not accepted other commenter suggestions that assignment could be made by an FQHC providing a list of patients for whom it considers itself accountable. Such an approach would also not be consistent with the statutory requirement that we develop an assignment process that is based on utilization of primary care services by an ACO professional, defined by the statute as a physician. We have also not adopted commenter suggestions that CMS should adopt the assignment processes that are being used in certain demonstration programs because these demonstration programs are not subject to the same statutory requirements that apply to this Shared Savings Program.

However, as explained later in this final rule, we are accepting suggestions from other commenters that, in combination, will enable us to adopt a policy in this final rule that will allow us to assign beneficiaries to ACOs on the basis of services furnished by FQHCs and/or RHCs. (As we have explained earlier in section II.B. (Eligible Entities) of this final rule, this will also allow FQHCs and RHCs to form an ACO independently, without the participation of other types of eligible entities. It will also allow the beneficiaries who receive primary care services from FQHCs and RHCs to count in the assignment process for any ACO that includes an FQHC and/or RHC as a provider/supplier.) As discussed previously, the assignment methodology we are adopting in this final rule is to assign beneficiaries to an ACO using a step-wise approach for assignment. Under this step-wise method, beneficiaries are first assigned to an ACO if they have received a primary care service from a primary care physician (defined as a physician with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine) who is a provider/supplier in the ACO, and also receive a plurality of their primary care services (which we identify by a select set of E&M services defined as ''primary care services'' in section 5501 of the Affordable Care Act, and the G-codes associated with the annual wellness visit and the Welcome to Medicare visit) from primary care physicians who are providers/suppliers in the same ACO. Those beneficiaries who have not received any primary care services from a primary care physician can be assigned to an ACO in the second step if they have received a primary care service from a specialist physician (that is, a physician that does not meet the definition of a primary care physician) who is a provider/supplier in the ACO, and also receive a plurality of their primary care services from physicians and other ACO professionals who are ACO providers/suppliers in the ACO. Thus, under the final rule, in order to be able to align beneficiaries with the entities that wish to participate in the Shared Savings Program, in general we require data that identify all of the following:

- Services rendered (that is, primary care HCPCS codes).
- Type of practitioner providing the service (that is, a physician, NP, PA, or CNS).
- Physician specialty.

For services billed under the physician fee schedule, these data items are available on the claims submitted for payment. In contrast, as discussed in the proposed rule, FQHCs and RHCs submit claims for each encounter with a beneficiary and receive payment based on an interim all-inclusive rate. These FQHC/RHC claims distinguish general classes of services (for example, clinic visit, home visit, mental health services) by revenue code, the beneficiary to whom the service was provided, and other information relevant to determining whether the all-inclusive rate can be paid for the service. The claims contain very limited information concerning the individual practitioner, or even the type of health professional (for example, physician, PA, NP), who provided the service.

(1) Identification of Primary Care Services Rendered in FQHCs and RHCs

Starting in 2011, FQHC claims are required to include HCPCS codes that identify the specific service provided, in order for us to develop a statutorily required prospective payment system for FQHCs. In addition, FQHCs were required to submit a HCPCS code to receive payment for the Welcome to Medicare visit (G0402) beginning in 2009. Therefore, we can identify primary care services for FQHCs that are participating in an ACO by using their HCPCS codes for services furnished on or after January 1, 2011, and by using HCPCS code G0402 furnished on or after January 1, 2009. RHCs are generally not required to report HCPCS codes, except that: (1) For services furnished on or after January 1, 2009, RHCs may submit HCPCS code G0402 to receive payment for the Welcome to Medicare visit, and (2) for services furnished on or after January 1, 2011, RHCs may submit HCPCS codes to receive payment for the annual wellness visits (G0438 and G0439). However, for purposes of assigning patients and calculating the benchmark, we will also need to identify other primary care services that were furnished by FQHCs and RHCs. In order to identify primary care services rendered in FQHCs and RHCs that are primary care services, and that are not required to be reported by HCPCS codes, we are adopting the commenters' suggestions to use the revenue center codes. We have reviewed these revenue center codes and agree that for purposes of the Shared Savings Program, the revenue center codes can be used as a substitute for the primary care HCPCS codes which RHCs do not report, and which FQHCs were not required to report prior to January 1, 2011. Specifically, we believe that it is possible to employ these revenue codes to identify primary care services by constructing an appropriate cross-walk between the revenue center codes and the HCPCS primary care codes based on their definitions.

In order to establish such a cross-walk, we compared the HCPCS codes that are considered as being primary care services for purposes of the Shared Savings Program with the revenue center codes that are reported on FQHC/RHC claims. As discussed previously, the primary care HCPCs codes used for assignment are as follows:

- 99201 through 99215; (office/outpatient visits).
- 99304 through 99340; (nursing facility visits/domiciliary home visits).
- 99341 through 99350; (home visits).
- Welcome to Medicare visit (G0402).
- Annual wellness visits (G0438 and G0439).

FQHCs and RHCs report services on their claims using the following revenue center codes:

0521—Clinic visit by member to RHC/FQHC

0522—Home visit by RHC/FQHC practitioner

0524—Visit by RHC/FQHC practitioner to a member, in a covered Part A stay at the SNF

0525—Visit by RHC/FQHC practitioner to a member in an SNF (not in a covered Part A stay) or NF or ICF MR or other residential facility

We are able to cross walk the ''primary care'' HCPCS codes to comparable revenue center codes based on their code definitions. For example, HCPCS codes 99201 through 99215 (office/outpatient visits) will be cross-walked to revenue center code 0521. Because the focus of FQHCs and RHCs is on primary care, we believe these revenue center codes, when reported by FQHCs/RHCs, would represent primary care services and not more specialized care. This cross-walk will allow us to use the available revenue center codes as part of the beneficiary assignment process for FQHC/RHC services in place of the unavailable HCPCS codes which will be used more generally. We will establish and update this crosswalk through contractor instructions. For FQHCs, we will use the HCPCS codes which are included on their claims starting on January 1, 2011.

(2) Identification of the Type of Practitioner Providing the Service in an FQHC/RHC

Secondly, in order to be able to align beneficiaries with the entities that wish to participate in the Shared Savings Program, we also generally require data that identify the type of practitioner providing the service (that is, a physician, NP, PA, or CNS). This is because, as discussed previously, section 1899(c) of the Act requires that assignment must be based upon services furnished by physicians. As previously noted, FQHC/RHC claims contain limited information as to the type of practitioner providing a service because this information is not necessary to determine payment rates for services in FQHCs and RHCs.

Based upon our review of the many helpful comments we received on these issues, we now agree that we can develop a process that will allow FQHCs and RHCs to fully participate in the Shared Savings Program. We can do this by using the limited provider NPI information on the FQHC/RHC claims in combination with a supplementary attestation requirement. This would be consistent with comments we received encouraging us to identify the provider that furnished services in FQHCs/RHCs by using the NPI of the attending provider, supplemented by additional information that the FQHCs/RHCs could separately submit.

More specifically, from the FQHC/RHC claims, we will use the Attending Provider NPI field data which is defined as being: ''the individual who has overall responsibility for the patient's medical care and treatment reported in this claim/encounter.'' Although the attending provider NPI is used to report the provider who is responsible for overall care, it does not identify whether this provider furnished the patient care for the beneficiary. Therefore, to meet the requirement of section 1899(c) of the Act which requires that assignment must be based upon services furnished by physicians, we will supplement these limited claims data with an attestation that would be part of the application process for ACOs that include FQHCs/RHCs. We will require ACOs that include FQHCs/RHCs to provide to us, through an attestation, a list of their physician NPIs that provide direct patient primary care services, that is, the physicians that actually furnish primary care services in the FQHC or RHC. Other physician NPIs for FQHCs/RHCs will be excluded from the assignment process, such as those for physicians whose focus is on a management or administrative role. The attestation must be submitted as part of the application for ACOs that include FQHCs/RHCs. Such ACOs will also be required to notify us of any additions or deletions to the list as part of the update process discussed in section II.C.4. of this final rule. The attestation by the ACO will better enable us to determine which beneficiaries actually received primary care services from an FQHC/RHC physician.

We will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to us through the attestation process to identify and assign beneficiaries to ACOs that include FQHCs/RHCs using the step-wise assignment methodology as previously explained.

In this way, we would then be able to assign beneficiaries to ACOs on the basis of services furnished in FQHCs and RHCs in a manner consistent with how we will more generally assign primary care services performed by physicians as previously described. We believe this approach meets the statutory requirement in section 1899(c)

of the Act that assignment be based on the utilization of primary care services ''provided'' by an ACO professional described as a physician in section 1899(h)(1)(A) of the Act.

(3) Identification of the Physician Specialty for Services in FQHCs and RHCs

As previously explained, the third type of information we generally need under the step-wise assignment process discussed previously to assign beneficiaries with the entities that wish to participate in the Shared Savings Program is data that identify physician specialty. However, we agree with commenters who pointed out that the Medicare FQHC health benefit was established in 1991 to enhance the provision of primary care services in underserved urban and rural communities. Commenters pointed out that virtually all services provided under the Medicare FQHC benefit are primary care services. We also agree with commenters that RHCs predominantly provide primary care services to their populations. Therefore, when a physician provides a service in an FQHC or an RHC, we believe the physician is functioning as a primary care physician comparable to those physicians that define themselves with a primary specialty designation of general practice, family practice, internal medicine, or geriatric medicine. As a result, we do not believe it is necessary to obtain more detailed specialty information (either through the claims NPI reporting or as part of the attestation process) for the physicians that furnish services in FQHCs and RHCs. Longer term, we will consider establishing definitions for data fields on the claims submitted by FQHCs and RHCs, such as for attending NPI or other NPI fields, which could be used to identify the type of practitioner providing the service. This may enable us to eliminate the attestation which will part of the application process for ACOs that include FQHCs/RHCs.

Final Decision: In § 425.404, we are modifying the policy that we proposed in response to comments to establish a beneficiary assignment process that will allow primary care services furnished in FQHCs and RHCs to be considered in the assignment process for any ACO that includes an FQHC and/or RHC. (These changes to the assignment process will also allow FQHCs and RHCs to form ACOs independently, without the participation of other types of eligible entities.) Operationally we will assign beneficiaries to ACOs that include FQHCs/RHCs in a manner consistent with how we will assign beneficiaries to other ACOs based on primary care services performed by physicians as previously described.

We will require that an ACO that include FQHCs and/or RHCs to provide us, through an attestation, with a list of the physician NPIs that provide direct patient primary care services in an FQHC or RHC. This attestation will be part of the application process for all ACOs that include FQHCs and/or RHCs as ACO participants. We will then use the combination of the ACO's TINs (or other unique identifiers, where appropriate) and these NPIs provided to us through the attestation process to identify beneficiaries who receive a primary care service in an FQHC or RHC from a physician, and to assign those beneficiaries to the ACO if they received the plurality of their primary care services, as determined based on allowed charges for the HCPCS codes and revenue center codes listed in the definition of primary care services, from ACO providers/suppliers.

2. Prospective vs. Retrospective Beneficiary Assignment To Calculate Eligibility for Shared Savings

Section 1899(d)(1) of the Act provides that an ACO may be eligible to share savings with the Medicare program if the ACO meets quality performance standards established by the Secretary (which we discuss in section II.F. of this final rule) and meets the requirements for realizing savings for its assigned beneficiaries against the benchmark established by the Secretary under section 1899(d)(1)(B) of the Act. Thus, for each performance year during the term of the ACO's participation agreement, the ACO must have an assigned population of beneficiaries. Eligibility for shared savings will be based on whether the requirements for receiving shared savings payments are met for this assigned population. In the proposed rule, we discussed two basic options for assigning beneficiaries to an ACO for purposes of calculating eligibility for shared savings during a performance year. The first option is that beneficiary assignment could occur at the beginning of the performance year, or prospectively, based on utilization data demonstrating the provision of primary care services to beneficiaries in prior periods. The second option is that beneficiary assignment could occur at the end of the performance year, or retrospectively, based on utilization data demonstrating the provision of primary care services to beneficiaries by ACO physicians during the performance year. However, as we discuss later in this final rule, these two basic approaches could be combined in any number of ways in an attempt to realize the most positive aspects of each approach and/or avoid the major disadvantages of each. For example, prospective assignment of beneficiaries could be combined with a retrospective reconciliation process that adjusts for certain prospectively assigned beneficiaries who have moved or changed health care providers during a performance year.

We proposed to adopt a retrospective approach for a number of reasons. First, the actual population served by a set of physicians changes significantly from year to year. Because Medicare FFS beneficiaries have the right to see any enrolled physician, there is typically more year-to-year variability in treating physicians for this population when compared to patients in managed care programs. Analysis of the PGP population did show approximately a 25 percent variation in assignment from year to year. If population seen by an ACO changes by 25 percent during the year, a prospectively assigned beneficiary population would reflect some beneficiaries who did not actually receive the plurality of their care from physicians in the ACO during the performance year. Final retrospective assignment of the population, on the other hand, would include in the actual performance year expenditures for an ACO only for those beneficiaries who received a plurality of their care from the ACO during the performance year.

Second, identifying an assigned beneficiary population prospectively may lead an ACO to focus only on providing care coordination and other ACO services to this limited population, ignoring other beneficiaries in their practices or hospitals. Given that the goal of the Shared Savings Program is to change the care experience for all beneficiaries, ACO participants and ACO providers/suppliers should have incentives to treat all patients equally, using standardized evidence-based care processes, to improve the quality and efficiency of all of the care they provide, and in the end they should see positive results in the retrospectively assigned population.

In the proposed rule, we acknowledged that there are merits in both approaches. It does seem appropriate for an ACO to have information regarding the population it will likely be responsible for in order to target its care improvements to those patients who would benefit the most. At the same time, we expressed our concern that we did not want to encourage ACOs to limit their care improvement activities to the subset of their patients that they believe may be

assigned to them. Finally, we considered that it was important that the assessment of ACO performance be based on patients who received the plurality of their primary care from the ACO in that performance year. Even under a more prospective assignment approach, there is reason to believe that a final retrospective redefinition of the assigned population to account for changes from prior periods would be required to ensure that the ACO is not held accountable for patients for whom it was not possible to provide care during the performance year. Under a more prospective system, the assignment would have to be adjusted every performance year to account for beneficiaries entering and leaving FFS Medicare and for those patients who move in and out of the geographic area of the ACO, as well as potentially other adjustments.

Considering the merits of both approaches, we took the position in the proposed rule that a retrospective approach to beneficiary assignment for purposes of determining eligibility for shared savings was preferable. We stated that the assignment process should accurately reflect the population that an ACO is actually caring for, in order to ensure that the evaluation of quality measures is fair and that the calculation of shared savings, if any, accurately reflects the ACO's success in improving the quality and efficiency of the care provided to the beneficiaries for which it was actually accountable. However, we also acknowledged the potential advantages of a more prospective approach, especially in providing ACOs with information about the patient population that is necessary for purposes of more effectively planning and coordinating care.

In the proposed rule, we also noted that in response to the November 17, 2010 RFI, of the few commenters favoring retrospective assignment, a group of commenters suggested the use of retrospective assignment for determining utilization and shared savings, but prospective assignment for purposes of determining which beneficiary identifiable data we would share with ACOs. We agreed that, given appropriate safeguards for maintaining the confidentiality of patient information, providing ACOs with meaningful information about their ''expected assigned population'' with the potential to identify an ''estimated benchmark target'' would be helpful. We discuss our policies regarding providing information to ACOs to help them understand their patient populations and better manage their care in section II.D. of this final rule.

Therefore, we proposed the combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of aggregate beneficiary level data for the historically assigned population of Medicare beneficiaries during the benchmark period. As we discussed in section II.D. of the proposed rule, we also proposed to provide ACOs with a list of beneficiary names, dates of birth, sex, and HCIN derived from the assignment algorithm used to generate the historical benchmark. We concluded that providing data on those beneficiaries that were assigned to an ACO in the benchmark period would be a good compromise that would allow ACOs to have information on the population they will likely be responsible for in order to target their care improvements to that population while still holding ACOs accountable only for the beneficiaries for whom they actually provided services during the performance year. We believed that such a combined approach would provide the best of both approaches while minimizing the disadvantages of either. We solicited comment on this approach.

Comment: The commenters were overwhelmingly in favor of prospective assignment. Many commenters, including MedPAC, argued that prospective assignment was important so that beneficiaries would have full knowledge of their inclusion in an ACO in advance and indeed that prospective assignment is necessary to engage beneficiaries effectively in the ACO process of more efficient and higher quality care. One commenter argued that retrospective assignment actually denies a beneficiary real choice, noting our observation in the proposed rule that under retrospective assignment it is not possible to inform beneficiaries of their assignment with an ACO in advance of the period in which they may seek services from the ACO. Most of these commenters also argued that prospective assignment is necessary to allow ACOs to plan care appropriately for the patients assigned to them. One commenter observed that a retrospective assignment method raises concerns about the ability of ACOs to manage population health in a way that generates savings. The commenter contended that providers need to know which patients for whom they are responsible in order to effectively coordinate care and implement care management program, and as a result, retrospective assignment could discourage participation in the Shared Savings Program.

Many commenters in favor of prospective assignment either denied that prospective assignment would lead to higher quality care for ACO patients than for others, or contended that the Shared Savings Program quality measures and monitoring activities would prevent and/or correct such behavior. One commenter argued that professional ethics and standards require that physicians not provide a lower level of care to one group of patients compared to another; the profession's commitment to its own ethics therefore will mitigate against ACO's providing a lower level of care to patients not prospectively attributed to it. Another commenter, however, acknowledged that an ACO would have a built-in incentive to discourage particularly high cost patients from joining their ACO since it would put the potential savings they might recoup at the end of the performance year in jeopardy, unless there is adequate risk adjustment.

A health care policy institute noted that 30 percent of beneficiaries attributed to an ACO in the current performance year were not attributed in the prior year. This suggests that basing attribution on data prior to the current performance year will lead to incorrect attribution of a substantial proportion of patients; using older years of data for attribution will lead to an even worse fit. Furthermore, 87.6 percent of patients seen by the ACO primary care physicians in a given performance year will be attributed to the ACO, so that the vast majority of patients utilizing services at an ACO will be attributed to the ACO. This commenter therefore recommended that we introduce a modified prospective methodology of attribution with current performance year data by adopting a near concurrent attribution model in which the ACO is held responsible only for the patients that received the plurality of their care from the ACO professionals within the ACO during a time period close enough to the performance year that it approximates the population seen during the year, and does not provide opportunities for gaming. Two commenters suggested alignment based on the prior 2 years weighted 50/50.

One commenter asserted that retrospective assignment undermines quality and cost objectives, and is unnecessary to avoid adverse selection. Noting that our stated goal is to prevent avoidance behavior around high-risk beneficiaries, this commenter recommended that an ACO applicant submit a panel of participating providers, including specialists, to CMS. We would use this list to look back at

the previous year's claims for primary care services provided by the primary care and/or specialty physician for the ACO beneficiaries. Patient assignment by CMS could be based on the plurality of primary care service visits provided. The ACO would then ensure that the individuals assigned by CMS were still the patients of the listed providers. One commenter argued that, by seeking to evaluate ACOs only on care actually rendered, we may be incentivizing ACOs to act directly contrary to the goal of having ACOs redesign care processes to improve care for all beneficiaries. Under the proposed rule, according to the commenter, ACOs will have every incentive not to redesign care processes so that high-risk, high-cost individuals are motivated to receive their care outside of the ACO.

Another commenter specifically questioned whether retrospective assignment would be appropriate for high risk populations and beneficiaries with special needs. Specifically, the commenter acknowledged that the methodology we proposed might be effective for the general Medicare population, but questioned how effective it would be for a high-risk population with complex medical problems and other special needs, stating that special needs beneficiaries would be better served by a more targeted approach that identifies a specific population, develops a model of care around the target risk group and predefines shared savings criteria in advance.

One commenter argued strongly for prospective assignment, but then stated: ''If CMS elects to use a retrospective patient assignment, then the Agency should consider providing the ACO with a list of 'potential' ACO patients prior to the beginning of the performance period.'' In a follow-up comment, however, this same commenter came down firmly in favor prospective assignment: ''We believe the final rule should include an option for an ACO to identify its population prospectively. With prospective assignment, ACOs can create systems to actively manage and engage patients * * * Restricting the beneficiary assignment to a retrospective methodology hampers ACOs' abilities to manage their patients proactively and effectively.''

A few commenters expressed conditional support for retrospective assignment. For example, one commenter stated that they understand the benefits and costs of both prospective and retrospective attribution. While recognizing the concerns that surround prospective attribution, including potential ''cherry-picking'' of patients, the commenter stated that patients have a legitimate interest in understanding which providers are in charge of their care and the incentives those providers have to provide quality care and reduce health care costs. Some of the commenters who argued for prospective assignment acknowledged that retrospective adjustments would be necessary to correct for changes such as beneficiaries that had moved out of the area, beneficiaries who had chosen to receive their services elsewhere, and for other similar matters. One commenter stated that the basic problem with ''pure'' prospective assignment (no reconciliation after the end of each performance year) in the Shared Savings Program is that it would: (1) Not give ACOs accountability for additional beneficiaries they take responsibility for during the performance year; and (2) give them accountability for beneficiaries they were no longer responsible for. A commenter also accepted retrospective assignment as manageable if the beneficiaries are assigned on a plurality of services provided, and if beneficiary data are shared prospectively during the benchmark period. Another commenter supported our hybrid approach to provide preliminary assignment information to ACOs combined with retrospective reconciliation, which will ensure ACOs are only assigned patients they provide care for during the performance year. Another commenter urged us ''at a minimum * * * to move further down the continuum toward some hybrid approach between prospective assignment and retrospective attribution.''

A few commenters recommended a hybrid approach combined with incentives for beneficiaries to enroll in an ACO, specifically, by modifying the patient assignment component of the rule to allow beneficiaries that prospectively enroll in an ACO to enjoy a portion of the savings that the ACO realizes, perhaps through a lower Part B premium.

A much smaller number of commenters agreed with our proposal for retrospective assignment. One commenter stated that retrospective assignment, though imperfect, is the only way to assign savings based on actual performance, and will encourage unbiased treatment. However, this same commenter requested an exception for primary care physicians who see high-risk patients for a single encounter. The commenter believed that omitting such patients from retrospective assignment for purposes of the shared savings payment calculations would avoid discouraging primary care physicians from taking on new, high-risk beneficiaries.

Another commenter was persuaded by the argument that retrospective assignment of beneficiaries to the ACO would create an environment where ACOs would be encouraged to provide effective care coordination for all beneficiaries with complex illnesses, but was nonetheless concerned that patient engagement would be more difficult when beneficiaries are not aware of the new delivery system. Another commenter strongly supported retrospective assignment as a more seamless approach, because prospective assignment would employ less reliable data, for example, data for patients who have moved or chosen a different provider. Another stated that early attribution may encourage providers to focus only on attributed beneficiaries and slow the implementation of wider scale changes.

A physician society believed the combined approach of retrospective beneficiary assignment for purposes of determining eligibility for shared savings balanced by the provision of beneficiary data and aggregate beneficiary level data for the assigned population of Medicare beneficiaries during the benchmark period is optimal, because it would provide ACO physicians with the information needed to manage their patient population, yet encourages high quality services to all beneficiaries. Another commenter was satisfied that the benefits of retrospective beneficiary assignment will likely outweigh any the concerns about choice that might remain because of the beneficiary notification, education and claims data-sharing opt-out provided for under the proposed rule. ''Retrospective assignment will likely encourage ACOs to provide the same level and type of services under consistent care delivery models to their entire beneficiary population.''

A patients' advocacy organization supported the agency's decision to assign beneficiaries retrospectively, out of fear that that prospective assignment might carry some risk that providers would ''cherry pick'' and seek to avoid certain high-risk individuals.

A physician society also supported our proposal: ''Because of [our] concerns with risk avoidance and other means to reduce costs and therefore create greater shared savings, we agree with the CMS decision to provide retrospective assignment. The proposal to provide prospective patient data to the ACO should provide the entity with the general patient population and other

demographic data that could help the ACO to make necessary decisions.''

A member of Congress also strongly supported our proposal for retrospective assignment: ''I support CMS' decision to assign Medicare beneficiaries retrospectively. I understand that many in the provider community would prefer prospective assignment, but fear it could create a two-tier system where assigned beneficiaries receive a heightened level of care and attention while the remainder of the patient population receives a lower level of care. Our intent in creating ACOs was to once again use Medicare to drive systematic, positive change in the delivery system. Retrospective assignment helps accomplish this goal by ensuring the best care for all.''

Another commenter believed that the method of assignment is less important than ensuring that ACOs receive information sufficient to understand and target their patient populations. Therefore, the commenter commended us for proposing to combine retrospective assignment with extensive data sharing about beneficiaries historically assigned and likely to be assigned to the ACO.

A few commenters suggested allowing ACOs a choice of prospective or retrospective assignment. One commenter would allow ACOs to elect either prospective or retrospective attribution of patients, adding that, if limited to one approach, prospective attribution is the only method compatible with population health management and its requirements.

Response: We appreciate the commenters' arguments about the advantages of a more prospective assignment methodology for purposes of patient care planning and other objectives. The intention of our proposal for retrospective assignment with prospective provision of beneficiary data was to strike an appropriate balance between the two approaches of prospective and retrospective assignment. In this final rule we similarly seek to strike an appropriate balance by accommodating the advantages of the prospective approach to a greater degree, moving, as one commenter suggested further down the continuum toward a more prospective approach, without abandoning our proposal to determine final assignment retrospectively.

We continue to believe that we should avoid as much as possible outcomes in which ACOs could be held accountable for costs related to beneficiaries who received care from ACO physicians in a prior year, but later moved away and received no services from the ACO during the performance year. We believe that ACOs should not be held accountable for the costs of patients for whom they are no longer to provide primary care due, for example, to a patient moving out of area during a performance year. Similarly, we believe that ACOs should have the opportunity to share in any savings realized through the application of the ACO's health planning, care coordination, and quality programs to patients who begin receiving primary care services from the ACO during a performance year. We took special note of the commenters who recommended prospective assignment with at least some retroactive adjustments to account for situations where prospective assignment would lead to negative or even unfair consequences for the ACO. We believe that the recommendations of these commenters amount to hybrid approaches that are not entirely dissimilar from our proposal, but that place a greater emphasis on the prospective elements of the hybrid than our proposal did. In light of the concerns raised by commenters, we agree that our proposal for a hybrid approach identifying a preliminary prospective population and then determining the final assignments at the end of the performance year should be modified in ways that further enhance its prospective aspects.

Therefore, in this final rule, we are modifying the policy that we proposed in response to comments to adopt a preliminary prospective assignment methodology with final retrospective reconciliation. Under this model, we will create a list of beneficiaries likely to receive care from the ACO based on primary care utilization during the most recent periods for which adequate data are available, and provide a copy of this list to the ACO. During the performance year, we will update this list periodically on a rolling basis to allow the ACO to adjust to likely changes in its assigned population. (We describe the nature and timing of this updating in the discussion of data sharing in section II.D. of this final rule.) At the end of each performance year, we will reconcile the list to reflect beneficiaries who actually meet the criteria for assignment to the ACO during the performance year. Determinations of shared savings or losses for the ACO will be based on this final, reconciled population. We believe this preliminary prospective assignment model with retrospective reconciliation will provide the ACO adequate information to redesign care processes while also encouraging ACOs to standardize care for all Medicare FFS beneficiaries instead of a subset. At the same time, we also believe that a preliminary prospective model with retrospective reconciliation will provide adequate incentives for each ACO to provide quality care to its entire beneficiary population.

It is important to note that the CMS Center for Medicare and Medicaid Innovation has announced a Pioneer ACO Model which will test alternative savings and alignment (the equivalent of assignment under the Shared Savings Program) () models as we proceed with implementing the Shared Savings Program. Under the Pioneer ACO Model, an ACO may select either prospective or retrospective alignment of beneficiaries. Under the prospective approach CMS will identify the population of Medicare beneficiaries for whom an ACO is accountable through analysis of the prior 3 years of fee-for-service claims data (weighted 60 percent for the most recent year, then 30 percent for the previous year, and 10 percent for the earliest year). The actual historical data for these beneficiaries will make up the benchmark spending. Pioneer ACOs that select prospective alignment will be accountable for the cost and quality outcomes of all their prospectively aligned beneficiaries at each end-of-period reconciliation, with certain exceptions. We will consider beneficiaries as no longer being in the ACO's designated patient population for purposes of performance measurement and expenditure calculations if they: (1) Have any months of Medicare Advantage enrollment or enrollment in only Part A or only Part B at any point during the performance period; (2) transfer their Medicare address to a Core Based Statistical Area (CBSA) or rural county that is not adjacent to that of the ACO's location (where the majority of its clinicians are located); or (3) receive more than 50 percent of their evaluation and management allowed charges in non-adjacent CBSAs or rural counties during the performance period. The adoption of this approach under the Pioneer ACO Model will provide us with an opportunity to gain experience and evaluate a more prospective hybrid model than the approach that we are adopting in this final rule. We will study the results of the Pioneer ACO Model very carefully, and will consider in our next rulemaking whether it is appropriate to revise our approach to assignment in the Shared Savings Program in the light of those interim results.

Comment: Many commenters, including MedPAC, argued that beneficiaries should be allowed to opt

out of assignment to an ACO (not just, as we proposed, of data sharing), even if they want to continue receiving services from ACO participants. A number of commenters went further to argue that beneficiary choice should be the sole basis for assignment to an ACO, that is, that beneficiary assignment to ACOs should actually be more like a process of beneficiary enrollment in an ACO. For example, one insurance organization recommended a ''physician-of-choice solution.'' A physician society recommended that CMS should prospectively allow patients to choose their own Medicare ACO. Other commenters referred to assignment based on the beneficiary's identification of their ''primary care provider or medical home.'' A national organization of physicians recommended that, instead of retrospective attribution, CMS should adopt a prospective approach that allows patients to volunteer to be part of the ACO and permits the ACOs to know up-front those beneficiaries for whom the ACO will be responsible.

Another commenter recommended that beneficiaries should opt in to the ACO (as the MA program is currently administered) rather than retrospective assignment. The commenter noted our statement in the proposed rule that the ''successful creation of this relationship is not possible when beneficiaries are not aware of the new delivery system available through ACOs and the possibility of being included in the population assigned to an ACO.''

Yet another commenter argued that, since Medicare beneficiaries must elect to participate in a MA organization, we should explain why we are not giving Medicare eneficiaries the option or the opportunity to elect to participate in the Shared Savings Program. The commenter believes that, by forcing Medicare beneficiaries into a shared savings program, the savings projected in the regulatory impact statement are unrealistic unless ACOs reduce care for their assigned Medicare beneficiaries.

These arguments were cast primarily in terms of giving beneficiaries the maximum opportunity for free choice about their participation in the Shared Savings Program. (Some of these commenters also contended that adopting this policy would allow us to abandon the proposal restricting primary care physicians to participation in one ACO, which we adopted to prevent uncertainty in the assignment process.)

Response: In the proposed rule, we emphasized that the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive their services. Rather, the statutory term ''assignment'' in this context refers only to an operational process by which Medicare will determine whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from a specific ACO so that the ACO may be appropriately designated as being accountable for that beneficiary's care. We also emphasized that the continued exercise of free choice by beneficiaries in selecting the physicians and other health care practitioners from whom they receive their services is a presupposition of the Shared Savings Program, in the sense that assignment would be based on each beneficiary's exercise of free choice in seeking primary care services.

We appreciate that those commenters advocating freedom for beneficiaries to opt out of assignment to an ACO, as well as those advocating that assignment actually be based on voluntary choice or enrollment by beneficiaries, are advancing these recommendations as means of extending the principles of beneficiary free choice that we enunciated in the proposed rule. However, we do not believe that ACO enrollment is an ''appropriate method to assign Medicare fee-for-service beneficiaries to an ACO'' as required by the statute because enrollment is a process that fits better in the context of MA, and the Shared Savings Program is certainly not intended to be a managed care program in a new guise. One important distinction between an ACO and many MA organizations is that beneficiaries are not locked into receiving services from the ACO to which they are assigned, and may continue to seek care from any provider they choose. Furthermore, the statute specifies that ''the methodology for assigning Medicare FFS beneficiaries to an ACO'' must be ''based on their utilization of primary care services provided under this title'' by physicians who are providers/suppliers in the ACO. A prospective approach that allows patients to volunteer to be part of the ACO would completely sever the connection between assignment and actual utilization of primary care services. A patient could volunteer to be part of an ACO from which he or she had received very few services or no services at all. An attempt could be made to mitigate this concern under a voluntary enrollment process for assignment by requiring that a beneficiary receive a minimum number or proportion of services from the ACO for the enrollment to be effective. But such measures would begin to transform a ''voluntary'' selection process into something more like the kind of statistical attribution model that we proposed and that most commenters endorsed (whether they preferred prospective or retrospective statistical attribution). Similarly, we do not believe it is necessary to provide an opportunity for a beneficiary to opt out of an ACO in order to preserve adequate beneficiary free choice. Beneficiaries remain free to seek services wherever they wish, and assignment results only from a beneficiary's exercise of that free choice by seeking and receiving services from ACO providers/suppliers. We understand the concerns of the commenters that beneficiaries may prefer leaving existing relationships with their provider in order to avoid being subject to the ACO's interventions. However, for the reasons we just stated, we do not believe that an enrollment mechanism or voluntary beneficiary ''opt-in'' would be appropriate.

Comment: Some other commenters argued for certain restrictions on beneficiary free choice. Some of these commenters argued that beneficiaries who opt out of data sharing should also be excluded from the ACO, on the grounds that it would not be fair to hold ACOs accountable for the care of patients unwilling to share the data necessary for planning efficient and high quality care. Another asserted that we had proposed ''the worst of both worlds for both the beneficiary and the providers,'' because beneficiaries can opt-out of data-sharing but not the program, which would prevent providers from having sufficient information to properly care for and manage the beneficiaries. The commenter argued that the best approach would be to allow beneficiaries the opportunity to fully withdraw from the program without having to seek care from another provider; structuring an opt-out option that prevents both data-sharing and attribution of that beneficiary to an ACO while allowing them to continue seeking care from their usual providers.

A commenter supported the patient's freedom to choose a provider and hoped that patients always have such a right. However, the commenter also argued that holding an ACO accountable for financial results of a patient who expressly chooses not to participate in critical elements of quality and care coordination is in conflict with the very purpose of an ACO. The commenter

therefore recommended that the experience and data for a beneficiary should be deleted for the entire year when the beneficiary chooses to ''opt out'' of the critical and core process of information sharing for quality improvement and care coordination, and would not be brought back in until the beneficiary has exercised an ''opt-in'' process or meets the criteria for assignment to a different ACO.

Other commenters argued that some restrictions on assigned beneficiaries seeking services outside the ACO may be necessary and appropriate in order for the ACO's measures to provide more cost-efficient care to be effective. One commenter suggested that unrestricted beneficiary choice poses a tremendous impediment to successful ACO operation, and that, while significant restrictions on beneficiary behavior may be undesirable, providing ACOs with the ability to more carefully direct and manage the care of high-cost patients would be a significant improvement to the Shared Savings Program.

Another commenter objected that ACOs may not discourage patients from seeking care outside an ACO, yet are financially liable for unmanageable patient behavior. The commenter recommended that ACOs should not be held responsible for unmanageable patient behavior unless the patients are restricted to using ACO-providers/suppliers, and that there should be some acceptable incentives to keep beneficiaries in the ACO, such as preferred provider rates.

Another commenter recommended adopting such restrictions along with establishing a ''gatekeeper'' model for ACOs, under which primary care physicians who are ACO providers/suppliers in an ACO would be in a position to identify the Medicare beneficiaries in the ACO and effectively coordinate care with efficient healthcare providers that are as equally focused (and incentivized) on both quality and cost. Without this control, the commenter believes that it would be difficult to hold the PCP accountable for the quality and cost of services received by the beneficiary.

Yet another commenter contended that ACOs need the ability to require or incentivize a patient to use ACO providers otherwise it will be nearly impossible to be held accountable for cost and quality of a population's health care. And another commenter argued that an ''any willing provider'' approach would prevent ACOs from developing specialty care focused networks and limiting network participation to providers that meet specific quality standards and other criteria that ACOs may wish to establish, thus compromising their' ability to meet cost and quality standards that qualify providers for shared savings.

On the other hand, some commenters urged us to confirm and/or emphasize certain basic beneficiary rights, such as the right ''to receive care outside the Medicare ACO at no penalty to the patient.'' A nursing organization recommended clear and explicit language to reassure beneficiaries about the process [of opting out] and its pros and cons, and that there is no limit, penalty, or modification to their services by choosing to opt out. Another commenter urged that we seek a mechanism to measure whether patients in an ACO are restricted by physician influence not to seek care outside the ACO and that patients are receiving necessary care in a timely manner, expressing the concern that primary care providers may try to manage a patient's condition and not appropriately refer the patient to a specialist because the potential higher cost of specialty care will potentially decrease the ACO's chances of meeting CMS benchmarks and achieving shared savings.

Another commenter strongly supported our decision to allow beneficiaries to seek care outside of the ACO if they desire. The commenter noted that this policy provides important reassurance to Medicare beneficiaries who can be wary of change and who may react negatively if they believe they are being ''locked in'' to a new system without their consent. Another commenter agreed that a beneficiary's freedom to choose providers is especially critical to Medicare beneficiaries who have multiple chronic conditions or other complex medical conditions. Furthermore, the commenter recommended that we should confirm that beneficiaries will also have the freedom to seek care for particularly complex medical conditions or treatments from experienced providers at recognized centers of excellence.

Response: We strongly believe that it would be inappropriate for the Shared Savings Program to incorporate features such as a beneficiary ''lock-in'' to providers within the ACO, automatic exclusion of certain types of beneficiaries, or similar measures advocated by some commenters. An essential element of what distinguishes the Shared Savings Program from a managed care program is precisely the absence of any ''lock-in'' restrictions and financial or other penalties for beneficiaries that seek services from the specialist physicians and other practitioners of their choice. Beneficiaries who are assigned to ACOs under the Shared Savings Program remain Medicare fee-for-service beneficiaries, retaining their full freedom of choice regarding where to receive services. We therefore take this opportunity, as requested by a number of commenters, to confirm and emphasize that basic beneficiary rights are maintained under the Shared Savings Program, most especially (but not exclusively) the right to receive care from physicians and other medical practitioners of their choice outside the ACO at no penalty to the patient.

Comment: A commenter recommended that ACOs should have the option of excluding from assignment certain patients, such as those patients expected, based on the most recent historical claims data, to get a very high percentage of their care from non-primary care physicians (the ''specialty-managed patient'' factor), and those permanently relocating away from the ACO's service area early in the contract period, for example before the six-month mark each year (the ''former patient'' factor).

Another commenter recommended a number of exclusions from assignment to ACOs, including Medicare beneficiaries older than age 75, Medicare beneficiaries living in a skilled nursing home or a nursing home, Medicare beneficiaries that receive Medicare based on end-stage renal disease, and Medicare beneficiaries who are diagnosed with AIDS, Alzheimer's, cancer, heart disease, or a similar diagnosis.

A commenter recommended that dialysis patients should be excluded from assignment to an ACO, on the grounds that there is a strong likelihood that ACOs will not want to assume the responsibility for patients on dialysis or at a high risk for initiating dialysis or receiving a kidney transplant. The commenter believes that this may have a negative effect on kidney patients' access to the most appropriate care, especially in regions with just one ACO, an ACO with the minimal number of beneficiaries, or with nominal provider diversity. The commenter thus urged that, to ensure patient access to, and the quality of, dialysis care and transplantation options are not compromised as a result of the ACO program, dialysis and transplant patients should not be included as ACO beneficiaries.

Response: We believe that adopting restrictions or exclusions on beneficiaries with certain conditions or utilization patterns from assignment to ACOs under the Shared Savings

Program would be inappropriate. The purpose of the Shared Savings Program is to promote accountability for a patient population and coordination of items and services under Parts A and B and to encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Because beneficiaries with serious conditions may receive the greatest benefits from greater accountability, enhanced coordination, and redesigned care processes, the goals of the program would be undercut if these beneficiaries were excluded from the program. The statute itself requires that we monitor ACOs to prevent avoidance of ''at risk'' beneficiaries. Specifically, section 1899(d)(3) of the Act provides that: ''[i]f the Secretary determines that an ACO has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO the Secretary may impose an appropriate sanction on the ACO, including termination from the program.'' The statute thus clearly assumes that beneficiaries with severe and chronic conditions that may increase costs will and should be included in beneficiary population assigned to an ACO. Otherwise, there would be no need to monitor whether ACOs have taken steps to avoid assignment of such beneficiaries to the ACO.

Comment: One commenter objected that Medicare beneficiaries do not get to pick their primary care physicians, but are assigned to them a year after they begin participating in the ACO based on who they used in the past. The commenter therefore asked: ''How is Medicare going to determine how to assign the beneficiaries without overloading one doctor more than others?''

Response: Beneficiaries are assigned to ACOs on the basis of services they actually receive from physicians in an ACO during a performance year. Assignment thus presupposes beneficiary choice of the specific physician or physicians from whom they receive services. Beneficiaries are assigned to ACOs for the purposes of holding the ACO accountable for the quality and cost of care provided to the beneficiary. However, beneficiaries are not assigned to a particular physician, and remain free to seek care from any physicians they choose. Similarly, physicians are not required to accept patients beyond the limits on patient loads that they establish for their practices. Therefore, the operation of the Shared Savings Program in no way threatens to overload some doctors more than others.

Comment: One commenter recommended against exclusive attribution of beneficiaries to only one ACO, on the grounds that it is likely that more than one ACO will provide services to a beneficiary during a performance year. The commenter recommended shared attribution with savings shared in proportion to the total billed services of each ACO.

Response: Section 1899(c) of the statute refers to the assignment of ''Medicare fee-for-service beneficiaries to *an* ACO.'' (Emphasis supplied.) Therefore it is not clear the statute would permit shared assignment and shared attribution of savings to more than one ACO. We also note that adopting this policy would create a degree of operational complexity for both the Medicare program and for participating ACOs that we do not believe to be acceptable, especially in the early stages of the program.

Final Decision: Under § 425.400 of this final regulation, we are revising our proposed policy to provide for prospective assignment of beneficiaries to ACOs in a preliminary manner at the beginning of a performance year based on most recent data available. Assignment will be updated quarterly based on the most recent 12 months of data. Final assignment is determined after the end of each performance year based on data from that year. We are also finalizing our proposal that beneficiary assignment to an ACO is for purposes of determining the population of Medicare FFS beneficiaries for whose care the ACO is accountable, and for determining whether an ACO has achieved savings, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services. Beneficiaries assigned to ACOs under the Shared Savings Program retain their full rights as Medicare fee-for-service beneficiaries to seek and receive services from the physicians and other medical practitioners of their choice. No exclusions or restrictions based on health conditions or similar factors will be applied in the assignment of Medicare FFS beneficiaries. We are also finalizing our proposal to determine assignment to an ACO under the Shared Savings Program based on a statistical determination of a beneficiary's utilization of primary care services, rather than on a process of enrollment or ''voluntary selection'' by beneficiaries. The specific methodology (the ''step-wise'' approach) is described in § 425.402. In that methodology, we are also finalizing our proposal to assign beneficiaries to no more than one ACO.

3. Majority vs. Plurality Rule for Beneficiary Assignment

Section 1899(c) of the Act requires that Medicare FFS beneficiaries be assigned to ''an ACO based on their utilization of primary care services'' furnished by an ACO professional who is a physician, but it does not prescribe the methodology for such assignment, nor criteria on the level of primary care services utilization that should serve as the basis for such assignment. Rather, the statute requires the Secretary to ''determine an appropriate method to assign Medicare FFS beneficiaries to an ACO'' on the basis of their primary care utilization.

An obvious general approach would be to make such an assignment on the basis of some percentage level of the primary care services a beneficiary receives from an ACO physician. In the proposed rule, we considered the more specific issue of whether to assign beneficiaries to an ACO when they receive a plurality of their primary care services from that ACO, or to adopt a stricter standard under which a beneficiary will be assigned to an ACO only when he or she receives a majority of their primary care services from an ACO.

Under the PGP demonstration beneficiaries were assigned to a practice based on the plurality rule. By employing a plurality standard for primary care services, our analysis indicates that between 78 and 88 percent of the patients seen for primary care services at the PGP during the year were subsequently assigned to that PGP group. As measured by allowed charges (evaluation and management CPT codes), the PGP provided on average 95 percent of all primary care services provided to the assigned patients.

We proposed to assign beneficiaries for purposes of the Shared Savings Program to an ACO if they receive a plurality of their primary care services from primary care physicians within that ACO. We believed that the plurality rule would provide a sufficient standard for assignment because it would ensure that beneficiaries will be assigned to an ACO when they receive more primary care from that ACO than from any other provider. This would result in a greater number of beneficiaries assigned to ACOs, which could enhance the viability of the Shared Savings Program, especially in its initial years of operation.

Comment: Some commenters addressed the specific issue of employing a plurality versus majority standard as the basis for beneficiary assignment. One individual maintained

(without elaboration) that deciding upon assignment of patients to ACOs on the basis of plurality rather than majority provider provision of services enhances the likelihood of financial penalties upon ACOs. A number of commenters recommended majority assignment in place of a plurality standard. One of these commenters contended that a plurality could lead to the undesirable consequence of accountability without responsibility whenever the percentage is less than the majority. The commenter noted that, by definition, a plurality is simply more than any other, and the proposed rule did not recommend any minimum percentage. Another commenter criticized our attribution proposal on the grounds that it would produce many patients who have very loose, if any, true connection to [an] ACO and its providers. The commenter recommended a majority standard as one of several measures to provide a stricter attribution standard that would only assign patients with relatively strong relationships to an ACO. Yet another commenter would revise and simplify the basis for assignment to be beneficiaries' receipt of a majority of their primary care visits, stating that the experience in local markets is that buy-in is greatest when providers are assured their population reflects the patients for whom they provide the most care and thus have maximum ability to affect through quality/efficiency improvements. This, according to the commenter, also helps to ensure the payment model will accurately reward (or penalize) their success (or deficiencies) in caring for their assigned population.

Some commenters expressed support for the plurality standard. One noted that using a plurality standard takes into account the variability in utilizing primary care physicians. Other commenters stated that a plurality standard was at least ''workable'' or ''acceptable.'' However, some of the commenters who expressed support for a plurality standard also endorsed adopting a minimum threshold for assignment

Response: We are finalizing our proposal to adopt a plurality rule as the basis for assignment. Adoption of a majority standard for assignment would necessarily result in the assignment of fewer beneficiaries to each ACO. Adopting a stricter majority standard would not be conducive to assignment of enough beneficiaries to ACOs for the Shared Savings Program to be viable or to make a contribution to improving quality and promoting more cost-effective care for Medicare beneficiaries. We also believe it is in the best interest of the participating ACOs to have more beneficiaries assigned to promote statistical stability. Moreover, we believe that use of a plurality standard creates a greater incentive for ACOs to redesign care processes for all FFS beneficiaries that receive care from the ACO and promotes accountability for patients that might otherwise fall through the cracks because they would not meet a majority standard. Finally, it is reasonable for an entity that provides more of a beneficiary's primary care than any other provider, to coordinate care for that beneficiary.

Comment: Several commenters were concerned about assignment of beneficiaries that received care outside of a reasonable geographic distance from the ACO. For example, a number of commenters expressed concern about the impact of ''snowbirds,'' beneficiaries who spend parts of each year in different locations, under the plurality standard for assignment. One noted that assigning patients to an ACO based on the plurality of primary care services provided will result in ACOs being responsible for patients who spend a significant portion of the year residing outside of the ACO service area, and that there is already great difficulty in trying to coordinate care for patients who split their residence between two locations. A number of these commenters cited the exclusion of ''snowbirds'' from MA plans as a precedent.

Another commenter also advocated a list of exclusions from assignment, including a geographic exclusion, noting that, by limiting the distance that the beneficiary may reside from the ACO participants, ACOs are more likely to be assigned beneficiaries who are able to seek other types of care from the ACO.

Similarly, a health care provider recommended that we should exclude beneficiaries who receive more than 50 percent of their evaluation and management allowed charges in non-adjacent communities during the performance year.

Response: With regard to the issues concerning ''snowbirds,'' beneficiaries who travel frequently, and similar situations, we believe that such situations pose a much smaller problem in the Shared Savings Program than they do in other programs, such as the MA program. This is because the assignment methodology under the Shared Savings Program is essentially self-correcting for the effects of seasonal migrations and extensive travel, since it directly reflects where a beneficiary receives the plurality of his or her primary care services. A beneficiary who travels or resides in more than one location will not be assigned to an ACO unless he or she receives the plurality of primary care from that ACO.

Furthermore, one reason for the exclusion of ''snowbirds'' from MA plans is that beneficiaries who make seasonal migrations cannot adhere to the network arrangements that are an intrinsic feature of managed care. The ACO model does not include the use of networks or any restrictions on where beneficiaries can receive care. It is true that ''snowbirds'' may be assigned to an ACO on the basis of receiving a plurality of primary care in one location, and that ACO will still be responsible for costs related to care in the alternate location. However, any beneficiary assigned to an ACO remains free to receive substantial amounts of care outside the ACO, even if they remain year-round within the geographical area of the ACO, and for reasons we have already discussed, we do not believe that it is appropriate to adopt restrictions and exclusions that hinder beneficiary freedom to choose where to receive care. We believe that this principle applies equally to the issue of seasonal migration (''snowbirds'') and other issues of geography (for example, distance from an ACO) that commenters raised. Therefore, we do not believe that it is appropriate to adopt restrictions or exclusions on assignment to account for seasonal migration or any other geographical factor in the Shared Savings Program

Comment: A CAH requested a very different assignment methodology, specifically, that all the beneficiaries in their service area be assigned to their rural ACO. The commenter explained that, if we were not to allow this model, rural patients would be unable to be properly assigned to an ACO, and the CAH would have to join other rural providers to meet the 5,000 beneficiary requirement.

Response: We believe that this suggestion is incompatible with the statute, which requires that assignment be based on the utilization of primary care services from a physician who is a provider/supplier in an ACO, not the location of beneficiaries within the area served by an ACO.

Comment: A number of commenters recommended establishing a minimum threshold of primary care services for assignment to prevent providers from being evaluated on beneficiaries for whom they provide limited services and thus have limited opportunities to influence care or coordination. Other commenters supported a two-visit threshold as the minimum for

beneficiary assignment. Several major medical institutions recommended that we establish a threshold of at least three visits which would provide more assurance of continuity with the ACO and more patients who have continuing needs. A medical association urged that there must be a floor to the plurality of primary care charges used for that assignment, recommending a floor of 20 percent—meaning that unless the ACO is responsible for at least 20 percent of a patient's primary care charges, that patient would not be assigned to any ACO. Another commenter recommended 25 percent. Yet another commenter advocated a minimum percentage between thirty and forty. And still another recommended 50 percent of primary care visits.

MedPAC discussed the possibility of establishing a 10 percent threshold (citing the Pioneer ACO demonstration threshold of 10 percent or less of E&M charges) in the course of endorsing the step-wise method of assigning beneficiaries: ''we would prefer the step-wise option which assigns beneficiaries first to primary care physicians if possible and then to certain specialty physicians if the share of evaluation and management visits (or charges) to primary care physicians falls below a threshold value. (The Pioneer ACO demonstration sets the threshold as 10 percent or less of E&M charges.)''

Response: In this final rule, we have decided not to adopt a threshold for assignment for reasons similar to those which motivated our decision to maintain a plurality standard for assignment. Adoption of a threshold, like adoption of a majority standard for assignment, would necessarily result in the assignment of fewer beneficiaries to ACOs generally and to each ACO in particular. We believe it is in the general interest of the Shared Savings Program, and in the best interest of each ACO, to have more beneficiaries assigned to promote statistical stability. Moreover, we believe that use of a plurality standard without a threshold creates a greater incentive for ACOs to redesign care processes for all FFS beneficiaries that receive care from the ACO, and thus promotes accountability for patients that may fall through the cracks because they fail to meet a minimum threshold.

Finally, in the proposed rule we considered the issue of how to determine when a beneficiary has received a plurality of primary care services from an ACO. We noted the plurality could be determined either on the basis of a simple service count or on the basis of the accumulated allowed charges for the services delivered. The method of using a plurality of allowed charges for primary care services would provide a greater weight to more complex primary care services in the assignment methodology, while a simple service count method would weigh all primary care encounters equally in determining assignment. We have previous experience with the method of using a plurality of allowed charges in the PGP demonstration. One advantage of this method is that it would have less need for tie-breaker rules, since it is unlikely that allowed charges by two different entities would be equal. On the other hand, this method does not necessarily assign the beneficiary to the entity that saw the patient most frequently, but rather to the entity that provided the highest complexity and intensity of primary care services.

We proposed to implement the method of using a plurality of allowed charges for primary care services to assign beneficiaries to ACOs. Allowed charges are a reasonable proxy for the resource use of the underlying primary care services, so the method of using a plurality of allowed charges assigns beneficiaries to ACOs according to the intensity of their primary care interactions, not merely the frequency of such services.

Comment: One commenter expressed concern that the method for determining from which primary care provider a patient received the ''plurality of care'' is problematic because it is measured by the ''sum of allowed charges.'' The commenter argued that this will tend to reward providers who may be paid more for the same service and providers who tend to provide higher priced procedures, and that while this does give the provider who generated the most costs the responsibility for containing costs, it may skew things if, for example, a patient gets one high cost procedure from one provider and the majority of their primary care somewhere else. The single procedure provider would generally be less able to improve care coordination and manage costs with respect to that patient than the ''regular'' provider.

Another commenter suggested that we modify the methodology for beneficiary assignment from plurality of allowed charges to number of encounters by a provider. ''If one of the goals of the Shared Savings Program is to achieve a healthier population, the greater the number of encounters, regardless of the allowed charges or the physician's specialty, provides increased opportunities to educate and impact the patient and influence his/her behavior.'' Another commenter also advocated using a visit-based standard to assessing majority, instead of the proposed allowed-charges approach. This commenter emphasized that the charges standard would skew patient attribution based on the illness severity of the patients. Another commenter cited the frequency of upcoding as a basis for using visit counts rather than charges.

Another commenter objected that we seem to believe that charges are reasonable proxy for the resource use of the underlying primary care service. The commenter argued that the potential downside of using charges is that it may entrench the overutilization or up-coding that we otherwise wish to avoid. The commenter thus suggested that ''a more balanced approach'' could be the use of the plurality of visits combined with an adjustment factor to reflect intensity.

A nursing association recommended, in conjunction with its proposal to count the services of NPs in the assignment process, an alternative to employing allowed charges as the basis for assignment. The commenter noted that, if non physicians such as NPs and PAs were to be included in the assignment process, they would be at a disadvantage if allowed charges are the basis for assignment. They explained: ''The problem here lies in the mandatory discount applied to approved charges from NPs and CNSs. Their approved charges for primary care services are set at 85 percent of the Medicare Physician Fee Schedule amount. This discounting of APRN primary care services can tip the balance as to whether the beneficiary is assigned to an ACO where he or she may have received primary care services from the ACO's primary care physicians but in lesser amounts than provided by the advanced practice registered nurse. Our preferred remedy in this case would be to follow the recommendations of the Chair of the IOM Study on the Future of Nursing and pay according to the value of the service rather than the specialty of the provider. Failing that, ACO assignment should be based on the plurality of the work RVUs associated with primary care services.''

Response: We considered most of the alternatives to the use of allowed charges in developing our proposal. We agree that the method of using a plurality of allowed charges would provide a greater weight to more complex primary care services in the assignment methodology, while a simple service method count would weigh all primary care encounters equally in determining assignment. However, we do not believe that a method of using allowed charges is

inappropriate. Although this method does not necessarily assign the beneficiary to the entity that saw the patient most frequently, the beneficiary will be assigned to the entity that provided the highest complexity and intensity of primary care services. This method also results in the assignment of the responsibility for containing costs to the provider who generates the most costs. Our previous experience with the PGP demonstration demonstrated an advantage of this method is that it does not require tie-breaker rules, since it is unlikely that allowed charges by two different entities would be equal. Assignment of beneficiaries on the basis of plurality in a simple service method count would require tie-breaker rules for those rare occasions when two or more entities delivered an equal number of services to a beneficiary.

We considered the nursing association's recommendation that we use RVUs rather than charges. Use of RVUs in place of allowed charges would retain many of the benefits of employing charges (for example, reduced need for a tie-breaker) while correcting for the effects of some factors in allowed charges that arguably should not affect assignment (for example, the application of GPCI values to the physician fee schedule payments). However, it is unclear whether it would be possible and how to include FQHC/RHC services in the assignment process if we were to base assignment on RVUs for specific HCPCS codes rather than allowed charges since, as discussed previously, we have not required that RHCs include HCPCS codes on their claims, and FQHCs have been required to report HCPCS codes only since January 1, 2012. Moreover, the use of allowed charges has resulted in satisfactory assignment results under the PGP demonstration. Therefore, we will retain this proven method of using allowed charges. We note that for purposes of the Shared Savings Program, allowed charges for FQHC/RHC services will be based on the interim payments, since any subsequent adjustments following settlement of their cost reports would not be available in time for assignment purposes. We will continue to consider the alternative of using RVUs as we gain experience under the Shared Savings Program.

Comment: Several commenters expressed concern about potential unintended consequences of the plurality rule, specifically consequences related to care coordination and manipulation of Medicare beneficiary attribution, particularly for beneficiaries who require SNF or NF care during the attribution time period. These commenters noted that similar concerns were raised in the Medicare Advanced Primary Care Practice Demonstration. As a result, they recommend that CMS monitor the plurality rule to ensure that it does not adversely impact patient care coordination or encourage ACO gaming of Medicare beneficiary attribution in the SNF or NF setting.

Response: We appreciate the commenters' recommendation, and we will certainly monitor the impact of the plurality rule to ensure that it does not adversely impact patient care coordination or encourage ACO gaming in any way. We discuss our monitoring plans in detail in section II.H. of this final rule.

Comment: One commenter had a technical comment about the plurality formula in the regulations text: ''Section 425.6(b) of the regulations provides the technical details of the assignment methodology in five steps. We have the following comments on the technical description: Step (3) calculates a single number—the total allowed charge for primary care services—for each beneficiary. The rule should clarify whether the intention for the plurality test is to calculate total allowed charges for each non-ACO provider or in aggregate for all non-ACO providers. Step (5) includes a plurality test but only references Step (4), which does not include non-ACO providers. Based on the rule, it appears that non-ACO providers are intended to be considered in the plurality test. Step (5), therefore, also should reference the total allowed charges for non-ACO providers in the plurality test.''

Another commenter noted that we proposed to assign beneficiaries to an ACO if they receive a plurality of their primary care services from primary care physicians within an ACO. In this formula, primary care services provided by specialists would be included in the total primary care services for the beneficiary, but would not be included in the count of the primary care services the beneficiary receives from an ACO. The commenter recommended that we should compare the primary care services beneficiaries receive from an ACO's primary care physicians only to the total primary care services beneficiaries receive from primary care providers, thereby excluding primary care services provided by specialists from the denominator in the plurality calculation.

Response: We agree with the first commenter that the regulations text needs to be revised to reflect the intention for the plurality test to calculate total allowed charges for each non-ACO provider for purposes of determining where the beneficiary received the plurality of his or her primary care services. In addition, we believe that our decision to include specialists in the assignment methodology by way of a step-wise process addresses the commenters' questions regarding whether primary care services furnished by specialists should be included in the computation of the plurality of allowed charges for primary care services.

Final Decision: In § 425.402, we are finalizing our proposal to adopt a plurality of primary care services, defined in terms of allowed charges, as the basis for assignment. However, we are modifying the way in which we will calculate that plurality in order to apply it in the two-step assignment process, as described previously.

F. Quality and Other Reporting Requirements

1. Introduction

In this section of the final rule, we discuss: Measures to assess the quality of care furnished by an ACO; requirements for data submission by ACOs; quality performance standards; the incorporation of reporting requirements under section 1848 of the Act for the Physician Quality Reporting System; and aligning ACO quality measures with other laws and regulations.

2. Measures To Assess the Quality of Care Furnished by an ACO

a. General

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization (such as rates of hospital admission for ambulatory sensitive conditions). Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. In the proposed rule, we indicated that we believe that the Secretary's authority to determine the form and manner of data submission allows for establishing requirements for submission of data on measures the Secretary determines to be appropriate for evaluating the quality of care furnished by the ACO, without regard to whether the Secretary has established a specific quality performance standard with respect to

those measures that must be met in order to be eligible for shared savings.

We proposed that an ACO be considered to have met the quality performance standard if it has reported quality measures and met the applicable performance criteria in accordance with the requirements detailed in rulemaking for each of the 3 performance years. We further proposed to define the quality performance standard at the reporting level for the first year of the Shared Savings Program and to define it based on measure scores in subsequent program years. We proposed the use of 65 measures to establish quality performance standards that ACOs must meet in order to be eligible for shared savings for the first performance period (76 FR 19571). We stated that quality measures for the remaining 2 years of the 3-year agreement would be proposed in future rulemaking.

Comment: While some commenters supported the 65 measures proposed without modification, the majority recommended that we adopt fewer, validated measures aligned with the three-part aim and currently in use in order to encourage participation, reduce reporting burden, and achieve more focused and meaningful improvements, particularly in the first agreement period. Commenters suggested paring down the number of quality measures in a number of ways, such as by using a more simplified framework and limiting measures to: A specific number; those that can be reported via a specific methodology such as claims; those currently reported through another program; only some of the proposed domains; outcomes measures; those related to the most prevalent and costly health conditions; or eliminating the measures that involve beneficiary compliance. Another commenter recommended having a ''performance set'' of measures that includes outcome-oriented, claims-based measures focused on utilization to determine eligibility for payment, and a ''reporting set of measures'' used for monitoring purposes only. A few commenters supported the number of measures proposed but were concerned about reporting burden. Another commenter noted that the proposed measure set may not be feasible initially but should be in the future, as it is in other sectors.

Response: We considered the commenters' recommendations carefully when determining the 33 final, required quality measures, which will be scored as 23 measures as discussed in section II.F.4. of this final rule. We are sensitive to the concerns raised by commenters regarding the administrative burden of the proposed measures, and we have modified our proposal by reducing the number of required measures by removing measures perceived as redundant, operationally complex, or burdensome and retaining those that would still demand a high standard of ACO quality, focus on priority areas and are areas of high prevalence and high cost in the Medicare population. We have also sought to finalize proposed measures or variations of proposed measures that align with the measures used in other quality programs and initiatives. We have also made certain adjustments to our proposed measures to align with updates in the measures, such as the retirement of certain measures. Further detail on the reasoning behind finalizing or removing specific measures is discussed in section II.F.2.c of this final rule.

Comment: Several commenters expressed concern about unintended negative consequences related to the quality measures and patients' role in improving quality of care outcomes. A number of commenters were concerned that ACOs might skimp or delay in providing specialty care, particularly high cost services or those not available within the ACO. Several commenters suggested a wider choice of measures for major illnesses in order to avoid underutilization. Another commenter was concerned that providers would treat patients based on the measures rather than on patients' needs. Several commenters were concerned that measures would track how many services are provided rather than how well care is provided.

One commenter suggested CMS consider patients' responsibility, and another commenter noted the proposed measures make providers accountable for patient decisions. One commenter suggested CMS add measures or program requirements that encourage ACOs to promote patient accountability for health and wellness. A few commenters suggested the proposed measures were not those that would have the greatest impact on quality or address the urgent need to evaluate the efficient use of healthcare resources. One commenter recommended that measures focus on misuse and overuse as much as underuse and suggested targeting the areas for misuse identified by the National Priorities Partnership.

Response: In addition to measuring quality for performance purposes, we also intend to monitor the quality of care furnished by ACOs in an effort to identify patterns of avoiding at-risk beneficiaries and misuse, underuse, and overuse of services over time. We will use data that we can calculate internally without requiring additional ACO reporting, such as claims and administrative data, to conduct this monitoring. Further information about program monitoring is addressed in section II.H of this final rule.

b. Considerations in Selecting Measures

We view value-based purchasing as an important step towards revamping how care and services are paid for, moving increasingly toward rewarding better value, outcomes, and innovations instead of volume. The Shared Savings Program is a critical element of our Medicare value-based purchasing initiative, in which we have sought to meet certain common goals, as described in the proposed rule (76 FR 19569).

Comment: Numerous commenters endorsed focusing measures around the three-part aim of better care, better health, and lower costs; some suggested that the proposed measures could go further in this regard. One commenter stated that the quality measures sufficiently address the care and improving health aims but do not address the reducing costs aim. Another commenter stated the proposed measures will add cost to providers and will not produce savings. Commenters also supported using tested, evidence-based and endorsed measures, and a number of commenters suggested that measures should: Be meaningful, improve patient outcomes, rely on clinically enriched administrative measures already in use and be consistent with measures used in other public programs, such as the PQRS, Electronic Health Record (EHR) Incentive Program, Medicare Advantage (MA), Hospital Value-Based Purchasing (HVBP), the Inpatient Prospective Payment System (IPPS), and others. Commenters also suggested a number of different measurement sets. One commenter was concerned that quality of care for individuals and populations are not genuine top priorities of the Shared Savings Program, since the proposed rule included only quality measures that cover the same patient populations, processes, and outcomes that are already addressed by existing measures used in other programs. A few commenters proposed only using PQRS measures initially. Many commenters suggested using only NQF-endorsed measures, while others asked that CMS not limit itself to NQF-measures.

Response: We agree that the quality measures should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare population, reflect priorities of the National Quality Strategy, address the

continuum of care to reflect the accountability that ACOs accept for their patient populations, and align with existing quality programs and value-based purchasing initiatives. At this time, we have concluded that it is most appropriate to focus on quality measures that directly assess the overall quality of care furnished to beneficiaries. We are adopting a measurement set that includes patient experience, outcomes, and evidence-based care processes. That said, we do not agree that specific measures addressing high cost services or utilization are necessary to incentivize ACOs to address these issues. We believe that the goal of lower cost growth will be achieved through improved coordination and quality and that the potential for shared savings will offer a sufficient incentive for ACOs to address utilization issues in a way that is most appropriate to their organization, patient population, and local healthcare environment. However, we may consider such measures in the future. Accordingly, the measures we are finalizing include a subset of the proposed measures that address the populations, processes, and outcomes that were the focus in the proposed rule.

In the proposed rule, we stated that our principal goal in selecting quality measures for ACOs was to identify measures of success in the delivery of high-quality health care at the individual and population levels. We considered a broad array of process and outcome measures and accounted for a variety of factors, prioritizing certain measures according to principles described in the proposed rule. (76 FR 19569) We believe endorsed measures have been tested, validated, and clinically accepted and have therefore selected the final measures with a preference for NQF-endorsed measures. However, the Act does not limit the Shared Savings Program to endorsed measures. As a result we have also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed.

c. Quality Measures for Use in Establishing Quality Performance Standards That ACOs Must Meet for Shared Savings

Based upon the principles described previously, we proposed 65 measures (76 FR 19571) for use in the calculation of the ACO Quality Performance Standard. We proposed that ACOs would submit data on these measures using the process described in the proposed rule and meet defined quality performance thresholds. We proposed that ACOs would be required to report quality measures and meet applicable performance criteria, as defined in rulemaking, for all years within the agreement period to be considered as having met the quality performance standard. Specifically, for the first year of the program, we proposed for the quality performance standard to be at the level of full and accurate measures reporting; for subsequent years, we proposed the quality performance standard would be based on a measures scale with a minimum attainment level. We proposed that ACOs that do not meet the quality performance thresholds for all measures would not be eligible for shared savings, regardless of how much per capita costs were reduced, which is discussed further in section II.F.4.b.2. of this final rule.

Comment: One commenter requested clarification on whether care provided outside the ACO would count toward the ACO's quality metrics. One commenter recommended we require measures reporting for all patients seen by the ACO, not just those assigned in order to simplify the reporting process and spur improvement across the ACO's entire patient population.

Response: Since ACOs will be accountable for all care received by their assigned beneficiary population, quality measures will reflect the care assigned beneficiaries receive from ACO providers and non-ACO providers. We will utilize claims data submitted by the ACO providers/suppliers as well as from providers outside the ACO in determining measure numerators and denominators.

Comment: A few commenters asked CMS to clarify whether the reporting performance standard would be applicable to ACOs only during the first year of the Medicare Shared Savings Program (that is, 2012) or for the first year of the ACO's agreement period and how this would affect a mid-year start date, if CMS decides to incorporate one. One of these commenters supported defining the quality performance standard at the reporting level for the first year of an ACO agreement period, regardless of whether this timeframe coincides with the calendar year.

Response: In this final rule, we have finalized first year start dates for ACO participants in April and July of 2012, but not for January 2012, as discussed in section II.C.1. of this final rule. We have also outlined a performance standard for each 12-month, calendar year quality measure reporting period. We indicated that ACOs requesting an interim payment calculation as described in section II.G.2.k of this final rule must completely and accurately report the ACO GPRO measures for 2012. We indicated that the final performance year 1 reconciliation for the first agreement period would be based on completely and accurately reporting all ACO quality measures—ACO GPRO, CAHPS and claims- and administrative-based measures—for CY 2013. Recognizing that ACOs' first performance year will be 18 to 21 months and carry from 2012 into 2013 if they start in the Shared Savings Program in April or July 2012, ACOs will need to comply with annual measures specifications updates detailed in subregulatory guidance. While we anticipate a relatively static set of quality measures for the first agreement period, ACOs will also be required to comply with any measures updates made in future rulemaking as clinical guidelines change and as other programs update their measure requirements. For instance, the EHR Incentive Program will release clinical quality measure requirements for Stage 2 Meaningful Use, and we believe it is advantageous and more efficient for the provider community if we can align measures across programs. It may also be necessary to add or remove measures from the Shared Savings Program as CMS gains experience with ACOs and develops a better understanding of the types of measures that are most important to assess the quality of care furnished by this new type of entity. Quality measures requirements for each performance year are discussed in Tables 1 and 2 as well as in section II.F.4 of this final rule.

ACOs that enter into an agreement period beginning in 2013 or subsequent years will be subject to the same rules unless they are revised in future rulemaking cycles. That is, absent some change to our policies, the quality performance standard for an ACO's first performance year will be set at the level of complete and accurate measures reporting. We expect that the measures we are finalizing will be maintained in the early years of the program as both ACOs and CMS develop infrastructure and gain experience with the program. We believe having one quality performance standard and set of measures for all ACOs will make for better longitudinal comparisons and be operationally more feasible and less burdensome.

In the proposed quality measures table (76 FR 19571), we categorized each of the measures into the goals of better care for individuals and better health for populations and included: The domain each of the proposed measures addresses, the measure title, a brief description of the data the measure

captures, applicable PQRS or EHR Incentive Program information, the measure steward or, if applicable, NQF measure number, the proposed method of data submission for each measure, and information on whether the quality performance standard for each measure is defined at the reporting or performance level for each year of the agreement period. We noted that while many of the proposed measures have NQF endorsement or are currently used in other CMS quality programs, the specifications for some of the proposed measures would need to be refined in order to be applicable to an ACO population. However, we proposed to align the quality measures specifications for the Shared Savings Program with the measures specifications used in our existing quality programs to the extent possible and appropriate for purposes of the Shared Savings Program. We also stated that we planned to make the specifications for the proposed measures available on our Web site prior to the start of the Shared Savings Program. We also acknowledged that we would expect to refine and expand the ACO quality measures in the future and expand measures reporting mechanisms to include those that are directly EHR-based. Specifically, we expect to expand the measures to include other highly prevalent conditions and areas of interest, such as frailty, mental health, substance abuse, including alcohol screening, as well as measures of caregiver experience. Finally, we also sought comment on a process for retiring or adjusting the weights of domains, modules, or measures over time.

We received the following comments about the proposed measures in general.

Comment: Many commenters expressed concern that few proposed measures were focused on outcomes as opposed to processes. One commenter who supported outcome measures wrote that a 3-year agreement period was too short to allow accurate outcomes assessment across diagnoses and expressed concern that the expectation that outcomes could be altered in this time frame might encourage gamesmanship and manipulation of data by ACOs.

Response: In selecting the final set of measures, we have sought to include both process and outcome measures, including patient experience of care. Process measures are typically easier to calculate based on administrative data, such as claims, and would require less reporting effort by ACOs, while outcomes measures would provide a more complete picture of quality of care improvement but would require more ACO reporting effort, such as GPRO measures that tend to rely on a combination of both claims and clinical quality data. Since ACOs are charged with improving and coordinating care and delivering high quality care but also need time to form and ramp up, we believe it is important to start with a combination of both process and outcomes measures, but may move to more outcomes-based measures and fewer process measures over time. We have modified our proposed domain structure in this final rule by combining the care coordination and patient safety domains to better align with other CMS value-based purchasing initiatives and the National Quality Strategy and to emphasize the importance of ambulatory patient safety and care coordination. In addition, we are moving certain proposed claims-based measures, such as inpatient safety measures and ambulatory care sensitive condition (ACSC) admissions measures, to our monitoring program to prevent ACOs from engaging in gamesmanship and manipulation of at-risk patients.

Comment: Many commenters suggested adopting a risk-adjustment strategy for measures that would account for beneficiary characteristics such as: geographic location, body mass index, socioeconomic status, education, severity or type of illness, race, ethnicity, gender, preferred language, disability status, or health literacy. One commenter recommended risk-adjusting outcomes measures in addition to process and patient experience measures. One of the commenters also noted that our proposed measure set provided no incentive for more accurate coding and failed to recognize that an aging population's health status is expected to deteriorate over time, not remain stable. One commenter was concerned about factors outside of an ACO may affect an ACO's quality measure performance, such as the patient's right to decide whether he or she will follow recommendations of health care professionals. One commenter requested clarification on how CMS will apply risk-adjustments when calculating ACO performance on specific quality measures.

Response: Risk adjustment is included for a number of the proposed measures, such as the ACSC measures, but is generally limited to age and gender. In addition, some measures include specific exclusions for patients, such as those in hospice, who may not benefit from an action targeted by the measure. Risk adjustment would also be used in the Risk-Standardized, All Condition Readmission measure, the details of which would be forthcoming in subregulatory guidance. We believe that our linkage of payment to accurate reporting requirements provides a strong incentive for complete and accurate reporting, since the quality performance standard must be met in order for an ACO to be considered eligible for shared savings. As discussed in section II.H.2. of this final rule, we may audit the quality measures data ACOs enter into the GPRO web interface by requiring the ACO to share beneficiary medical record information with CMS. As discussed in II.B. of this final rule, ACOs will also have to agree, as a condition of receiving any shared savings and participating in the program, that the quality data they submit to CMS is accurate, complete, and truthful. We believe that including a process to audit quality measures data and a certification requirement provides ACOs with an incentive to more accurately report quality measure data. In addition, we agree that the personal preferences of beneficiaries play an important role in their health behaviors. However, the lack of patient adherence may also represent a legitimate dimension of care, as it could be indicative of poor communication between ACO providers/suppliers and their patients. Beneficiary incentives are discussed further in section II.B. of this final rule.

We also received a number of comments on the specific measures proposed. We received the following comments on proposed measures 1–7: Patient/Caregiver Experience.

Comment: A number of commenters supported a prominent role for patient experience and health status in the measure set. One commenter applauded the inclusion of a measure on shared decision making while another advocated for additional shared decision making measures. One commenter was supportive of including measures of caregiver as well as patient experience. One commenter noted the importance of patient experience of care but cautioned that such measures are subjective, and do not always accurately measure the quality of care furnished and that ACO marketing materials could influence beneficiary responses.

Response: While we recognize the concern about patient subjectivity to surveys, we believe patients' perception of their care experience reflects important aspects of the quality of the care they receive, such as communication and patient engagement in decision-making, that are not adequately captured by other measures. As such, patient surveys are important complements to the other process of care and outcomes measures. For the

same reason, we intend to expand the quality measures over time to include more caregiver experience measures. In addition, we intend to retain some level of ACO marketing oversight, as discussed in section II.H.2 of this final rule, and will refine our processes over time as appropriate.

Comment: Many commenters supported using Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) surveys to measure patient experience but varied in their recommendation of which version to use. One commenter stated that CG–CAHPS and Hospital CAHPS (HCAHPS) do not include the desired shared decision making modules that are included in the draft Patient Centered Medical Home CAHPS (PCMH–CAHPS) and the Surgical CAHPS. Others supported the use of CAHPS but recommended adding additional measures to the domain. A few commenters suggested adding more care coordination and specialty care constructs to the patient/caregiver experience domain. One commenter suggested adding the new CAHPS cultural competence modules. One commenter stated that CAHPS did not adequately capture the team care experience of an ACO and suggested adding specific supplemental questions to CG–CAHPS.

Some commenters suggested other modifications to the proposed approach. One commenter suggested allowing ACOs to incorporate CAHPS constructs into existing surveys. Another commenter wrote that CMS should not allow ACOs to use existing experience tools because this approach would not produce comparable data and suggested that CMS require all ACOs to use the same, standardized tool, with the same sampling methodologies. Another commenter suggested a hybrid approach with some standardized measures but also with some flexibility for ACOs to replace survey items of no or limited relevance to their practice with other questions. One commenter recognized the importance of measures related to patient experience of care but recommended that they not be incorporated into the performance standard for the first agreement period. One commenter did not believe patient satisfaction should be used to assess ACO performance.

A few commenters cautioned CMS that there is limited experience with the CG–CAHPS tool, making it unfeasible for setting benchmarks initially and raising possible issues of its reliability and validity for ACOs. A couple of commenters suggested that survey information not be used to assess ACO performance until validated. One commenter recommended that until more proven measures become available, survey measures should include a ''control group'' of non-ACO FFS beneficiaries in the ACO's service area and be used for program monitoring and public information only. One commenter expressed doubt about whether the timeframe for implementing the survey and using the results to improve care would be feasible. One commenter stated that CG–CAHPS was not particularly actionable as many items included would not be under the control of ACOs and suggested visit-specific questions be used, such as those in the AMA Patient Experience Survey. A few commenters stated that CAHPS does not address communication, environmental factors, resource utilization, patient role in care, care coordination, or transition quality and suggested additional questions related to those areas. A few commenters found CAHPS both administratively burdensome and costly. One recommended CMS adopt a sampling approach to mitigate these factors, while another commenter recommended the survey be collected at CMS' expense. One commenter was concerned about duplicative CAHPS reporting through this program, PQRS and HCAHPS. Several commenters suggested methods other than CAHPS, or patient surveys in general, for collecting patient experience data. One commenter recommended CMS permit the use of other validated instruments, such as the American Board of Internal Medicine's condition specific patient surveys. Another commenter expressed concern that allowing ACOs to choose a survey instrument other than CG–CAHPS would limit the validity and utility of such data. One commenter recommended that the survey be tailored to the setting where care was received such as an inpatient rehabilitation unit or mental health.

Response: We believe the CG–CAHPS is the most appropriate version of CAHPS for ACOs, given the Shared Savings Program's primary care focus and the ambulatory care focus of the CG–CAHPS. We note, however, that our decision to require use of this survey instrument as part of the quality performance measures does not preclude an ACO from continuing to use other tools it may already have in place. We do not think HCAHPS is appropriate as a Shared Savings Program tool at this time, since not all ACOs will include a hospital. We recognize the PCMH–CAHPS currently in development may offer modules applicable to ACOs, so we may consider these modules, when available, in future rulemaking. While the CG–CAHPS is among the more recently developed CAHPS surveys, the modules have undergone field testing by a number of public and private organizations and are endorsed. There are already a number of users contributing experience with the CG–CAHPS, including regional collaboratives, member boards of the American Board of Medical Specialties, and a growing number of individual health plans and medical groups. In addition, national benchmark data are now available for the CAHPS Clinician & Group Survey through the National CAHPS Benchmarking Database. We also believe there is sufficient time to test the CG–CAHPS for ACO use.

In response to comments recommending that we add a care coordination and specialty care construct, we intend to add an Access to Specialists module as we think it is responsive to comments, will emphasize the importance of specialty care for patients served by the ACO, and complements our program focus on care coordination and our monitoring activities to ensure ACOs are not engaged in practices to avoid at risk patients. It also will align with the two-step methodology for assigning beneficiaries to ACOs, discussed in section II.E, of this final rule, which considers primary care services furnished by providers other than primary care physicians and will ensure that the CAHPS survey meaningfully assesses patient experience with ACO providers other than primary care physicians. This would mitigate the risk of issuing a survey to beneficiaries that does not necessarily reflect their care experience, which could be perceived as confusing and/or unduly burdensome.

Thus, we are finalizing the CAHPS modules listed in Table 1 for quality performance purposes as we believe they offer the best alternative for ACO patient experience of care measurement at this point in time. We are not finalizing the Helpful, Courteous, Respectful Office Staff module proposed for quality performance measurement and reporting or scoring purposes but note that this module is still a core part of the CAHPS survey to be collected and we will collect the data and feedback to ACOs for informational purposes only. We also believe there is evidence that CAHPS assesses important aspects of provider-patient interaction that can be influenced by an ACO's level of organizational support, training and incentive structure. These items may be combined with existing data in devising appropriate quality improvement

interventions as demonstrated by case studies and a guide available on the CAHPS Web site. We recognize that not all relevant areas of the patient experience are covered and will consider additional items in future rulemaking. We are sensitive to the data collection issues related to the patient experience survey and we have taken the commenters' implementation strategy suggestions under consideration. We will also consider the comments regarding adding additional CAHPS questions in the future. As described in section II.F.3. of this final rule CMS will fund and administer the survey for the first two calendar years of the Shared Savings Program, 2012 and 2013.

Comment: A number of commenters asked for clarification or made other specific comments regarding use of the CAHPS surveys for ACOs. One of these commenters recommended CMS: Use the six-point response scale, clarify if only the primary care CG-CAHPS should be used, and clarify how ACOs might add additional measures not included in the final measure set. One commenter expressed concern that various CAHPS tools do not recognize care provided by registered nurses and certified registered nurse anesthetists. One commenter stated that CAHPS data could include visits outside the ACO reporting period.

Response: We will consider comments regarding which CAHPS response scale is most appropriate for the Shared Savings Program and concerns that CAHPS data could include visits outside the reporting period and will release detailed instructions subregulatorily, outside of rulemaking. In response to the request that we clarify whether only the primary care version of the CG–CAHPS should be used for those modules from the CG–CAHPS, we note that the core CAHPS items proposed are identical for the CG–CAHPS primary care and specialty versions. The shared decision-making module, a supplemental module for both adult primary care and adult specialty care versions, is also identical in both versions. However, the health promotion and education module is a supplemental module from the adult primary care version only. With respect to the comment recommending that the included CAHPS modules reflect care furnished by registered nurses and certified registered nurse anesthetists, we recommend the commenter contact the measure steward directly with this suggestion.

Comment: Several commenters had varying recommendations about how the CAHPS data would be collected, including use of a web-based survey or cloud application and use of both mail and telephone as opposed to one or the other. A few commenters were concerned that mail and phone surveys would be unlikely to reach a large number of low-income beneficiaries with low English proficiency or with disabilities and urged us to allow on-site patient surveys. One commenter suggested providing detailed survey guidelines regarding the fielding of the patient/caregiver experience survey. One commenter noted that survey results are affected by survey mode and methodology; this commenter suggested CMS require ACOs to follow clear guidelines for survey administration in order to make data more comparable. A few commenters urged CMS to encourage patient surveys to be done by or under the supervision of the Regional Health Information Collaboratives. One commenter suggested oversampling to allow ACOs to internally report individual provider level feedback and to ensure that patients with chronic conditions, who would have the most ACO contact, are sufficiently represented. The commenter also suggested not restricting surveys to Medicare beneficiaries only, similar to HCAHPS. Finally, one commenter suggested a phased approach to implementing the survey.

Response: Because of these and other comments described in this final rule, we have decided to pay for the first two years of the survey in 2012 and 2013. We agree that survey mode and methodology can affect survey results and believe that, at this juncture, standardized administration and comparable results will be best achieved through the use of trained and certified vendors as is done with other CAHPS surveys administered to the Medicare population. We, too, are concerned about reaching low-income beneficiaries, as well as beneficiaries with limited English proficiency, chronic disease, or disabilities and will take these populations (and other relevant considerations) into account as we develop the sampling methodology for the CAHPS surveys. We will review carefully the results of the ACO patient experience of care survey in 2012 and 2013 to adjust and refine the sampling and/or survey methodology as we move forward.

We received the following comments regarding proposed measure 7: Health Status/Functional Status.

Comment: One commenter noted that this measure was appropriate for a survey item and recommended it be added to the CAHPS instrument. A few commenters thought patient survey tools should account for primary care services furnished by providers other than primary care physicians. A few commenters stated NQF #6, MA–CAHPS, was noted in the table, but NQF #6 is from the HP–CAHPS. Either way, the commenters expressed concern that while health status and functional status have been used for risk adjustment, these constructs are not currently used for accountability purposes in any pay for performance initiatives and may have limited value in determining high and low-performing physician group practices, particularly in small geographic areas, where patients have more limited choice in selecting providers. Many commenters advocated for stronger measures of functional status, including measures outside of CAHPS surveys, to help ensure providers with a higher proportion of patients for whom a cure is not available are not punished. A few commenters advocated adding functional status as a sixth domain. One commenter strongly supported measures of changes in functional status from admission and discharge but stated that the proposed measure is not measured from the patient or caregiver perspective and did not believe it is sufficiently objective. One commenter recommended development of ways to measure pre- and post-care health status of patients treated by ACOs.

Response: To clarify our original proposal, we intended to propose NQF #6. Health Status is intended to be self-reported in order to adequately represent the patient or caregiver perspective. Patient-reported outcomes, although subjective, provide valuable information not captured by other means, and many are well established and widely used with demonstrated reliability and validity. That said, we will consider suggestions for alternatives in the future.

We are also finalizing the health status survey as pay for reporting for all 3 years of the agreement period. While we agree with commenters that the information is important for improving the overall health and functioning of a patient population, we also recognize that it is not currently used for accountability purposes in any pay for performance. Therefore we will keep the measure as pay for reporting for the entire agreement period in order for ACOs to gain experience with the measure and to provide important information to them on improving the outcomes of the population they serve.

We received the following comments on proposed measures 8. to 23. Care Coordination.

Comment: Several commenters wrote in general support of the Care Coordination measures. One commenter supported the emphasis on care coordination but did not want this focus to be at the expense of specialty care. One commenter thought these measures were unclear and would be difficult to measure. One commenter suggested evaluating the incidence of ACSC admissions in each ACO. If the frequency of ACSC admissions in many ACOs is likely to be insufficient for statistical stability of admission rates, such instability should be considered before tying performance results to shared savings. One commenter believed CMS should reduce the number of measures until new and better care measures for this domain are developed and require reporting only (not performance) on all measures for the first 3-year agreement. However, another commenter recommended CMS add new quality measures to this category that define the responsibilities of both the sending and receiving provider and measure accountability and performance of these providers during patient care transitions. One commenter believed the proposed care coordination measures were inadequate to ensure that patient care is truly coordinated among providers and settings.

Regarding proposed measures 8–10. Risk-Standardized, All Condition Readmission; 30 Day Post-Discharge Physician Visit; and Medication Reconciliation, one commenter believed these measures were all based primarily on hospital performance and should be dropped. One commenter appeared to support electronic capture of the 30 Day Post-Discharge Physician Visit and Medication Reconciliation, but cautioned that only would be possible for readmissions and discharge visits that occurred among entities connected to that particular electronic medical record.

Response: We agree that care coordination is an important part of patient care and that sample size is an important consideration in measure selection. We also believe that accountability for patients, including knowledge of services rendered outside of an ACO, is important for achieving the three-part aim goals previously described. As a result, we note that all Shared Savings Program quality measures are intended to measure performance in relation to a defined set of assigned beneficiaries and not the performance of an individual entity, such as a hospital. Given the population focus of ACOs and refinements to the list of ACSC conditions, coupled with the phase in of these measures for performance, we believe that ACO assigned populations should be sufficient to reliably measure performance. We may consider including the additional measures suggested by commenters in the future.

Comment: Proposed Measure 8. Risk-Standardized, All Condition Readmission. A few commenters supported inclusion of measure 8 as proposed, but a few were not supportive. Some noted that this measure was not NQF-endorsed and that CMS had not provided specifications for this measure, making it impossible to evaluate the risk adjustment methodology or the measure exclusions, such as planned readmissions and transfers. A few commenters noted that there is already a readmission payment policy, and as a result, hospitals would potentially be penalized multiple times for the same readmission. Many commenters expressed support for a readmission measure but several of these commenters urged CMS to specify the measure to include only unplanned readmissions for heart attack, heart failure, and pneumonia. However, one commenter stated that CMS should not adopt the three CMS disease-specific all-cause readmission measures for heart attack, heart failure, and pneumonia currently reported to CMS because they leave out 85–90 percent of readmissions. One commenter stated that the proposed readmission measure lacked clinical credibility and could undermine quality improvement efforts. This commenter stated that the Affordable Care Act requires that readmission measures ''have exclusions for readmissions that are unrelated to the prior discharge'' and argued that the proposed measure failed to do this. This commenter also argued that certain readmissions related to the prior discharge are planned and unavoidable, such as planned chemotherapy. One commenter questioned how this measure would be used in an ACO context. Another commenter believed that review of patient medications within 24 hours of discharge/transition or communication with the patient within 72 hours of discharge/transition were better measures of care coordination. One commenter suggested the measure be changed to include readmission or admission to observation status within 30 days of discharge from an acute care hospital.

Response: Readmissions is an area in which we believe an ACO's coordination of care and accountability can have a significant impact in improving patient care and are finalizing this measure as proposed. While we recognize concerns that the measure has not been endorsed, this is one area in which we wish to exercise our discretion to include appropriate quality measures even if they have not been endorsed. We do not believe including this measure would be duplicative of any current readmission payment policy, since ACOs are a new concept and the Shared Savings Program is a new care model, and since this measure is not currently utilized in any other CMS quality reporting program. During the development of the proposed measures, we considered including the three disease-specific readmissions measures suggested by several commenters, but did not propose these measures for the reason another commenter noted: These types of readmissions represent only a small percentage of all readmissions. We recognize that certain readmissions are planned, unavoidable, and even advantageous to the patient, and will consider this prior to releasing specifications for this measure. That said, we also note that this measure has been under development and that finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012. We are also finalizing the measure as a pay for reporting measure for the first two years of the program to allow more time for ACOs to gain experience with the measure and to redesign care processes to improve outcomes and reduce avoidable readmissions.

Comment: Proposed measure 9. 30–Day Post Discharge Provider Visit. One commenter suggested this measure could be captured through claims data, rather than through the GPRO web interface. A few commenters believed this measure should not only pertain to ACO providers. One commenter believed the 30-day period was too long and that a 5–7 day follow-up was necessary to avoid readmissions.

Response: We have decided not to include the measure at this time in response to comments regarding duplicity and reporting burden, as the medication reconciliation measure we are finalizing includes both the act of post-discharge medication reconciliation and a post-discharge provider visit. However, we would like to clarify the original proposal to collect this measure through the GPRO web interface rather than via claims data. In our proposed measures set development process, we concluded that although claims data would capture many post discharge visits, the GPRO web interface

would allow visits not discernable from claims, such as those that may be included in a bundled hospital payment, to be included in this measure. Although we are not finalizing the measure at this time, we will consider the comments received and revisit the appropriateness of adding this measure at a future time during future rulemaking.

Comment: Proposed measure 10. Medication Reconciliation. Several commenters commended including medication reconciliation in the measure set. One commenter stated that the 60-day time frame post-hospitalization appears to be a typographical error as NQF Measure #554 calls for a 30 day timeframe. One commenter recommended variations of the proposed measure, because the proposed measure is a self-reported, unidirectional measure. Another commenter proposed a self-reported adherence assessment measure should be included as well as measures that identify other barriers to medication adherence. This commenter also believed medication behavior assessment should not be limited to post-discharge but would also be indicated for all patients on chronic maintenance therapy, particularly those with diabetes, hypertension, coronary artery disease, or heart failure. A few commenters recommended that discharges from inpatient rehabilitation hospitals and units, long term care hospitals, skilled nursing facilities, and any of the multiple post-acute care outpatient settings be included in the final rule. One commenter stated this measure should include verification that medication reconciliation was conducted and documented prior to hospital discharge. A few commenters recommended a more limited time frame to avoid complications and readmissions; one mentioned a 3–7 day range. A number of commenters recommended deferring the introduction of this measure until EHRs are fully implemented and this measure can be captured electronically. One commenter recommended clarification that the medication reconciliation should be documented in a medical record rather than be a medication claim.

Response: The commenter that pointed out the error in the proposed rule is correct. NQF #554 is a 30 day post discharge medication reconciliation measure rather than a 60 day measure as we indicated in the measure description (76 FR 19572). The correct NQF number for the 60 day measure that we proposed is NQF #97. Accordingly, in this final rule, we are adopting NQF #97, the 60 day measure, in an effort to align with PQRS. Since this measure would be collected through the GPRO web interface, which will have ability to both accept manual data uploads and interface with an EHR as described in section II.F.4.b. of this final rule, we do not think this measure needs to be deferred until there is greater EHR implementation in the provider community. We recommend commenters direct comments regarding alternative time frames, care settings and other deviations from the endorsed specification to the measure steward. We will consider the other suggested medication-related measures and propose them through future rule making if appropriate.

Comment: Proposed measure 11. Care Transitions. One commenter generally endorsed measures related to transition plans of care, while others specifically endorsed this measure. One commenter recommended that this measure be eliminated as it is already captured via CAHPS, while another cautioned against adoption of any measure that requires chart abstraction. Another commenter expressed concern that this is not an objective measure and lacks evidence it improves outcomes. A few commenters requested that CMS clarify whether this is a survey measure or reported through GPRO. One commenter suggested CMS consider other care coordination measures that assess whether: the patient received a reconciled medication list upon discharge, the patient received a transition record with specified information, and the transition record was transmitted to the receiving provider in a timely manner.

Response: We are not finalizing this measure at this time in an effort to be responsive to comments about reporting burden. We recognize this measure is typically collected within 48 hours to six weeks after discharge via phone or mailed survey. In exploring options for operationalizing this measure in an ACO context, we recognize that it would be difficult to require this measure for an ACO that does not have a hospital, as it could require substantive infrastructure, education, and development to have an ACO disseminate the survey questions to patients timely post-discharge and report the results to CMS. Nevertheless, we continue to believe that assessing care coordination, and in particular care transitions, is an important aspect of evaluating the overall quality of the care furnished by ACOs. One way we will do this is by including an access to specialists module in the CAHPS survey as previously described. We also intend to continue exploring ways to best capture ACO care coordination metrics as suggested, including the proposed measure, and will consider adding new care coordination measures for future years.

Comment: Proposed measures 12–18. Ambulatory Care Sensitive Conditions Admissions. Several commenters expressed concern about the use of various AHRQ Prevention Quality Indicators (PQIs) for the Ambulatory Care Sensitive Conditions (ACSC) Admissions measures as these are designed as screening tools rather than quality measures and are not adequately risk-adjusted. A few of these commenters thought the PQIs might be useful for monitoring but not for inclusion in performance scores, since they could inadvertently drive underutilization. One commenter suggested evaluating the incidence of ACSC admissions in each ACO and if the size of many ACOs' enrollment is insufficient to assure that these measures are statistically stable, such instability should be considered before tying performance results to shared savings. One commenter suggested developing a methodology to address how measures for ACOs with small eligible populations (for example N<30) can be reliably and fairly scored. Two commenters recommended we consider consolidating measures with small sample sizes into one measure at least for scoring purposes. One commenter believed beneficiary compliance to be outside the provider's control and recommended that CMS monitor these measures rather than include them in the performance score.

One commenter supported the intent of ACSC: Congestive Heart Failure (proposed measure 15) but stated there are technical issues with the measure in that it may not accurately capture patients with CHF. This commenter urged CMS to remove monitor implementation of this measure to ensure its reliability. We did not receive any comments on ACSC: Dehydration (proposed measure 16). One commenter wrote in support of ACSC: Bacterial Pneumonia (proposed measure 17). Another commenter stated that ACSC: Bacterial Pneumonia assumes that administrative claims can identify preventable cases of pneumonia, fails to recognize that the pneumonia vaccine has limited effectiveness, and does not adjust for regional differences in patient and environmental characteristics associated with risk for pneumonia. One commenter wrote in support of ACSC: Urinary Infections (proposed measure 18).

Response: We note that the AHRQ PQIs for Ambulatory Care Sensitive Condition admissions are well-established as indirect measures of access to and performance of timely and effective primary care services. That is, timely and effective care for managing patients' chronic conditions should result in fewer hospital admissions for these admissions. These were among the measures recommended by major provider groups in Listening Sessions conducted by CMS to inform the rule-making proposals. We recognize the commenters' risk adjustment concerns and believe that the adjustment for age and sex included in these measures establishes a fair baseline for comparing ACO performance to national benchmarks, so that both very high and very low rates can be investigated. The ACSC admissions represent common conditions among Medicare FFS beneficiaries, but we recognize the concern of small numbers of admission events. We have accounted for this concern in our selection of final ACO quality measures to include those PQIs that we believe are most important as indicators of ACO care coordination and remove those that we believe are still important but may have sample size issues or are less central to ACO goals. We are not finalizing the following ACSC measures for quality performance purposes but may still consider calculating them from claims for monitoring and informational purposes: diabetes, short-term complications (proposed measure 12); uncontrolled diabetes (proposed measure 13); dehydration (proposed measure 16); bacterial pneumonia (proposed measure 17); and urinary infections (proposed measure 18). We are finalizing the ACSC measures for COPD (proposed measure 14) and heart failure (proposed measure 15). Once we have actual ACO performance data on the measures, we will review again to determine if sample size is truly an issue in the ACO context and will address in the future if needed. We suggest that commenters contact the measures steward directly regarding any technical issues identified with these measures. Finally, we do not believe it would be appropriate to combine measures with small sample sizes into one measure, as one commenter suggested. Such combination would require further testing and coordination with the measures steward. Additionally, we are unclear how an ACO could take action based on a consolidated ACSC measure score that does not distinguish between types of ACSC events.

Comment: Proposed measures 19–23. Care Coordination/Information Systems. One commenter wrote in support of all 5 of these measures. Another recommended CMS require ACOs to implement the use of electronic medical records as soon as practicable. Many commenters wrote in support of a single measure of EHR program participation, such as proposed measure 19. Percent of all Physicians Meeting Stage 1 Meaningful Use Requirements or proposed measure 20. Percent of PCPs Meeting Stage 1 Meaningful Use Requirements. A number of commenters recommended removing these measures for a variety of reasons. A few commenters recommended CMS remove these measures or collect them only for monitoring purposes because they are structural measures and not necessarily accurate indicators of quality performance. Another commenter echoed this recommendation and added that the incentive should not be based upon the tools or processes used by an ACO but rather the outcomes achieved by the ACO. A few commenters stated that adoption of health information technology is already the subject of penalties and incentives under the EHR Incentive Program and including these measures for the Shared Savings Program is redundant. A few commenters believed it unfair to penalize ACO providers for not meeting meaningful use in advance of the penalty phase of the EHR Incentive Program. One of these commenters noted that these measures are not core measures for the EHR Incentive Program and meeting the proposed requirements would be feasible only for ACOs that already have experience with a robust EHR. One commenter believed certain EHR Incentive Program measures were susceptible to inaccurate reporting, such as whether medication reconciliation is performed.

A few commenters recommended proposed measures 19 (Percent of All Physicians Meeting Stage 1 Meaningful Use Requirements) and 20 (Percent of PCPs Meeting Stage 1 Meaningful Use Requirements) be dropped or that CMS should exempt specialists. One commenter thought Stage 1 Meaningful Use measures made it difficult for specialists to achieve meaningful use, while another objected to requiring specialists to report on primary care-based measures. One commenter asked CMS to consider how specialists, who are permitted to contract with multiple ACOS, would be able to communicate electronically across various ACOs, who may be using different EHRs that are not interoperable. One commenter requested that the ACOs' EHR-related measures not be limited to the categories of providers designated as EPs under Stage 1 of Meaningful Use.

A few commenters requested clarification of the definition of clinical decision-support in proposed measure 21 (Percent of PCPs Using Clinical Decision Support), and one commenter urged CMS to include cardiovascular imaging decision support tools in the measure. Proposed measure 22 (Percent of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program) and proposed measure 23 (Patient Registry Use) each received one comment of support.

Response: We considered these comments in finalizing our measures set and have decided to finalize only proposed measure 20 and expand it to include any PCP who successfully qualifies for an EHR Incentive Program incentive rather than only including those deemed meaningful users. One reason for retaining this measure is that we believe it is important to encourage EHR adoption as a means for ACOs to better achieve the goals of the three-part aim, recognizing that some organizations may currently be achieving better quality outcomes using EHRs, even if they are not yet considered ''meaningful users,'' than organizations that have not yet adopted such technology. To this end, we recognize that first-year Medicaid EHR Incentive Program participants can earn an EHR incentive for adopting, implementing, or upgrading an EHR, and do not need to be ''meaningful users'' in order to earn an incentive, and would like to include such EHR participants in this measure. A second reason for retaining this measure but not proposed measure 19, percent of all physicians meeting Stage 1 HITECH Meaningful Use Requirements, is that we recognize some ACOs may be comprised of PCPs only. An ACO's score on proposed measures 19 and 20 would be the same if the ACO is only comprised of PCPs. As a result, the use of both measures could be considered redundant. The third reason for finalizing proposed measure 20 with modification is that it is a structural measure of EHR program participation that is not measured in any other program, and therefore is not duplicative of any existing measures. In addition, CMS can calculate the measure based on data already reported to the EHR Incentive Program, such that no additional reporting would be required by ACOs other than what EPs have already reported. Overall, we believe relaxing this measure definition is more inclusive and promotes

participation, while still signaling the importance of healthcare information technology (HIT) for ACOs.

Regarding the decision not to finalize the other proposed Care Coordination/ Information Systems measures (that is proposed measures 21–23), we have removed these measures based on commenters' recommendations and in an effort to pare down the proposed measures set to those measures that will have the most impact and are most aligned with ACO goals. Our intent is to align the Shared Savings Program measures with the EHR Incentive Program measures, however since we are not incorporating the EHR Incentive Program or eRx Incentive Program incentives under the Shared Savings Program, as discussed in section II.F.5. of this final rule, we have decided not to finalize EHR and eRx structural measures that may be considered redundant. For instance, we recognize that some ACOs may be comprised predominantly of primary care physicians, which would make proposed measure 19 largely redundant of proposed measure 20.

In response to the comment on proposed measure 21. Percent of PCPs Using Clinical Decision Support, to clarify, the measure proposed was an EHR Incentive Program core measure for clinical decision support. We have removed this measure from the final set, since it is included in the meaningful use requirements and could be considered redundant. Some of the EPs who successfully qualify for an EHR incentive payment are meaningful users of HITECH, and clinical decision support is one of the requirements to be considered a meaningful user. Similarly, we did not finalize proposed measure 22 (Percent of PCPs who are Successful Electronic Prescribers Under the eRx Incentive Program), since EPs cannot earn both an eRx Incentive Program incentive and a Medicare EHR Incentive Program incentive. As a result, any measures that reflect successful incentive qualification for the eRx and Medicare EHR incentives would conflict with one another. In addition, we believe there is some redundancy between proposed measures 21 and 22 with proposed measure 20. Percent of PCPs Meeting Stage 1 Meaningful Use Requirements, since clinical decision support and electronic prescribing are part of the meaningful use criteria included in proposed measure 20., which we are finalizing with minor modifications as previously described.

We are not finalizing the Patient Registry Use measure (proposed measure 23), since it is not a required, ''core'' measure in the EHR Incentive Program's meaningful use criteria. We have concerns that, by requiring this measure, we will inadvertently provide an incentive for ACOs to make an optional, EHR Incentive Program ''menu set'' measure a ''core'' measure for their ACO providers/suppliers who are EPs. We also recognize that patient registry use is fundamental to measuring, improving and reporting quality measures so we expect that most, if not all, ACOs will have some form of patient registry use already in place to support quality measurement and improvement activities. As a result, we believe this measure is unlikely to provide an incentive for more widespread adoption of EHRs or registries or improved ACO performance.

Comment: Proposed measures 24. Health Care Acquired Conditions Composite and 25. CLABSI Bundle. One commenter endorsed measures related to hospital-acquired conditions and patient safety, but many commenters stated that hospital-based measures should be removed or were not applicable to ACOs that do not include hospitals as ACO participants. One commenter stated that the information exchange required would generally not be in place for ACOs without hospitals, and another thought these measures were duplicative of IPPS reporting. Others stated that hospitals were already being held accountable through the hospital value-based purchasing program and that, in many markets, an ACO simply wouldn't have the ability to impact the various hospitals where an ACO's members might receive treatment. Commenters proposed various alternatives: That ACOs without hospitals be exempted from reporting on these measures; that hospital measures be made voluntary; that these be dropped completely; or that we use process measures that are already widely used in the hospital value-based purchasing program until true population-based outcomes measures are available. Several commenters expressed concern about including the HAC composite but supported inclusion of the CLABSI bundle until better ACO patient safety measures are developed. One commenter thought it duplicative to have two different measures of central line infections and preferred the CLABSI bundle as a more reliable and valid measure. Regarding the proposed method of data submission, one commenter noted the difficulties of using claims data to accurately detect healthcare acquired conditions and supported the CDC National Healthcare Safety Network (NHSN) surveillance data as a more reliable source. One commenter recommended CMS apply the recently released regulations specifying that state Medicaid programs may use more comprehensive approaches to payment adjustment to ACOs. One commenter stated some hospital acquired conditions can be reduced but not eliminated and programs that expect elimination may cause providers to avoid caring for high-risk patients and recommended identification of evidence-based exceptions, development of alternative systems to encourage providers to adopt processes to reduce HACs, and systems to measure process steps taken.

Proposed measure 24. Health Care Acquired Conditions Composite. A few of commenters wrote in support of this measure; one recommended CMS only score the measure on an ''all or nothing'' basis to eliminate rewards for preventable medical errors. One commenter argued that measurement alone would motivate improvement as long as scores are transparent and visible. Another commenter recommended this composite only be used for monitoring and not for performance scores.

Many commenters expressed concerns about including the HAC composite, most commonly on the grounds that it is untested or because it is a hospital-based measure. A few commenters stated that the proposed composite HAC measures lack clarity and do not provide useful or timely information to improve performance. These commenters were concerned about the measure being a compilation of nine CMS HACs combined with an AHRQ Patient Safety Indicator which is itself a composite of eight measures, some of which are only slightly different from other proposed components (for example pressure ulcers and decubitus ulcers are both included). These commenters were concerned about how risk adjustment would be handled in this composite, since sicker patients are at higher risk for HACs. These commenters were also concerned that the data could be submitted from either administrative/claims data or NHSN and that the resultant measure including both sources has not been validated. These commenters recommended that CMS use the HAC measures individually as separate measures and not a composite as currently defined in the Hospital Inpatient Quality Reporting Program; use CLABSI from NHSN with data submitted as a separate patient safety measure; and delete AHRQ PSI #90 since it overlaps with several HAC measures and imposes redundant, duplicative effort. Another commenter

with similar concerns recommended inclusion of the first five HAC measures along with additional NQF measures such as, patient death or serious injury associated with medication errors, or failure to follow up on or communicate clinical information as soon as practicable.

Commenters were also concerned that: the complexity and lack of validation for the composite would discourage organizations or groups from participation; risk adjustment is needed since sicker patients have a greater chance for these events; and many of the HACs are low-incidence complications that have not been tested for rate-based comparisons. One commenter opposed the inclusion of accidental puncture or laceration and iatrogenic pneumothorax, arguing that including measures for rare complications is ineffective and may result in unintended consequences. This commenter stated that it is difficult to identify statistically significant differences rather than random variation in the data and raised concern that measuring such rare events could drive increased use of less safe procedures such as femoral catheterization. A few commenters recommended this measure be used for monitoring and not be used as part of the performance score. One commenter stated that there are ambiguous coding guidelines regarding inadvertent laceration or puncture not considered to be accidental (for example serosal tears) and recommended CMS field test patient safety measures prior to adopting them for the Shared Savings Program. Another commenter noted that the proposed ACO HAC Composite includes CLABSIs rather than vascular catheter-associated infections, consistent with reporting requirements in the Hospital Inpatient Quality Reporting program. However, this commenter urged CMS to further align measurement requirements and use CLABSIs across programs in order to reduce duplicative reporting burden and to support the use of what the commenter believed to be superior quality data.

A few commenters noted that proposed measure 25. Health Care Acquired Conditions: CLABSI Bundle is the CDC National Healthcare Safety Network (NHSN) process measure of central line insertion practices and questioned how it would be possible to measure this based on claims data. The commenters stated that the measure is very labor intensive, and is not in widespread use even in NHSN, which means there are minimal baseline data. The commenters recommended that this measure not be included given the lack of baseline data, the labor intensity of the required chart abstraction, and the number of proposed ACO quality measures. Another commenter preferred this measure over the proposed HAC Composite.

Response: Medical errors are a major source of morbidity and mortality in the United States, and patient safety initiatives that reduce the number of these events are a critical focus for CMS and the Department. However, we recognize that not all ACOs will have participating hospitals, but, for those ACOs that do have hospitals, we do not believe this approach is duplicative of hospital value-based purchasing program efforts, which calculate such measures at a hospital patient population level and not at an ACO assigned beneficiary population level. We also recognize that some HACs may be reduced but not eliminated, as one commenter noted. Reporting remains an important issue for effectively tracking health care acquired conditions. Measuring ACO performance on HACs would potentially serve as an incentive to improve reporting. We agree many of the hospital acquired conditions are rare events and proposed the composite in an effort to produce a larger, more meaningful sample size, since ACOs will have smaller populations and even fewer events than would a hospital. However, we recognize there are challenges with combining claims and surveillance-based measures that have different calculation methodologies into one measure. There are also challenges with using hospital-reported measures based on aggregate, all payer data, as is the case with measures reported to the NHSN, particularly for ACOs that do not include hospitals. Upon further consideration of our proposal, we agree with the suggestion that, if these measures were to be finalized, we should break out the components and score the measures individually. We recognize there are operational complexities combining endorsed measures that reflect different population bases and have different timeframes, data sources and risk adjustment methodologies. In addition, we realize that combining these measures may result in a larger number of incidents in the measure numerator, due to the larger sample size, but may not result in more meaningful information for an ACO. That is, in combining the HACs into one measure, the ACO cannot discern which HACs are of concern and which are not, whereas measuring the HACs individually would provide such information.

That said, we have decided not to finalize these measures at this time. However, we may consider claims-based HAC measures that can be calculated at an ACO assigned beneficiary population level for quality monitoring purposes, regardless of whether an ACO includes a hospital. That is, we would determine from claims whether any ACO-assigned beneficiaries who had been hospitalized (regardless of whether the hospital is an ACO provider/supplier) experienced a HAC. We believe the approach of considering claims-based HAC measures that can be calculated at a patient level emphasizes the importance of monitoring HACs among an ACO's assigned beneficiary population but eliminates reporting burden and operational complexity, particularly for those ACOs that do not include a hospital. We would not calculate the CLABSI Bundle, even for monitoring purposes, at this time as this measure can only be calculated from NHSN surveillance data, as one commenter clarified. Since NHSN data are hospital-reported, all-payer data, we are unclear at this time how to translate such data to a Medicare FFS ACO population, particularly when ACOs do not include a hospital. However, we will continue exploring how to leverage NHSN data in the Shared Savings Program.

Comment: Proposed measures 26–34. Preventive Health. A few commenters wrote in general support of preventive care measures while one commenter recommended that all preventive health measures should be dropped until they can be studied further. One commenter suggested CMS work with CDC to add additional prevention measures as the program matures.

Response: We believe preventive health is critical to reducing chronic, costly conditions, and that primary care is critical to the ACO model of care. As a result, we believe it is important to retain preventive health quality measures in the Shared Savings Program. However, we will monitor these measures and work with the measures community in an effort to ensure we are using the most appropriate, high impact measures.

Comment: Proposed measures 26 and 27. Influenza Immunization and Pneumococcal Vaccination. Several commenters wrote in support of one or both of these measures particularly given the burden of death, disease and high cost care resulting from pneumococcal disease and influenza among the elderly. One commenter stated that these measures are not geared towards population health and should be removed. One commenter recommended that providers not be penalized for vaccine shortages. Another commenter recommended

deferring introduction of these measures until EHRs are in widespread use because vaccine administration would be difficult to document if the vaccine was received outside of the ACO. Another commenter noted the burden of using EHR data to populate GPRO and suggested CMS instead consider the survey-based measure from NCQA HEDIS, which could be added to the CG–CAHPS. One commenter suggested updating the pneumococcal vaccination measure to include the new ACIP recommendations for pneumococcal vaccine for patients age 5–64 that have a high-risk condition.

Response: We believe vaccinations are important to population health, particularly in the Medicare population, and are finalizing the proposed measures with minor modification as discussed later in this final rule. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention states effectiveness estimates for vaccines range from 50 percent to 80 percent for prevention of pneumonia among immunocompetent older adults and adults with various underlying illnesses.[2] The CDC has also shown that elderly citizens vaccinated against influenza have reductions in the rates of hospitalization and death from influenza, as compared with the rates in unvaccinated elderly persons. These measures were not intended to penalize providers in cases of vaccine shortages. Commenters should contact the measures stewards regarding such concerns.

The CAHPS questions relevant to health care services are intended to assess the patient's experience with care furnished in the ACO rather than whether the ACO providers are actively tracking immunization status. Since ACOs are charged with better coordinating and improving care, we believe these immunization measures should be ACO-reported not patient-reported. Our ACO GRPO reporting process uses patients' claims data to the extent that they are available when calculating the measure, thus reducing the burden on providers for reporting on their population while allowing the ACO to update the numerator with information from its clinical or administrative systems, such as patient-reported information.

Additionally, in response to other comments requesting that we align measures with those used in PQRS and the EHR Incentive Program, as discussed in section II.F.5. of this final rule, we have finalized the pneumococcal vaccination measure to reflect NQF #43 instead of #44. Both measures have the same denominator population—patients over the age of 65—and reflect the same outcome, whether pneumococcal vaccination was obtained in the previous 10 years; however, we believe NQF #43 offers an advantage to ACOs over NQF #44 in that a provider collects NQF #43 through discussion with the patient, whereas NQF #44 requires medical chart abstraction. Because of the level of effort required to obtain a 10 year chart abstraction (for purposes of NQF #44), the decision was made to use NQF #43, which can be collected at the point of care during a current patient visit and reported electronically through the GPRO web interface. We believe the use of this measure would help address the general comments regarding reporting burden and would align with quality measures used in other programs, such as PQRS.

Comment: Proposed measure 28. Mammography Screening. Several commenters noted that this measure was not aligned with professional guidelines that do not support routine mammograms for women 40–49 and recommended shared decision making between woman and provider. Some of these commenters also noted that guidelines recommend screening for women until age 74, not 69 as proposed. One commenter favored inclusion of women 40–49 but stated that the upper age limit should be at 5 years of life expectancy. One commenter stated that this measure should be eliminated because it has potential for the unintended consequence of interfering with a woman's right to refuse mammography until age 50, by measuring the quality of an ACO's care based on whether she received biennial exams starting at 40. One commenter thought the measure should begin at age 40, since this age is included in health plan coverage and as a measure of provider counseling given to the woman. Another commenter recommended that this measure be excluded because the denominator population (women, 40–69 years of age) is comprised primarily of patients who are not Medicare beneficiaries.

Response: We are finalizing the measure as proposed. The proposed measure follows guidelines established by NCQA and endorsed by NQF. We recognize that the age 40–49 category applies to a small percentage of Medicare beneficiaries, however early detection allows women to obtain timely treatment and potentially lead a longer, healthier, life. We believe early preventive health is important for deterring many of the chronic conditions and illnesses more prevalent later in life that are more specific to the Medicare population. Additionally, this age range aligns with preventive health measures with similar age ranges used in other CMS quality programs. We also appreciate the recommendation to extend the age range to 74, however the current measure specification is for years 40–69. We expect that the specifications for the endorsed measures may be updated to reflect the change in clinical guidelines, at which time we would also adopt such specifications.

Comment: Proposed measure 29. Colorectal Cancer Screening. We did not receive any comments on this proposed measure.

Response: We will finalize this measure as we believe colorectal cancer screening is an important component of preventive health in the Medicare FFS population.

Comment: Proposed measure 30. Cholesterol management for Patients with Cardiovascular Conditions. One commenter wrote in support of this measure.

Response: We note that the correct title of the measure corresponding with the NQF number proposed (NQF #75) is: Ischemic Vascular Disease: Complete Lipid Profile and LDL Control <100. We have finalized this measure to reflect the correct title and also added an Ischemic Vascular Disease subcategory in the At Risk Population domain. This measure also aligns with other cardiovascular disease prevention initiatives that are priorities for CMS, CDC, and HHS, such as the Million Hearts initiative.

Comment: Proposed measure 31. Adult Weight Screening and Follow-up. One commenter expressed concern that this was a process measure that does not measure actual weight management.

Response: We believe the processes of weight and BMI screening and follow-up are important steps for preventing and reducing obesity and complications related to other chronic conditions in which weight plays a factor. BMI measurement can also be considered an intermediate outcome, since BMI can be used to monitor patients' progress with respect to weight reduction as well as weight gain that can exacerbate chronic conditions. Therefore, we are finalizing this measure.

Comment: Proposed measure 32. Blood Pressure Measurement. One commenter stated that a measure of the percentage of patients with uncontrolled blood pressure did not represent a best practice of care. A few commenters

[2] Centers for Disease Control and Prevention. Influenza and Pneumococcal Vaccination Levels Among Adults Aged greater than or equal to 65 Years—United States. MMWR 1998 Oct 2; 47(38); 797–802.

questioned the meaningfulness of this measure; one urged CMS to go beyond structure and process measures to measures that solidly address clinical appropriateness and overuse. One commenter suggested deleting this blood pressure process measure, because we also proposed a blood measure level measure.

Response: Blood pressure measurement for patients with diagnosed hypertension is a best practice according to clinical guidelines; however the measure community recognizes the high rate of compliance and the need for even greater quality improvement. We agree with the suggestion to remove this measure, since the AMA–PCPI is retiring this measure (NQF #13), and because it is similar to proposed measure 58. Hypertension: Blood Pressure Control (NQF #18).

However, we believe blood pressure measurement is an important preventive health measure and therefore have included ''Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years,'' in the final measures set, consistent with the measure that has been proposed for the PQRS for 2012. The measure we are finalizing also aligns with the Million Hearts Initiative and blood pressure measurement standards of care recommended by the USPSTF and the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. We believe this measure is more appropriate for the Preventive Health domain of the Shared Savings Program than the measure proposed as it is a quality measure intended for patients without diagnosed hypertension whereas the proposed measure was intended for BP management for patients with diagnosed hypertension. Similar to the proposed measure, the measure we are finalizing targets a Medicare FFS population age 18 and older, requires two face-to-face provider encounters for assigned patients, and would be reported via the GPRO web interface.

Comment: Proposed measure 33. Tobacco Use Assessment and Tobacco Cessation Intervention. Several commenters wrote in support of the tobacco use measure. One commenter proposed use of NQF Measure #27 as a stronger measure of cessation efforts. One commenter questioned the fairness of holding ACOs responsible for patients who might choose to continue using tobacco. One commenter expressed concern that this measure could be gamed and suggested excluding or modifying the measure. One commenter recommended replacing this measure with PQRS measure #226.

Response: Tobacco use is harmful to patient health, but among diabetics, it is particularly dangerous as it increases the risk of complications, and we are therefore including this measure in the final set. To substantially lower the risk for cardiovascular and stroke events, it is critical that the specified tobacco use assessment and cessation goals are achieved. This quality measure aims to encourage even greater engagement by physicians and their patients in achieving tobacco free status. We recognize the potential for gaming and will monitor this measure closely, for instance, through the GPRO audit and validation process described in section II.F.4.b. of this final rule. We will consider suggestions for other measures in the future. We also note that at the time of our proposed rule the PQRS measure number was ''TBD'' and has since been numbered 226; thus, the measure we proposed and are including in the final measure set for the Shared Savings Program is the same measure used by PQRS.

Comment: Proposed measure 34. Depression Screening. A few commenters wrote in support of the depression screening measure. One commenter stated that this measure would require significant changes in primary care workflow, even though it has not been linked with improved chronic disease outcomes in clinical trials. One commenter recommended modifying the measure to incorporate elements of NQF #17 that specify screening, monitoring, and reassessment with the Patient Health Questionnaire. One commenter recommended CMS replace this measure with other measures or expand it to include other mental health assessment tools. Another commenter stated that while several useful tools are available in the public domain, many lack standardization of scoring and data collection modalities, or lack sufficient normative data and condition-specific benchmarks useful for interpreting health scores and reducing interpretation bias. In addition, the commenter stated, many publically available health measures lack culturally validated translations for non-English speaking patients.

Response: We disagree with the comment that depression screening has not been linked to improved chronic disease outcomes in clinical trials. In a systematic review of the evidence, the USPSTF concluded that depression screening significantly improves patient outcomes. (*http://www.ncbi.nlm.nih.gov/books/NBK36406/*) Another study found that the presence of depression is associated with reduced compliance with treatment.[3] Because patients in whom depression goes unrecognized cannot be appropriately treated, systematic screening has been advocated as a means of improving detection, treatment, and outcomes of depression. As a result, we are finalizing this measure in order to encourage ACOs to adopt system changes that ensure timely identification and adequate treatment and follow-up if needed. Since the NQF #17 measure suggested is Hypertension Plan of Care we believe the commenter was actually referring to NQF #712, Depression Utilization of the PHQ–9 Tool.

Comment: Proposed measure 35. Diabetes Composite (all or nothing scoring) and 52. Coronary Artery Disease (CAD) Composite (all or nothing scoring). A few commenters wrote in support of these measures. A few commenters stated opposition to scoring these measures in an ''all-or-nothing'' manner. Other commenters cautioned against use of both the composite measures and counting the components of the composite as individual measures because of resultant ''double counting.'' A few commenters recommended using only the individual measures to allow ACOs to target processes for improvement but others recommended retaining only the composite.

A few commenters recommended CMS replace the diabetes composite measure proposed with NQF measure #0729 and use the specifications for measure #0729 for proposed measures 36–39 and 41. One commenter recommended CMS include microalbumin screening in the diabetes composite measure as well as an individual measure. One commenter questioned the fairness of holding ACOs responsible for patients who might choose to continue using tobacco, under the diabetes composite. One commenter recommended replacing either the diabetes or CAD composites with the Optimal Vascular Care Composite (NQF #0076).

Response: To clarify, the diabetes composite measure proposed is the Optimal Diabetes Care composite, NQF #0729, as one commenter suggested. At the time of the proposed rule, this measure was pending NQF endorsement. As a result, we proposed similar NQF numbers for the components of this composite to provide the public the opportunity to review and comment on similar and/or

[3] DiMatteo MR, Lepper HS, Croghan TW. Depression is a risk factor for noncompliance with medical treatment: meta-analysis of the effects of anxiety and depression on patient adherence. Arch Intern Med. 2000 Jul 24;160(14):2101–7.

related component measures. Since the time of proposed rulemaking, the measure has been endorsed and numbered #0729. We also note this composite is currently NQF-endorsed with 5 components, of which microalbumin screening is not included, so we advise the commenter that supported inclusion of this measure to contact the measure steward directly about the addition of other components. Although we appreciate that there are concerns about all-or-none scoring, there are also advantages. For instance, AMA–PCPI states that the ''all-or-none method is the most patient-centric approach and provides the most opportunities for improvement, especially if the individual components are reported out separately.'' (*http://www.ama-assn.org/resources/doc/cqi/composite-measures-framework.pdf*)

We also understand concerns about the redundancy of scoring both the composites and individual measures and are finalizing the proposed diabetes and CAD composites, with modification to the CAD composite as described later in this final rule, and are not finalizing the individual proposed measures that were also within the proposed composites, consistent with the AMA–PCPI statement cited previously. However, we will report back to ACOs their results on individual measures within the composites in addition to their overall composite measure score. We believe the diabetes and CAD composites raise the bar for diabetes and CAD care, consistent with Shared Savings Program goal of improving quality of care, by providing an incentive for ACOs to ensure that a number of important care processes are performed for diabetic and CAD patients, and that appropriate outcomes are achieved. In contrast, the individual measures would award points if only some of the processes are performed and some outcomes are achieved. We recognize the concern about holding ACOs accountable for patient choices such as continued tobacco use. However, since tobacco use causes greater complications among diabetics, we believe the tobacco use component of this composite measure will incentivize greater provider involvement in smoking cessation counseling.

Comment: Proposed measures 35 and 39. Diabetes Mellitus: Aspirin Use. One commenter wrote in support of this measure. One commenter stated that these measures are not evidence based as aspirin should be given to patients with diabetes only after consideration of their 10-year risk of a significant coronary event in accordance with current USPSTF and American Diabetes Association guidelines. One commenter considered this measure of limited value and noted that it only applies to those with diabetes and ischemic vascular disease but is not included as a measure for those with just coronary artery disease.

Response: To clarify, we proposed the Minnesota Community Measurement ''Optimal Diabetes Care'' composite for its up-to-date research, extensive testing, and relevance to the Medicare FFS beneficiary population, as discussed previously. The composite measure received NQF endorsement in March 2011, too late for this information to be included in the Shared Savings Program proposed rule. Regarding the aspirin use component of proposed composite measure 35, which we also proposed as individual measure 39, the recommendation for aspirin use for diabetics with known cardiovascular disease is based on American Diabetes Association guidelines for daily aspirin use.[4] Evidence no longer supports daily aspirin for all diabetics age 40 and older, and, as a result, the aspirin component of the composite measure only includes diabetic patients with known cardiovascular disease.

We are finalizing diabetes aspirin use as part of the diabetes composite (proposed measure 35) but are not finalizing it as an individual measure at this time. Instead of the individual aspirin use measure, we are finalizing Ischemic Vascular Disease: Use of Aspirin or Another Antithrombotic (NQF #68), which we believe is a broader measure that is more aligned with Departmental efforts to improve cardiovascular care and with other agency programs, such as PQRS. Both proposed measure 39 and NQF #68 measure aspirin or antithrombotic use in beneficiaries diagnosed with ischemic vascular disease (IVD), use a common set of ICD–9 codes to define the condition, and are calculated for Medicare FFS beneficiaries age 18 and older. However, we believe the IVD measure is more appropriate as an individual measure, since it is intended for the entire IVD population, rather than only those with IVD and diabetes, which the diabetes composite measure already captures.

The IVD measure also includes use of other antiplatelet medications, which we believe reduces the need for a separate CAD: Oral Antiplatelet Therapy Prescribed for Patients with CAD measure, as discussed in more detail later in this final rule in connection with proposed measure 53. Thus, we believe the IVD measure reduces the burden of quality measure reporting for ACOs, since it is one GPRO measure that captures the data that would otherwise have been required be reported via 2 separate measures. It also aligns with PQRS efforts for 2012, the Million Hearts initiative, and the other IVD measures we are finalizing in this rule.

Comment: Proposed measures 36 and 40. Diabetes Mellitus: Hemoglobin A1c Control and Hemoglobin A1c Poor Control. A few commenters recommended that, in order to pare down measures, CMS retain only one of these measures as there is some overlap. One commenter recommended CMS use age limits for these measures.

Response: We note that these measures do address somewhat different aspects of diabetes control. HbA1c Control targets good control in patients, with an aim of monitoring to keep levels in range, while HbA1c Poor Control targets patients whose diabetes is poorly-controlled and may require additional intervention. Accordingly, we believe it is appropriate to retain both measures. Although we are not finalizing proposed measure 36 in this final rule, HbA1c Control is part of the all or nothing diabetes composite measure under proposed measure 35. We suggest that the commenter concerned about age limits contact the measure steward directly.

Comment: Proposed measure 38. Diabetes Mellitus: Tobacco Non Use. A few commenters believed this measure was unnecessary as it was duplicative of proposed measure 33. Tobacco Use Assessment and Tobacco Cessation Intervention or suggested that the measure be broadened to all tobacco users, regardless of diagnoses. One commenter expressed concern that this measure could be gamed and suggested excluding or modifying the measure.

Response: Tobacco use is harmful to patient health, but among diabetics, it is particularly dangerous as it increases the risk of complications. To substantially lower the risk for cardiovascular and stroke events among patients with diabetes, it is critical that the specified outcome goals are achieved. This quality measure aims to encourage even greater engagement by physicians and their diabetic patients in achieving tobacco free status. Although we are not finalizing this individual measure, it is part of the diabetes composite under proposed measure 35 that we are finalizing in this rule. At the time the proposed rule was published,

[4] *American Diabetes Association. Standards of Medical Care in Diabetes—2011. Available at http://care.diabetesjournals.org/content/34/Supplement_1/S11.full.*

some aspects of the measure had not yet received NQF endorsement. Since the measure has now been endorsed as part of the Optimal Diabetes Care composite (NQF #0729), we can clarify that this has now been changed to a different NQF measure, ''Tobacco Non-Use.'' This measure is specifically endorsed for use in diabetics, whereas the measure proposed (NQF #28) is a general preventive health measure we would have calculated for a diabetic population. We recognize concerns for gaming and intend to use the GPRO audit and validation process described in section II.F.4.b. of this final rule, to monitor such activities.

Comment: Proposed measure 40. Diabetes Mellitus: Hemoglobin A1c Poor Control. One commenter questioned inclusion of this measure stating it was not evidence-based, citing research suggesting that interventions to maintain glycemic control in the frail elderly may adversely affect outcomes. One commenter recommended CMS remove this measure as it is not aligned with patient goals.

Response: We are finalizing this measure as we believe glycemic control is an important quality issue. The American Geriatrics Society guidelines currently state that avoiding poor glycemic control is important even for frail older adults; therefore, we believe this measure is consistent with the standard of care and aligned with patient goals.[5]

Comment: Proposed measure 41. Diabetes Mellitus: High Blood Pressure Control in Diabetes Mellitus. One commenter stated that this measure is not geared towards population health and should be removed.

Response: We included this measure as a population health measure because diabetes is prevalent in the Medicare population and has high rates of morbidity and mortality. Most people with diabetes have other risk factors, such as high blood pressure, that increase the risk for heart disease and stroke. However, we are not finalizing this as an individual measure, because it is part of the diabetes composite, proposed measure 35. that we are finalizing.

Comment: Proposed measures 42.–44. At Risk Population—Diabetes. One commenter supported including proposed measure 42. Diabetes Mellitus: Urine Screening for Microalbumin or Medical Attention for Nephropathy in Diabetic Patients. Another commenter believed this measure could be removed as it only measured process. One commenter stated that, regarding proposed measure 43. Diabetes Mellitus: Dilated Eye Exam in Diabetic Patients, there are alternatives to dilated eye exams and recommended providers not be penalized for using those alternatives. We did not receive any comments on proposed measure 44. Diabetes Mellitus: Foot Exam.

Response: We are not finalizing these measures at this time. While we agree that nephropathy screening, eye exams, and foot exams are important for diabetics, in order to reduce the burden of the quality reporting at the start of the Shared Savings Program, we have sought to include only the most high impact diabetes intermediate outcome measures and are not finalizing these measures at this time. If the commenter that recommended eye exam alternatives is referring to fundus photographs as the alternative, the 2011 American Diabetes Association (ADA) Standards of Medical Care in Diabetes still recommend dilated eye exams and state that while retinal photography may serve as a screening tool for retinopathy, it is not a substitute for a comprehensive eye exam.

Comment: Proposed measures 45–51. At Risk Population—Heart Failure. One commenter supported proposed measures 45. Heart Failure: Left Ventricular Function (LVF) Assessment and 46. Heart Failure: Left Ventricular Function (LVF) Testing. A few of commenters stated that LVF assessment reflects a minimal standard of care and urged CMS to go beyond structure and process measures to measures that solidly address clinical appropriateness and overuse. Another commenter questioned how meaningful these measures are as they may already have high performance levels and, therefore, have little room for additional quality improvement. Another commenter wrote in support of proposed measure 49. Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).

One commenter was concerned that proposed measure 47. Heart Failure: Weight Measurement was duplicative to proposed measure 31 (Adult Weight Screening and Follow-up). One commenter stated that the measure developer had retired this measure. Another commenter stated the measure was of limited value because it fails to differentiate between providers.

One commenter stated proposed measure 48. Heart Failure: Patient Education was of limited value because it fails to differentiate between providers. Another commenter wrote in support of proposed measure 50. Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction, while another commenter questioned the value of this measure as it already has high performance levels in some regions.

One commenter wrote in support of proposed measure 51. Heart Failure: Warfarin Therapy for Patients with Atrial Fibrillation. Another commenter noted that this measure is outdated and should be modified to include thrombin inhibitor therapy, and one commenter recommended removing this measure entirely.

Response: While we agree that LVF testing has improved, 2011 AMA–PCPI guidelines cite LVF assessment, Patient Education, and ACEI/ARB Therapy for LVSD as opportunities for improvement. (*http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/hfset-12-5.pdf*) However, in response to comments about reducing the number of quality measures and in an effort to finalize higher impact measures, we are not finalizing LVF assessment (proposed measure 45), LVF testing (proposed measure 46), Patient Education (proposed measure 48), or ACEI/ARB Therapy for LVSD (proposed measure 50). We are also not finalizing the Heart Failure: Weight Measurement measure (proposed measure 47), as it is retired, as one commenter noted. We are also not finalizing the Warfarin Therapy measure (proposed measure 51) but intend to further research the implications of such a measure of warfarin therapy as opposed to one of thrombin inhibitor therapy and revisit this in the future.

Of the measures proposed for heart failure, we believe there is greatest opportunity for quality improvement in the Beta-Blocker Therapy for LVSD (proposed measure 49) and ACSC: Congestive Heart Failure (proposed measure 15), aimed at reducing avoidable admissions, and are finalizing both measures.

Comment: Proposed measure 52. Coronary Artery Disease (CAD) Composite: All or Nothing Scoring. Comments discussed previously with proposed measure 35.

Response: We have finalized this measure with modification to include only the following components: Drug Therapy for Lowering LDL-Cholesterol and Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction

[5] Guidelines for Improving the Care of the Older Person with Diabetes Mellitus. California Healthcare Foundation/American Geriatrics Society Panel on Improving Care for Elders with Diabetes. American Geriatrics Society. May 2003—Vol. 51, No. 5 Supplement, JAGS.

(LVSD). Since CAD is a common chronic condition and is an underlying condition for individuals with other chronic conditions, we are narrowing our composite measure to focus on CAD measures that better align with final measures in other chronic disease areas. In addition, while we will score this measure as a composite measure, we will provide feedback on the individual components so ACOs can identify areas of lower performance and design strategies to improve performance.

Comment: Proposed measure 53. Coronary Artery Disease (CAD): Oral Antiplatelet Therapy Prescribed for Patients with CAD. One commenter wrote in support of this measure.

Response: We are not finalizing this measure at this time, as we believe the aspirin use component of the diabetes composite (proposed measure 35) and the IVD: Use of Aspirin or Another Antithrombotic measure (discussed under proposed measure 39) align and complement the CAD measures given the overlap in the chronic disease population. Therefore, we are finalizing the diabetes composite and the IVD: Use of Aspirin or Another Antithrombotic measures in lieu of proposed measures 39 and 53.

Comment: Proposed measure 54. Coronary Artery Disease (CAD): Drug Therapy for Lowering LDL–Cholesterol. One commenter wrote in support of this measure. One commenter suggested dropping this measure and retaining proposed measure 56 (Coronary Artery Disease: LDL Level <100 mg/dl) in order to pare down measures and retain those with the most impact on health outcomes. Another commenter questioned whether there is demonstrated variability on this measure and whether it was of value.

Response: We note that AMA–PCPI identified this measure as an opportunity for improvement and as a result have retained the measure in the final measure set under the CAD composite (proposed measure 52) but not as an individual measure, since we believe CAD is an area in which we can raise the bar for quality improvement through all or nothing scoring.

Comment: Proposed measure 55. Coronary Artery Disease (CAD): Beta-Blocker Therapy for CAD Patients with Prior Myocardial Infarction (MI). One commenter wrote in support of this measure. Another commenter cautioned CMS to use the most recent version of this measure, which was updated to include patients with left ventricular systolic dysfunction. One commenter expressed concern about the sample size for most ACOs, whether there is demonstrated variability in the measure, and exclusions for patients who have contraindications to beta blockers.

Response: We have taken the measure update into consideration and decided not to finalize the measure at this time as we believe the IVD measure we are finalizing (discussed under proposed measure 39) is a broader measure that encompasses this aspect of CAD care and allows us to reduce reporting burden to ACOs by requiring fewer measures to be reported.

Comment: Proposed measure 57. Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Dysfunction (LVSD). One commenter questioned whether there is demonstrated variability in this measure and whether allowances would be made for patients with contraindications to ACEs/ARBs.

Response: We believe this measure has room for improvement and have decided to finalize this measure under proposed measure 52, the CAD composite measure, rather than as an individual measure, as we believe CAD is an area in which we can raise the bar for quality improvement through all or nothing scoring. We will take contraindications into account prior to releasing measures specifications.

Comment: Proposed measure 58. Hypertension: Blood Pressure Control. One commenter stated that this measure is dependent on medical record data making it particularly difficult for ACOs to collect and report and recommended it not be included, at least initially. One commenter stated that this measure is not geared towards population health and should be removed. One commenter believed beneficiary compliance to be outside the provider's control and recommended that CMS monitor this measure rather than include it in the performance score.

Response: Many of these measures are based on medical record data and will be collected through the GPRO web interface, which will allow data collection from electronic medical records, patient registries and other administrative systems, as well as from paper records. Hypertension is one of the most common chronic illnesses in the Medicare population and a major cause of morbidity and mortality and a contributing risk factor for other highly prevalent conditions such as diabetes and heart disease. Although some factors influencing outcome measures are outside the provider's control, many others, such as tailoring blood pressure medications and nutrition education, can be influenced by services received through the ACO. Therefore, we are finalizing this measure in the final set.

Comment: Proposed measure 59. Hypertension: Plan of Care. Several commenters recommended removing this measure. Their reasons included: Concerns that the measure is not geared towards population health; it is inefficient; labor intensive; and not scalable. Another commenter believed this measure could be removed as long as Hypertension: Blood Pressure Control was retained.

Response: We believe this measure is important, but may have some overlap with the Adult Weight Screening and Follow-up measure (proposed measure 31), which also includes a plan of care component. Thus, we are not finalizing this measure in an effort to be sensitive to general measures comments about the number of required measures and redundancy. We are, however, retaining the Hypertension: Blood Pressure Control measure, consistent with one commenter's suggestion.

Comment: Proposed measure 60. Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation. One commenter wrote in support of retaining this measure. One commenter recommended CMS use age limits for this measure.

Response: We are not finalizing the measure at this time, in an effort to respond to general comments about the number of required measures and reporting burden. If the commenter that recommended the use of age limits for this measure is suggesting changes to the endorsed specification, we recommend communicating with the measure steward directly. We note, however, that we are finalizing the ACSC: COPD measure (proposed measure 14) as previously discussed.

Comment: Proposed measure 61. Chronic Obstructive Pulmonary Disease (COPD): Smoking Cessation Counseling Received. One commenter wrote in support of retaining this measure. One commenter expressed concern that this measure could be gamed and suggested excluding or modifying the measure.

Response: Tobacco use is harmful to patient health, but among patients with COPD, it is particularly harmful as it can cause progression of the illness. We acknowledge the potential for gaming, which is why we proposed a GPRO audit and validation process. However, we have decided not to finalize this measure at this time, as we believe smoking cessation counseling is important for all patients. Accordingly, we are instead finalizing the Tobacco Use Assessment and Tobacco Cessation Intervention measure (proposed measure 33), which includes

individuals with COPD. We believe this decision is also responsive to general comments about the number of required measures, redundancy in the measures, and reporting burden.

Comment: Proposed measure 62. Chronic Obstructive Pulmonary Disease (COPD): Bronchodilator Therapy based on FEV1. Two commenters wrote in support of this measure.

Response: We are not finalizing this measure at this time, but we are finalizing the ACSC: COPD measure (proposed measure 14), which aims to reduce avoidable admissions and is outcome focused.

Comment: Proposed measure 63. Falls: Screening for Fall Risk. Several commenters supported this measure. One commenter stated that this is a survey-based measure and should not be submitted via GPRO but could be added to CG CAHPS. This commenter also noted that the proposed measure does not match the current measure description in the 2011 NCQA HEDIS Specifications Volume II.

Response: We believe it is important for an ACO to conduct a fall risk screening or have one noted in a patient's medical record and to report this measure. The CG CAHPS is a patient-reported survey, which we do not think is appropriate for this measure, given the required involvement of a provider educated about requirements for a meaningful assessment. We are finalizing this measure and have adjusted the measure description in Table 1 to reflect the NQF description. We agree that the proposed measure does not match the 2011 HEDIS measure description, but HEDIS includes a different measure (NQF #35) than the one proposed for ACO (NQF #101). We are also moving this measure to the Care Coordination/Patient Safety domain as we believe it is more accurately characterized as a patient safety measure.

Comment: Proposed measure 64. Osteoporosis Management in Women who had a Fracture. Two commenters wrote in support of this measure. One commenter commended CMS for inclusion of this measure but recommended that it be expanded to include men who have had a fracture based on recent literature. One commenter believed that CMS should align ACO and PQRS measures by replacing this measure with the four NQF-endorsed osteoporosis measures in PQRS.

Response: At this time, we have decided not to finalize this measure in order to allow ACOs to focus their efforts to redesign their care processes to incorporate fall risk assessments and to use those results in meaningful conversations with their patients about fall risks and ways to reduce them. As ACOs gain more experience in integrating the fall risk screening measure more broadly into their day-to-day practices, we will revisit the frail elderly measures in future rulemaking to build upon these achievements and to address additional issues for the frail elderly.

Comment: Proposed measure 65. Monthly INR for Beneficiaries on Warfarin. One commenter wrote in support of this measure. One commenter suggested CMS use ACOVE guidelines for INR. One commenter suggested CMS modify its proposal to measure the quality of warfarin therapy by measuring patients on stabilized warfarin therapy within the critical INR range. Several commenters recommended removing of this measure and believed it was out of date.

Response: We have decided not to finalize the measure at this time. We intend to investigate the appropriateness of warfarin therapy further, including developments regarding of alternative therapies and gaps in monthly INR monitoring, and will consider this measure and/or other related measures that may be appropriate in future rulemaking cycles.

Comment: While a majority of commenters suggested paring down the measure set, we received a number of suggestions for additional measures and measure categories that were not included in our proposed measures set, such as measures of: emergency room visits, comprehensive medication management, patient safety, additional potentially preventable complications, care transitions, more robust mental health measures, substance use, underuse of health care services, perioperative care, cancer survivorship care, hematology care, kidney disease, COPD, asthma and other allergic diseases, patient engagement, recovery and wellness. Several commenters recommended including risk-adjusted mortality measures for the entire ACO population, not limited to those who have been hospitalized. A few commenters advocated for more emphasis on continued quality improvement rather than quality assurance.

Response: Given that many ACOs will be newly forming organizations, we concluded that ACO quality measures should focus on discrete processes and short-term measurable outcomes derived from administrative claims and limited medical record review facilitated by a CMS-provided web interface to lessen the burden of reporting. For both the proposed rule and this final rule, we selected a set of quality measures based on the criteria discussed in section II.F.2.b. of this final rule. Because of the focus on Medicare FFS beneficiaries, our measure selection emphasized prevention and management of chronic diseases that have high impact on these beneficiaries such as heart disease, diabetes mellitus and chronic obstructive pulmonary disease.

Comment: A number of commenters were concerned that the program measure quality across the spectrum of care settings including not just outpatient clinics and short-term acute hospital care but also federally qualified health centers, rural environments, convenient care clinics, home health, telehealth, remote patient monitoring, SNFs or long-term care, behavioral health, rehabilitation care, anesthesia care, hospice and palliative care, and case management. A number of these commenters suggested adding specific measures. One commenter advocated for a separate domain of palliative care.

Response: We selected final measures with a predominantly ambulatory care focus, consistent with the primary care focus of, and beneficiary assignment methodology used for, the Shared Savings Program. It is important to note, however, that ACOs may use information from additional care settings types of providers in reporting quality information via the GPRO web interface and that patients' total Medicare Part A and B claims history will be used in determining GPRO measure denominators and calculating claims-based measures. We encourage ACOs to work with providers across the care spectrum to better coordinate care and improve the quality of care for their mutual patient population.

Comment: A number of commenters suggested that new measures are needed for ACOs and that CMS should partner with others, such as Regional Health Improvement Collaboratives and AHRQ, to identify gaps and develop new measures. One commenter supported development of new patient-centered functional outcome measures that are site-neutral, focused on the coordination of services, and based on individual needs and preferences for care. Another stated that new measures specific to the ACO patient experience should be developed in the future but not prior to the launch of the ACO program. One commenter recommended development of measures of appropriate use of new technologies. One commenter expressed concern that current measures reflect limitations of the current payment system, while ACO metrics should

include population-based outcomes measures such as emergency room use, potentially preventable admission rates, in-hospital mortality rates, and possibly patient safety measures. One commenter supported measures of how ACO professionals use their performance on quality measures to improve care as well as the quality measures themselves. One commenter proposed that emergency medicine measures should be developed, while another urged CMS to work with NQF to develop more robust measures of medication management.

Response: We appreciate the commenters' interest in measures that address additional areas of specialty care, inpatient and post acute care while working to move our measurement strategy to more outcome-oriented measures and will consider these in the future.

Comment: A number of commenters recommended CMS include measures that are more inclusive of specialty care, pediatric care, and non-physician professionals, such as nurse practitioners and registered nurses. Many of these commenters noted that the proposed measures were heavily focused on primary care. One commenter believed the emphasis on primary care measures would result in much less data on which to judge ACO quality for specialty care, which could either inappropriately reward or punish specialist providers. Other commenters expressed concern that specialty care and care for those with disabilities might be negatively affected by the lack of specialty measures or incentives to skimp on necessary care. One commenter added that most proposed measures have no direct relationship to cost management that could be achieved during the ACO agreement period, particularly since specialty care is a driver of cost differences. Without specific quality measures related to specialty care, the commenter argues, specialists in ACOs will face pressure to reduce the costs of specialty care, which may translate into inferior care for beneficiaries by limiting access to specialty care and ignoring quality. Several commenters recommended measures that reflect the interprofessional nature of an ACO and the mix of clinicians providing primary care.

Response: We believe that the final set of measures is appropriately focused and measures care furnished by a variety of providers including specialists, nurses, and nurse practitioners. We also believe the issue of including specialty providers who furnish primary care services is addressed in the two-step beneficiary assignment methodology discussed in section II.E of this final rule. We also agree that monitoring is necessary to ensure providers do not skimp on care or avoid at-risk beneficiaries. Our final policies regarding monitoring of ACOs are discussed in section II.H. of this final rule. Finally, we do not think including pediatric measures is appropriate at this time, since the Shared Savings Program is designed for the Medicare FFS population, which includes very few children and would not allow for reliable and valid pediatric measures.

We also received suggestions for a process to retire and add measures over time.

Comment: A few commenters recommended CMS take steps to assure that the most recent version of a specification, per the measure developer, is being used and that measures keep pace with current evidence. One commenter suggested that we conduct an annual review of the quality measures as well as new scientific evidence published in peer-reviewed medical literature and comparative effectiveness research of the Patient-Centered Outcomes Research Institute (PCORI) and remove any measures that are no longer supported by the evidence. Another commenter suggested that CMS should plan to update evaluation tools and methods as advances allow. One commenter requested that CMS assure that quality measures keep pace with new technologies and advances in medical care. Another commenter recommended CMS specify its criteria for selecting future measures and suggested beginning with: correlation with outcomes; NQF endorsement; measure impact (that is, high-volume, high-cost); sufficient sample size; existence of complete and clear specifications; compound or composite measures; and degree of opportunity for improvement, as indicated by high variability across organizations. One commenter stated that measures should be meaningful to consumers.

A few commenters suggested that measures not be modified or added during the first agreement period or, at minimum, that we institute a system similar to the final value-based purchasing system where measures must be reported for a year without specification changes before they are eligible to be added to the performance standard. These commenters stated that keeping measures constant would allow ACOs to compare results from year to year. One of these commenters thought, at a minimum, any new measures added during an agreement period should be reasonable in number and limited to those that have been publicly reported for one year, in line with the HVBP model. One commenter requested CMS clarify how ACOs will be notified of changes to quality reporting in subsequent years and how new quality measures would be vetted. Another commenter recommended measures be added through an approval process open to all interdisciplinary health providers through their professional organizations while another commenter recommended that CMS use a formal notice and comment process to retire or add measures so that all stakeholders have the opportunity for input. One commenter suggested CMS add new measures during the agreement period for reporting only and not include those in the shared savings calculation. This commenter also recommended that more than 90 days lead time should be given before new measures are added. A few commenters recommended publishing final measure specifications at least 90 days in advance for 2012 and at least 180 days notice be given for subsequent years, while another commenter recommended that CMS publish sample approach, sample size and data collection rules for any survey tools at least 12 months in advance. Another commenter recommended measures be published at least 18 months in advance. One commenter suggested that measures which are substantially modified be reported for a year prior to being incorporated into the performance standard. One commenter suggested measures be added only if they meet an ACO's patient population needs and removed if they are found to be unreliable, unactionable, or do not meet the needs of the population served.

Response: As discussed previously, detailed measure specifications, including the measure title, for the Shared Savings Program quality measures may have been updated or modified during the NQF endorsement process or for other reasons prior to 2012. Specifications for all Shared Savings Program quality measures must be obtained from the specifications document for Shared Savings Program quality measures. As measures stewards frequently make their measures updates for a given year during the 4th quarter of the preceding year or the 1st quarter of the applicable year, we expect to release specifications during the 4th quarter of 2011 or the 1st quarter of 2012 for most of the measures. We expect to release specifications for the CAHPS survey later in 2012. We will also add and retire measures as

appropriate through the rulemaking process. We are working with the measures community to ensure that our specifications are the most up-to-date for the 2012 Shared Savings Program performance period. We have to balance timing the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications.

Comment: One commenter requested that CMS clarify exclusion options for situations when following an evidence-based guideline would be inappropriate for a given ACO patient. A few commenters noted many of the proposed measures are inappropriate for terminally ill patients and recommended excluding such patients from quality measure calculations without consequence to the ACO.

Response: Measure owners identify appropriate exclusion criteria as part of their measure specifications. Additionally, measures collected via the GPRO web interface allow providers to exclude patients per the measure specifications and for other defined reasons related to the reporting methodology as appropriate. The ACO measures specifications and reporting methodology will be provided in subregulatory guidance. However, in the proposed rule, we included information, such as the NQF number, for each measure so that the public could view measures specifications information on the NQF Web site and as currently used in other CMS programs, such as PQRS and the EHR Incentive Programs. Our audit and validation process and monitoring activities will also look at exclusions to determine if ACOs are excluding large numbers of patients from quality reporting as a way to avoid reporting or to game the methodology.

Comment: Many commenters suggested that CMS outline quality reporting requirements over the entire ACO agreement period since Medicare ACOs are required to commit to participating for at least 3 years. One commenter was disappointed that we only aligned with PQRS measures for the first year of the agreement period. One commenter recommended a 2 year reporting-only period for any future new measures that are not currently being collected. One commenter suggested that if measures for the agreement period are not specified up front, an ACO should be able to withdraw from its agreement if the second and third year measure reporting requirements are too burdensome and resource intensive. One commenter urged CMS to specify the reporting period, due date of submission, and the population that is being measured for each of the quality measures in the final rule. One commenter recommended that ACOs not be required to develop clinical guidelines and instead we should encourage them to use those developed by medical specialty societies. There was widespread support among commenters for a ramp-up approach to measurement and linking the degree of measure reporting—or in later years, measure performance—to the degree of shared savings. Many commenters believed phasing in measures or having a tiered approach, rather than requiring ACOs meet all thresholds would encourage wider participation, allow ACOs time to develop the necessary infrastructure and capacity, and reduce startup costs. Several commenters proposed a tiered approach to the performance standard. A few commenters stated that this approach would not only encourage participation but would help avoid some of the learning curve issues that occur in new programs. Several commenters pointed to the approach taken by the PGP Demonstration, in which an initial set of measures was phased in over time, and suggested the Shared Savings Program take a similar approach.

While a number of commenters endorsed the first year quality performance standard at the reporting level, a number of commenters recommended extending it for 2 years, and a few endorsed a pay-for-reporting standard for the entire first agreement period. Another commenter requested that, if measures which are not in current use are included in the final rule, these be kept at the reporting standard for the entire agreement period. One commenter thought the proposed Ambulatory Care Sensitive Conditions and Risk Standardized All Condition Readmission measures proposed should be pay for reporting measures only during the entire agreement period, due to the associated cost and risk, similar to the way in which new measures have been treated under the PGP demonstration. One commenter urged CMS not to use the reporting standard and to establish at least a minimum performance threshold from the outset of the program.

Response: We have outlined in Tables 1 and 2 the quality measure requirements for the ACO agreement period. We do not intend to develop specific clinical guidelines for ACOs. Rather, we intend to adopt existing clinical guidelines as appropriate for ACOs in our measure specifications. Withdrawal from the Shared Savings Program is discussed in section II.H.5. of this final rule. A subset of these measures will be phased in for performance scoring starting in performance year 2 of the agreement period, as illustrated in Table 1 and summarized in Table 2. We believe this approach emphasizes all domains and measures as important, provides a longer phase in of measures to pay for performance than in our original proposal, and aligns closely with the phase in used in the PGP Transition Demonstration.

We expect to require ACOs to report all measures listed in Table 11 during each ''reporting period,'' as defined in § 425.20, of its agreement. This means that while an ACO's first ''performance year,'' as defined in § 425.20, for shared savings purposes would be 18 or 21 months, quality data will be collected on a calendar year reporting period basis, beginning with the reporting period starting January 1, 2012 through December 31, 2012 for ACOs electing an interim payment. Thus, the first performance year of the ACO agreement period begins April 1, 2012 or July 1, 2012 and ends December 31, 2013, while quality performance for this first performance year will be based on complete and accurate reporting of measures January 1, 2013 through December 31, 2013. Quality data submitted via the GPRO web interface for the 2012 reporting period would also be used for purposes of the PQRS incentive under the Shared Savings Program, as discussed in II.F.5. of this final rule and for the interim payment calculation, as discussed in II.G.2.k. of this final rule. Furthermore, for all ACOs starting in 2012, we will conduct a CAHPS survey with assigned ACO beneficiaries and will measure claims- and administrative-based quality measures. Complete and accurate reporting on all quality measures in Table 1 for both the calendar year 2013 will be used to determine shared savings eligibility for an ACO's first performance year. The pay for performance phase-in of measures and second performance year for shared savings purposes would begin January 1, 2014. Table 2 summarizes the number pay for reporting and pay for performance measures for each performance year.

TABLE 1—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS

	Domain	Measure title	NQF measure #/measure steward	Method of data submission	Pay for performance phase in R = Reporting P = Performance		
					Year 1	Year 2	Year 3
AIM: Better Care for Individuals							
1.	Patient/Caregiver Experience.	CAHPS: Getting Timely Care, Appointments, and Information.	NQF #5, AHRQ.	Survey	R	P	P
2.	Patient/Caregiver Experience.	CAHPS: How Well Your Doctors Communicate.	NQF #5 AHRQ.	Survey	R	P	P
3.	Patient/Caregiver Experience.	CAHPS: Patients' Rating of Doctor.	NQF #5 AHRQ.	Survey	R	P	P
4.	Patient/Caregiver Experience.	CAHPS: Access to Specialists.	NQF #5 AHRQ.	Survey	R	P	P
5.	Patient/Caregiver Experience.	CAHPS: Health Promotion and Education.	NQF #5 AHRQ.	Survey	R	P	P
6.	Patient/Caregiver Experience.	CAHPS: Shared Decision Making.	NQF #5 AHRQ.	Survey	R	P	P
7.	Patient/Caregiver Experience.	CAHPS: Health Status/ Functional Status.	NQF #6 AHRQ.	Survey	R	R	R
8.	Care Coordination/Patient Safety.	Risk-Standardized, All Condition Readmission*.	NQF #TBD CMS.	Claims	R	R	P
9.	Care Coordination/Patient Safety.	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease (AHRQ Prevention Quality Indicator (PQI) #5).	NQF #275 AHRQ.	Claims	R	P	P
10.	Care Coordination/Patient Safety.	Ambulatory Sensitive Conditions Admissions: Congestive Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8).	NQF #277 AHRQ.	Claims	R	P	P
11.	Care Coordination/Patient Safety.	Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment.	CMS	EHR Incentive Program Reporting.	R	P	P
12.	Care Coordination/Patient Safety.	Medication Reconciliation: Reconciliation After Discharge from an Inpatient Facility.	NQF #97 AMA–PCPI/ NCQA.	GPRO Web Interface.	R	P	P
13.	Care Coordination/Patient Safety.	Falls: Screening for Fall Risk.	NQF #101 NCQA.	GPRO Web Interface.	R	P	P
AIM: Better Health for Populations							
14.	Preventive Health	Influenza Immunization	NQF #41 AMA–PCPI.	GPRO Web Interface.	R	P	P
15.	Preventive Health	Pneumococcal Vaccination	NQF #43 NCQA.	GPRO Web Interface.	R	P	P
16.	Preventive Health	Adult Weight Screening and Follow-up.	NQF #421 CMS.	GPRO Web Interface.	R	P	P
17.	Preventive Health	Tobacco Use Assessment and Tobacco Cessation Intervention.	NQF #28 AMA–PCPI.	GPRO Web Interface.	R	P	P
18.	Preventive Health	Depression Screening	NQF #418 CMS.	GPRO Web Interface.	R	P	P
19.	Preventive Health	Colorectal Cancer Screening.	NQF #34 NCQA.	GPRO Web Interface.	R	R	P
20.	Preventive Health	Mammography Screening	NQF #31 NCQA.	GPRO Web Interface.	R	R	P
21.	Preventive Health	Proportion of Adults 18+ who had their Blood Pressure Measured within the preceding 2 years.	CMS	GPRO Web Interface.	R	R	P
22.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Hemoglobin A1c Control (<8 percent).	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P

TABLE 1—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

	Domain	Measure title	NQF measure #/measure steward	Method of data submission	Pay for performance phase in R = Reporting P = Performance		
					Year 1	Year 2	Year 3
23.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Low Density Lipoprotein (<100).	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
24.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Blood Pressure <140/90.	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
25.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Tobacco Non Use.	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
26.	At Risk Population—Diabetes.	Diabetes Composite (All or Nothing Scoring): Aspirin Use.	NQF #0729 MN Community Measurement.	GPRO Web Interface.	R	P	P
27.	At Risk Population—Diabetes.	Diabetes Mellitus: Hemoglobin A1c Poor Control (>9 percent).	NQF #59 NCQA.	GPRO Web Interface.	R	P	P
28.	At Risk Population—Hypertension.	Hypertension (HTN): Blood Pressure Control.	NQF #18 NCQA.	GPRO Web Interface.	R	P	P
29.	At Risk Population—Ischemic Vascular Disease.	Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL Control <100 mg/dl.	NQF #75 NCQA.	GPRO Web Interface.	R	P	P
30.	At Risk Population—Ischemic Vascular Disease.	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.	NQF #68 NCQA.	GPRO Web Interface.	R	P	P
31.	At Risk Population—Heart Failure.	Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	NQF #83 AMA–PCPI.	GPRO Web Interface.	R	R	P
32.	At Risk Population—Coronary Artery Disease.	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Drug Therapy for Lowering LDL-Cholesterol.	NQF #74 CMS (composite)/ AMA–PCPI (individual component).	GPRO Web Interface.	R	R	P
33.	At Risk Population—Coronary Artery Disease.	Coronary Artery Disease (CAD) Composite: All or Nothing Scoring: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Patients with CAD and Diabetes and/or Left Ventricular Systolic Dysfunction (LVSD).	NQF #66 CMS (composite)/ AMA–PCPI (individual component).	GPRO Web Interface.	R	R	P

*We note that this measure has been under development and that finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012.

TABLE 2—ACO AGREEMENT PERIOD PAY FOR PERFORMANCE PHASE-IN SUMMARY

	Performance year 1	Performance year 2	Performance year 3
Pay for Performance	0	25	32
Pay for Reporting	33	8	1
Total	33	33	33

Final Decision: In summary, in response to comments, we have modified this final rule by reducing the measure set to 33 measures total, or 23 scored measures when accounting for the patient experience survey modules scored as 1 measure and the all or nothing diabetes and CAD measures scored as 1 measure each. We believe judiciously removing certain redundant, operationally complex, or burdensome measures would still provide a high standard of quality for participating ACOs while providing greater alignment with other CMS and HHS quality improvement initiatives. This measure set will be the starting point for ACO measurement, as we plan to modify measures in future reporting cycles to reflect changes in practice and quality of care improvement and continue aligning with other quality programs.

For the patient/caregiver experience measures, we believe requiring a standardized, patient experience of care survey that is based on CAHPS will better allow comparisons of ACOs over time and benchmarking for future years of the program. Additionally, it will help ensure the patient survey is measuring patient experience for the ACO as a whole rather than for one specific practice, since there is currently no survey instrument in existence, that we are aware of, that measures patient experience of care in an ACO specifically. We will also fund the administration of an annual CAHPS patient experience of care survey for ACOs participating in the Shared Savings Program in 2012 and 2013. Starting in 2014, ACOs participating in the Shared Savings Program must select a survey vendor (from a list of CMS-certified vendors) and will pay that vendor to administer the survey and report results using standardized procedures developed by CMS. We will develop and refine these standardized procedures over the next 18 to 24 months.

We will consider the individual CAHPS modules together as one measure for scoring purposes, consistent with Hospital Value-Based Purchasing and the PGP Transition Demonstration, except for Health Status/Functional Status. We have also added an access to specialists module to align with our final step-wise assignment methodology that incorporates specialists. This module will also promote care coordination and allow monitoring for avoidance of at-risk patients and underutilization of care by adding a patient perspective on access to specialty care. We will score the two finalized coronary artery disease measures as one composite and the recently endorsed Optimal Diabetes Care Composite, which has 5 components, will also be scored as one composite.

ACOs will be required to completely and accurately report on all 33 measures for all reporting periods in each performance year of their agreement period, and we will phase in pay for performance in performance years 2 and 3, as previously described above. Of the 33 measures we are finalizing, 7 are collected via patient survey, 3 are calculated via claims, 1 is calculated from EHR Incentive Program data, and 22 are collected via the GPRO web interface.

While we are removing the hospital patient safety measures from the final measures set, we plan to use the claims-based hospital measures as part of our ACO monitoring efforts. We also intend to consider any other claims-based measures proposed but not finalized in our program monitoring efforts. Please note that detailed measure specifications, including the measure title, for the 2012 Shared Savings Program quality measures may have been updated or modified during the NQF endorsement process or for other reasons prior to 2012. Specifications for all 2012 Shared Savings Program quality measures must be obtained from the specifications document for 2012 Shared Savings Program quality measures, which we expect to make available on the CMS Web during the 4th quarter of 2011 or 1st quarter of 2012, with the exception of the CAHPS measures, for which separate documentation will be available during 2012. We also note that the risk standardized, all condition readmission measure (final measure #2) has been under development and that finalization of this measure is contingent upon the availability of measures specifications before the establishment of the Shared Savings Program on January 1, 2012.

Finally, we have modified this final rule to define the quality performance standard at the reporting level in the first year and based on performance in subsequent years. Rather than transition all measures from pay for reporting to pay for performance in the second performance year of the ACO agreement period as proposed, we will transition only a portion of the measures to pay for performance in the second performance year, and then all but one of the measures to pay for performance in the third performance year, as outlined in Table 2.

3. Requirements for Quality Measures Data Submission by ACOs

a. General

Under section 1899(b)(3)(B) of the Act, ACOs are required to submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. In the proposed rule, we stated that most of the proposed measures were consistent with those reported for PQRS, others would rely on survey instruments, eRx, and HITECH program data, and some might rely on Hospital Compare or the Centers for Disease Control and Prevention National Healthcare Safety Network data (76 FR 19592). We recognized that there are a number of limitations associated with claims-based reporting, since the claims processing system was designed for billing purposes and not for the submission of quality data. For this reason, we stated we would make available a CMS-specified data collection tool for certain measures, which is now referred to as a ''web interface.'' We proposed that during the year following the first performance period, each ACO would be required to report via the GPRO web interface the applicable proposed quality measures with respect to services furnished during the performance period. We proposed that we would derive the claims-based measures from claims submitted for services furnished during the first performance period, which therefore would not require any additional reporting on the part of ACO professionals. We also proposed that for survey-based measures data would also reflect care received during the first performance period. We also noted that we would use rulemaking to update the quality measure requirements and mechanisms for future performance periods.

We welcomed comments on the proposed data submission requirements. We also sought comment on whether alternative data submission methods should be required or considered, such as limiting the measures to claims-based and survey-based reporting only.

We received the following comments about data submission requirements in general.

Comment: Several commenters requested more complete specifications about data submission requirements in the final rule. A few commenters stated that multiple formats of reporting are expensive and confusing and suggested a single reporting format. One commenter supported the multiple

approaches to capture quality data. A few commenters recommended that CMS require ACOs to measure quality for all patients, not just Medicare beneficiaries. One commenter recommended CMS require ACOs to give ACO providers/suppliers access to claims data arguing that such transparency is needed to ensure that all ACO providers/suppliers understand how their performance rates are being calculated. A few commenters expressed concern about whether CMS has the resources to handle the incoming data. One commenter did not believe ACOs should be held accountable for CMS problems with implementation.

Response: We were as specific as practicable in the proposed rule regarding the data submission requirements. More detailed instructions regarding data submission will be provided through subregulatory guidance. We agree with the commenters' concern about a standard format for reporting purposes to ensure consistent reporting over years and by multiple ACOs. We believe the GPRO web interface provides this mechanism for ACOs to report data at the individual beneficiary level. It was developed with provider input and is currently used in multiple physician pay for performance demonstrations and in the PQRS group practice reporting option. The tool is pre-populated with Medicare claims data for a sample of assigned beneficiaries for each ACO to minimize reporting burden and to ensure complete and accurate reporting. While CMS encourages ACOs to measure quality for all their patients, it is beyond the scope of this regulation to require that they do so for patients other than Medicare beneficiaries. We also embrace the concept of data transparency and availability. While we cannot foresee all possible future implementation issues, we will strive to mitigate any unforeseen issues swiftly and fairly.

We received the following comments about survey-based quality data.

Comment: A few commenters stated that the survey data specifications were not sufficiently detailed. One commenter requested clarification on CAHPS timeframe of the last 12 months and asked whether visits outside of the reporting period may be included. A few commenters requested CMS clarify who would administer the survey, required timing, and sample size, while another questioned whether implementation of this measure was feasible for the first year given that this would be a new activity for most ACOs.

Response: As discussed in section II.F.2. of this final rule, we agree with the concerns that have been raised regarding the initial burden of survey administration and have decided to pay for the administration of the CAHPS survey for 2012 and 2013. We are developing the necessary specifications and infrastructure to prepare vendors to administer the survey. Starting in 2014, ACOs will be required to select and pay for a CMS-approved vendor to administer the survey.

Comment: One commenter requested that the final rule clearly articulate the reporting period, due date of submission, and the population that is being measured for each of the quality measures. One commenter wrote in support of the 12-month performance period as it allows for more valid and reliable measurement than would be possible under a shorter time period. A few commenters stated that 100 percent reporting may not be achievable in year one.

Response: To clarify, all quality measures will have a 12-month, calendar year reporting period, regardless of ACO start date. Quality measures specifications and processes related to all quality measures will be made available in subregulatory guidance along with the specific dates for reporting and submission. Because of the measures and the methodology we are finalizing in this rule, our experience with GPRO measures and reporting methods to date, along with our plans to administer the CAHPS survey for the first 2 years of the program, we believe ACOs can achieve complete and accurate reporting in all years of the agreement period as we phase in pay for performance. CMS survey vendors will have responsibility for measuring the patient experience measures, and CMS will be able to calculate the claims-based measures and EHR Incentive Program measure without requiring any additional ACO reporting. ACOs will be directly responsible for reporting measures collected through the GPRO web interface. Starting in 2014, ACOs will also be responsible for selecting and paying for a CMS-certified vendor to administer the CAHPS survey.

Comment: Numerous commenters suggested a core and menu set approach to quality measurement, which would require all ACOs to report on a core measure set but allow flexibility to choose among measures in a menu set, similar to that used for the EHR incentive program. Different suggestions as to how to select core measures were received. One commenter suggested a performance score during the first year for a limited set of 11 core measures available through claims data in order to immediately focus on quality performance. Another commenter suggested separating the measures as core, interim clinical process, and advanced sets, with ''core'' referring to administrative claims and patient survey measures and ''advanced'' referring to more advanced, outcomes measures. Advanced measures would be those requiring clinical data such as the proposed preventive health screening measures. One commenter suggested requiring a core set of measures but offering higher shared savings for successful implementation of additional voluntary measures. One commenter suggested reducing the number of measures in each domain to three; another advocated reducing the number within patient/caregiver experience, care coordination, patient safety and preventive health domains to an initial core similar to EHR Incentive Program and emphasized that measures for specific clinical areas should eventually include measures in several domains in as well as for at-risk populations and the frail elderly. This commenter also suggested CMS begin to identify measures for each clinical area within those domains.

Response: We agree with the basic suggestions of a more limited measure set with some type of phased in approach. Table 2 illustrates the desire to have a phased in approach and a smaller, core set of measures that aligns with quality improvement priorities and value-based purchasing, in response to comments received. We do not agree that arbitrarily requiring all domains to have the same number of measures would be beneficial. Rather, we have reduced the number of initial measures, independent of domain, based on feasibility, impact, program goals, and specific comments. At this time, we believe it is important all ACOs report on the same measures in order to emphasize quality improvement across a variety of important areas. We believe that a menu approach would provide incentives for ACOs to select areas in which they are already performing well, rather than those areas in which there is room for improvement.

We received the following comments about claims-based quality measure data.

Comment: Several commenters stated measures should be derived from claims data when possible for ease of reporting and to give ACOs real-time feedback of results. One commenter stated that using existing data for most measures would also be advantageous in that ACOs could be more focused on quality improvement from the outset rather than having to spend resources simply

to track and report quality measures. One of these commenters recommended that measures with HEDIS claims specifications should be collected in that manner. Several commenters recommended beginning with a measure set based on claims data and expanding to registry or EHR-based measures over time. Another commenter indicated that Medicare claims data would yield a limited set of measures and that CMS should instead focus on requiring ACOs to demonstrate core capabilities critical to improving quality and reducing costs. This commenter suggested different levels of scoring similar to NCQA's proposed criteria. One commenter suggested CMS consider, in the future, ABIM's Comprehensive Care Practice Improvement Module, which is designed to assess generalist practice.

Response: We have included measures collected from a variety of sources, including claims, in the final measures set. We recognize that using claims offers a benefit in easing reporting burden but claims do not necessarily reflect the improvement outcomes that ACOs will seek to affect. We also recognize that the availability of measures from electronic health records may change significantly in the future, which we will consider accordingly. We are unable to add new measures in this final rule that were not proposed or that are not closely related to proposed measures. Accordingly, we are finalizing a combination of both claims-based measures and other measures collected from clinical quality data, patient experience surveys, and EHR Incentive Program data.

b. GPRO Web Interface

In 2010, 36 large group practices and integrated delivery systems used GPRO to report 26 quality measures for an assigned patient population under the PQRS. As we indicated in the proposed rule, the GPRO web interface affords a key advantage in that it is a mechanism through which beneficiary laboratory results and other measures requiring clinical information can be reported to us. The web interface would allow ACOs to submit clinical information from EHRs, registries, and administrative data sources required for measurement reporting. We believe the web interface would reduce the administrative burden on health care providers participating in ACOs by allowing them to tap into their existing Information Technology (IT) tools that support data collection and health care provider feedback, including at the point of care. Accordingly, we proposed that the existing GPRO web interface would be built out, refined, and upgraded to support clinical data collection and measurement reporting and feedback to ACOs participating in the Shared Savings Program.

For quality measures collected via the GPRO web interface, we proposed to determine a sample for each domain or measure set within the domain using a sampling methodology modeled after the methodology currently used in the 2011 PQRS GPRO I, as described in section II.F.3.b of the proposed rule. Assigned beneficiaries, for purposes of the GPRO web interface, would be limited to those Medicare FFS beneficiaries assigned to the ACO.

We indicated in the proposed rule that we would provide each ACO with access to the GPRO web interface that would include a sample of its assigned beneficiary population and the GPRO quality measures listed in Table 1 of the proposed rule (76 FR 19592). We stated we would pre-populate the web interface with the beneficiaries' demographic and utilization information based on their Medicare claims data. The ACO would be required to populate the remaining data fields necessary for capturing quality measure information on each of the beneficiaries as applicable.

Using the same sampling method used in the 2011 PQRS GPRO I, we would require that the random sample for measures reported via ACO GPRO must consist of at least 411 assigned beneficiaries per measure set/domain. If the pool of eligible, GPRO assigned beneficiaries is less than 411 for any measure set/domain, then we proposed to require the ACO to report on 100 percent, or all, of the assigned beneficiaries. For each measure set/domain within the GPRO web interface, the ACO would report information on the assigned beneficiaries in the order in which they appear consecutively in the ACO's sample.

We stated that some GPRO measures would not rely on beneficiary data but rather on ACO attestation. We proposed to validate GPRO attestation for such measures through CMS data from the EHR Incentive Program and Electronic Prescribing (eRx) Incentive Program. For the other measures reported via the GPRO web interface, we proposed to retain the right to validate the data entered by ACOs via a data validation process based on the one used in phase I of the PGP demonstration. In the GPRO audit process, we would abstract a random sample of 30 beneficiaries previously abstracted for each of the quality measure domains/measure sets. The audit process would include up to three phases, depending on the results of the first two phases. Although each sample would include 30 beneficiaries per domain, only the first eight beneficiaries' medical records would be audited for mismatches during the first phase of the audit. A mismatch represents a discrepancy between the numerator inclusions or denominator exclusions in the data submitted by the ACO and our determination of their appropriateness based on supporting medical records information submitted by the ACO. If there are no mismatches, the remaining 22 of the 30 beneficiaries' records would not be audited. If there are mismatches, the second phase of the audit would occur, and the other 22 beneficiaries' records would be audited. A third phase would only be undertaken if mismatches are found in more than 10 percent of the medical records in phase two. If a specific error is identified and the audit process goes to Phase 3, which involves corrective action, we proposed to first provide education to the ACO on the correct specification process and provide the opportunity to correct and resubmit the measure(s) in question. If, at the conclusion of the third audit process the mismatch rate is more than 10 percent, we proposed that the ACO would not be given credit for meeting the quality target for any measures for which this mismatch rate still exists. We noted that the failure to report quality measure data accurately, completely and timely (or to timely correct such data) might subject the ACO to termination or other sanctions.

We invited comment on the proposed GPRO quality data submission requirements and on the administrative burden associated with reporting.

Comment: A few commenters supported the use of GPRO although one of the commenters stated that this type of reporting requires considerable time, effort and knowledge to do well and suggested automating measures as much as possible. One commenter encouraged CMS to rapidly develop the GPRO interface for ACOs and requested guidance for data submission in the meantime. One commenter suggested that CMS work with EHR vendors, DIRECT HISPs and HIEs to support efficient interfaces between EHRs, HIE, and the web interface and that the Quality Data Model developed by NQF should be supported to standardize data collection. This commenter also suggested that GPRO should be evaluated for expanded use. However, a few commenters expressed concern about whether GPRO is capable of being expanded for ACO use or its applicability for ACO populations as it has been used primarily for large group practices to date. A few commenters recommended further testing before

using it as proposed. Several commenters did not believe enough information was available about GPRO and baseline metrics from GPRO. One commenter stated that GPRO reported measure specifications are not available for review and interpretation. One commenter requested provider assistance if GPRO reporting is required. Another commenter requested clarification about whether the intent was for GPRO to cover all measures, and whether practices within an ACO would continue to report separately under GPRO for purposes of a PQRS incentive payment. Another commenter recommended that GPRO be populated soon with the prior two years of likely ACO assigned members, including an analysis of claims only results.

Response: We have attempted to weigh the burdens of various reporting mechanisms against the benefits. The original GPRO tool evolved from the PAT tool used for the PGP Demonstration, which was developed with significant physician involvement. Over 600 physicians in a range of practice sizes used it as part of the Medicare Care Management Performance Demonstration, the PQRS had 35 groups using the GPRO tool in 2010 and 61 have signed up for 2011. Additionally, the tool has migrated to a web interface, which will offer the additional capability of data upload from an EHR. As a result, we believe this reporting mechanism is capable and well-tested and represents the best current option for quality reporting. We do not think it would be appropriate or effective to populate the web interface with the prior 2 years of beneficiaries likely to be assigned to an ACO, as one commenter suggested, since this is not the population for which the ACOs will be responsible for being accountable for quality or financial performance. Rather, the ACO will be required to report on the beneficiaries actually assigned to the ACO in 2012. As a result, the web interface will be populated based on a sample of the 2012 assigned beneficiaries. Additionally, the calendar year reporting period for the ACO GPRO quality measures aligns with the PQRS GPRO reporting period for purposes of qualifying ACO TINs for a 2012 PQRS incentive payment, which is discussed in section II.F.5. of this final rule.

We are finalizing our proposal to build upon GPRO experience for ACO use. We have specified in Table 1 which final measures must be reported through the GPRO web interface.

Comment: Several commenters discouraged CMS from using the GPRO web interface because it does not provide a long-term solution to data collection and may hinder development of robust EHR solutions. One commenter encouraged CMS to establish its intent to collect electronic measures in subsequent years of the Shared Savings Program. A number of commenters noted GPRO is a labor intensive reporting method requiring chart abstraction, prone to error, and not derived from the normal workflow of providing patient care and encouraged the use of measures that could be captured by EHRs. One commenter expressed concern about the limited amount of time proposed for data entry in GPRO. Several commenters suggested alternate approaches to reporting. One commenter suggested a parallel reporting pathway via EHR for practices that have invested in health IT. One commenter suggested another standardized option to the GPRO web interface. One commenter recognized that medical record data would result in increased accuracy and recommended CMS prioritize measures for electronic exchange of clinical data between ACOs and CMS in the future rather than introduce the burden associated with the use of the GPRO web interface. Another commenter suggested content analysis of unstructured data available from encounters to more objectively measure some dimensions of quality without increasing reporting burden. This commenter also suggested that content analysis methodology be tested prior to building out the GPRO web interface.

Response: We agree that it is important to foster innovation and support the development and uptake of electronic medical records. For this reason, we are including a measure related to EHR Incentive Program participation in our final measure set. However, we must rely on other means of collecting quality data for the Shared Savings Program until there is much more widespread use of electronic medical records and available means for group reporting based on ACO beneficiary level data. We note that the original GPRO tool evolved from the PAT tool used for the PGP Demonstration, which was developed with significant physician involvement, and over 600 physicians in a range of practice sizes used it as part of the Medicare Care Management Performance Demonstration. PQRS had 35 groups using the GPRO tool in 2010 and currently have 61 signed up for 2011. As a result, we believe this reporting mechanism is sound and well-tested, and we intend to build upon this experience for ACO use. Additionally, the tool has migrated to a web interface, which will offer the additional capability of data upload from an EHR. We do not believe content analysis of unstructured data, as one commenter suggested, would be an efficient or operationally feasible way of collecting and analyzing ACO quality data as it would be difficult and time-consuming to make quality performance standard determinations from non-uniform data. Additionally, the GPRO web interface represents a first step in EHR-based reporting, which we believe is more efficient and cost-effective, since it will allow ACOs to upload data directly from their EHR systems. Meanwhile, those ACOs that would prefer to manually submit data through the GPRO web interface could do so, in a uniform way.

Comment: A few commenters expressed concern about the proposed GPRO data validation process and discussed the difficulty of obtaining medical records across an entire ACO and reconciling those records with quality performance data reported by the ACO. One of these commenters further stated that the data validation process should be tested prior to implementation.

Response: We agree that data validation may be a challenge but do not believe that use of the GPRO web interface significantly adds complexity. Rather, we believe the data validation process implicitly incentivizes ACOs to keep organized and up-to-date medical records and is necessary to protect against the gaming concerns other commenters have noted.

c. Certified EHR Technology

In July 2010, HHS published final rules for the EHR Incentive Programs. The final regulations included certain clinical quality measures on which EPs and eligible hospitals must report as part of demonstrating they are meaningful EHR users. In the proposed rule, we included information on which of the proposed quality measures for the Shared Savings Program are currently included in the EHR Incentive Programs and stated our intent to continue to further align the measures between the two programs. As we intend to further align both the Shared Savings Program and EHR incentive program through subsequent rulemaking, we stated that we anticipated that certified EHR technology (including EHR modules certified to calculate and submit clinical quality measures) would be an additional measure reporting mechanism used by ACOs under the Shared Savings Program in future program years.

Comment: Several commenters supported the use of EHR-derived

measures whenever possible, particularly as the use of EHRs becomes more widespread. One commenter was concerned that EHRs do not currently generate all the data necessary for the proposed performance measures. Others supported the move toward EHR-based measures over time. One commenter was concerned that the proposed measures require providers to have already adopted an EHR. Several commenters suggested special consideration for EHR adoption be given to smaller practices. Several commenters supported movement toward using Health Information Exchange (HIE) as a means of measures reporting. Another commenter expressed concern that the proposed regulations require a level of functional health information exchange that is not yet available, such as a patient online portal to meet the patient-centeredness objective and the need to electronically exchange information with entities outside of the ACO. This commenter suggested that allowing ACOs to determine their own technology needs would result in greater participation and more widespread adoption of best practices. One commenter stated that differences in technology access among providers would inhibit information sharing and care coordination and stated that, if beneficiaries see non-ACO providers, care coordination may be diminished. This commenter requested a separate policy to address care coordination and exchange of information.

Many commenters also recommended that CMS allow data submission through clinical registries and encourage their use as a proven tool to improve quality and control costs and as a way of having real-time actionable data. One commenter also recommended that CMS allow data to be submitted via registry or additional means that have been established by regional collaborative.

Response: While we hope to have more robust capabilities for EHR-derived measures and reporting in the future, at this point we are finalizing one quality measure that rewards and encourages greater EHR use, which is the percent of primary care providers who successfully qualify for an EHR Incentive Program payment. We are also double weighting this measure for scoring purposes as well as for determining poor performing to reflect the importance of HIT for ACOs to redesign care, provide practitioners actionable information at the point of care, and to align incentives and encourage broader EHR adoption. As providers gain more experience with EHR technology, we will reconsider using certified EHR technology as an additional reporting mechanism used by ACOs under the Shared Savings Program.

Final Decision: After considering the comments and for the reasons discussed previously, we are finalizing our proposal to use survey based measures, claims and administrative data based measures, and the GPRO web interface as a means of ACO quality data reporting for certain measures, as listed in Table 1. For the ACO GPRO measures, we are finalizing our proposal to use the same sampling method used in the 2011 PQRS GPRO I, as described previously. We are also finalizing our proposal to retain the right to validate the data ACOs enter into the GPRO web interface via a data validation process based on the one used in phase I of the PGP demonstration, as described previously.

4. Quality Performance Standards

a. General

A calculation of the quality performance standard will indicate whether an ACO has met the quality performance goals that would deem it eligible for shared savings. As discussed previously in section II.F.2. of this final rule, we are finalizing the 33 measures in Table 1 to establish the quality performance standards that ACOs must meet in order to be eligible for shared savings.

In the proposed rule, we considered two alternative options for establishing quality performance standards for the measures: Rewards for better performance, and a minimum quality threshold for shared savings. We proposed the performance score approach and sought comment on the threshold approach. The performance score approach would reward ACOs for better quality with larger percentages of shared savings. The threshold approach would ensure that ACOs exceed minimum standards for the quality of care, but allows full shared savings if ACOs meet the minimum level of performance.

b. Performance Scoring

Under the proposed rule, quality performance standards would be used to arrive at a total performance score for an ACO. We proposed to organize the measures by domain, and to score the performance on each measure. We proposed to roll up the scores for the measures in each domain into domain scores and to provide ACOs with performance feedback at both the individual measure and domain level. We proposed that the percentage of points earned for each domain would be aggregated using a weighting method to arrive at a single percentage that would be applied to determine the final sharing rate used to determine any shared savings or losses. We proposed that the aggregated domain scores would determine the ACO's eligibility for sharing up to 50 percent of the total savings generated by the ACO under the one-sided model or 60 percent of the total savings generated by the ACO under the two-sided risk model. We also discussed our proposal to set the quality performance standard in the first year of the Shared Savings Program at the complete and accurate reporting level and set the standard at a performance level in subsequent years.

(1) Measure Domains and Measures Included in the Domains

The proposed quality performance standard measures in Table 1 were subdivided into 5 domains, including: (1) Patient/Caregiver Experience; (2) Care Coordination; (3) Patient Safety; (4) Preventive Health; and (5) At-Risk Population/Frail Elderly. We proposed that the At-Risk Population/Frail Elderly domain would include a frail elderly category as well as the following chronic diseases: Diabetes mellitus; heart failure; coronary artery disease; hypertension and chronic obstructive pulmonary disorder.

(2) Methodology for Calculating a Performance Score for Each Measure Within a Domain

We proposed that an ACO would receive a performance score on each proposed measure. For the first year of the Shared Savings Program, these scores would be for informational purposes, since we proposed to set the quality performance standard at the reporting level. For subsequent years of the program, we proposed setting benchmarks for each measure using national Medicare FFS claims data, MA quality performance rates, or, where appropriate, the corresponding national percent performance rates that an ACO will be required to demonstrate. For each measure, we proposed to set a performance benchmark and a minimum attainment level as defined in Table 3 of the proposed rule (76 FR 19595). We proposed that the benchmarks would be established using the most currently available data source and most recent available year of benchmark data prior to the start of the Shared Savings Program annual agreement periods. We would determine Medicare FFS rates by pulling a data sample and modeling the measures. For

MA rates, we would check the distribution from the most recent available annual MA quality performance data for all MA plans and set the benchmark accordingly. Furthermore, since MA quality performance rates utilize both claims and clinical data, we proposed to use those rates when they are available.

We proposed that benchmark levels for each of the measures included in the quality performance standard would be made available to ACOs, prior to the start of the Shared Savings Program and each annual performance period thereafter, so ACOs would be aware of the benchmarks they must achieve to receive the maximum quality score. In the proposed rule, we stated that in future program years, we anticipate incorporating actual ACO performance to update the national benchmarks.

We also proposed that if an ACO fails to meet quality performance standard during a performance year (that is, fails to meet, the minimum attainment level for one or more domain(s)), we would give the ACO a warning, provide an opportunity to resubmit, and reevaluate the ACO's performance the following year. If the ACO continues to significantly under-perform, the agreement may be terminated. We further proposed that ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program. We noted that since meeting the quality standard is a condition for sharing in savings, the ACO would be disqualified from sharing in savings in each year in which it underperforms.

We proposed that performance below the minimum attainment level would earn zero points for that measure under both the one-sided and two-sided risk models. We also proposed that performance equal to or greater than the minimum attainment level but less than the performance benchmark would receive points on a sliding scale based on the level of performance, for those measures in which the points scale applies. We also proposed setting the initial minimum attainment level for both the one-sided and two-sided shared savings models at a 30 percent or the 30th percentile of national Medicare FFS or the MA rate, depending on what performance data are available.

We proposed ''all or nothing'' scoring for the diabetes and CAD composite measures. We proposed that measures designated as all or nothing measures would receive the maximum available points if all criteria are met and zero points if at least one of the criteria are not met. We defined ''all or nothing'' scoring to mean all of the care process steps and expected outcomes for a particular beneficiary with the target condition must be achieved to score positively. This means all sub measures within the diabetes and CAD composites would need to be reported in order to earn any credit for these measures. We stated we recognized that all or nothing scoring implies that all beneficiaries can and should receive the indicated care process, which may not necessarily be appropriate for all beneficiaries. As a result, we also proposed scoring the diabetes and CAD sub measures individually. We also proposed a HAC composite measure for which we did not propose all or nothing scoring, since the HACs are rare events.

We also stated our intent to post performance rates for the final measures set, including the applicable benchmarks, on the CMS Web site prior to the start of the first performance period.

(3) Methodology for Calculating a Performance Score for Each Domain

Similar to our proposal for setting a quality standard for each individual measure at the reporting level in the first program year, we also proposed setting a quality standard for each domain at the reporting level. For subsequent program years, we proposed to calculate the percentage of points an ACO earns for each domain after determining the points earned for each measure. We planned to divide the points earned by the ACO across all measures in the domain by the total points available in that particular domain. Each domain would be worth a predefined number of points based on the number of individual measures in the domain.

We proposed that under both the one-sided and two-sided shared savings models, the quality measures domain scoring methodology would treat all domains equally regardless of the number of measures within the domain. We stated in the proposed rule that we believed the key benefit of weighting the domains equally is that it would not create a preference for any one domain, which we consider important as we expect ACOs to vary in composition, and, as a result, to place more emphasis on different domains. Furthermore, we want to encourage a diverse set of ACOs and believe that emphasizing certain domains over others would encourage a certain type of ACO to participate but discourage other types from participating.

We proposed to aggregate the quality domain scores into a single overall ACO score which would be used to calculate the ACOs final sharing rate for purposes of determining shared savings or shared losses. All domain scores for an ACO would be averaged together equally to calculate the overall quality score that would be used to calculate the ACO's final sharing rate used to determine the amount of shared savings or losses an ACO would receive or owe. We also proposed that ACOs must report completely and accurately on all quality measures within all domains to be deemed eligible for shared savings consideration. Finally, we stated we also considered scoring measures individually under a method that weights measures equally as well as an approach that would weight quality measures by their clinical importance.

(4) The Quality Performance Standard Level

We proposed to set the quality performance standard for the first year of the Shared Savings Program at the reporting level. That is, under the one-sided model, we proposed that an ACO would receive 50 percent of shared savings (provided that the ACO realizes sufficient cost savings under) based on 100 percent complete and accurate reporting on all quality measures. Similarly, we proposed that under the two-sided risk model, ACOs would receive 60 percent of shared savings (provided that the ACO realizes sufficient cost savings) based on 100 percent complete and accurate reporting on all quality measures. We stated that setting the quality performance standard for the first year of the Shared Savings Program at full and accurate reporting would allow ACOs to ramp up, invest in their infrastructure, engage ACO providers/suppliers, and redesign care processes to capture and provide data back to their ACO providers/suppliers to transform care at the point of care. We also noted that setting the quality performance standard at the reporting level would be consistent with other value-based purchasing programs that started as pay for reporting programs.

We indicated that we planned to raise the quality performance standard requirements in future years through future rulemaking, when actual performance on the reported measures would be considered in establishing the quality benchmarks (in addition to the national flat percent or FFS/MA percentile). We stated in the proposed rule that we believe this approach would be consistent with section 1899(b)(3)(C) of the Act, which requires that the Secretary ''seek to improve the quality of care furnished by ACOs over time by specifying higher standards,

new measures, or both for the purposes of assessing such quality of care.''

While we proposed the performance scoring methodology, we also considered adopting a minimum quality threshold to assess the performance of participating ACOs, as described in the proposed rule (76 FR 19597–98).

Comment: A few commenters suggested weighting each domain equally or balancing the number of measures in each domain to prevent any single measure from having a greater impact on the overall score. Another commenter stated that proposed measures are unfairly weighted and measured. One commenter believed process measurements should be scored higher since they are under provider control, whereas another commenter suggested that outcome measures be weighted heavier than structure and process measures. One commenter thought the measures should be more evenly distributed across the 5 equally weighted domains, so that domains with fewer measures do not have a greater impact on overall score. A few commenters did not agree with measures having equal weighting. One commenter recommended that the Patient/Caregiver Experience and Care Coordination domains be more heavily weighted as they are the foundation for improving process and outcomes, while another commenter stated the domains of care coordination and patient caregiver experience are untested.

One commenter suggested scoring clinical process measures individually rather than by domain. A number of commenters thought the proposed approach would exclude a large number of ACOs from sharing in savings even though they were providing high quality care. Many commenters took issue with the notion that failing to attain the standard for one single measure would eliminate the possibility for sharing in any savings and recommended that the threshold be set at the domain level rather than the individual measure level. One commenter suggested CMS provide each ACO with their historical 50th percentile for each quality metric which the ACO would have to exceed in each domain to fully share in savings. For each domain that exceeded benchmark, this commenter recommended the ACO's share of savings would increase by 20 percent but the ACO would still be responsible for shared losses under the two-sided model.

Response: We believe that all 4 domains we are adopting in this final rule are of considerable importance and, therefore, agree with the comments that supported weighting each domain equally and will finalize our proposal to do so. This means the 4 measure domains (patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population) will be weighted at 25 percent each in calculating an ACO's overall quality performance score for purposes of determining its final sharing rate. Additionally, we are finalizing the following disease categories within the At-Risk population domain: Diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease.

Equally weighting the measure domains, and individual measures within the domains, is consistent with our view that all of these domains are important to achieving the Medicare Shared Savings Program goals and should be a focus of ACOs, with the exception of the measure, Percent of PCPs who Successfully Qualify for an EHR Incentive Payment. We are double-weighting this measure, as discussed in section II.F. of this final rule, in an effort to signal the importance of EHR adoption to ACOs for achieving success in the Shared Savings Program. We note that, since the Shared Savings Program has not yet begun and ACOs have not yet formed, we are unsure how we could provide any ACO historical data on its quality performance since it would require participating organizations to submit a historical baseline for quality which we believe would add unnecessary burden to newly forming ACOs.

Comment: Many commenters suggested CMS reward a higher level of quality and not just a threshold. Several commenters expressed concern that the quality points scale failed to reward ACOs who are already providing high quality, efficient care in the first year and fails to reward high performance, as opposed to minimum threshold, in subsequent years.

Response: We believe the proposed approach offers a greater incentive for continuous quality improvements, since it has a sliding scale in which higher levels of quality performance translate to higher sharing rates. High performing ACOs should do well under this approach since it recognizes and provides incentives for ACOs to maintain high quality performance in order to maximize their sharing of savings and minimize their sharing of losses.

Comment: Many commenters took issue with the proposed 30 percent/30th percentile threshold. Several commenters stated that if CMS establishes benchmarks solely on the participating ACOs, it would be unfair to assume the bottom 30 percent should receive no credit toward retaining savings when they may very well be performing well above the rest of the nation. Several commenters suggested CMS should, instead, establish specific thresholds for each measure such as a certain percentage with blood pressure under control or a certain percentage improvement, particularly for measures which have not been validated or are not in widespread use among Medicare beneficiaries. However, another commenter suggested a minimum attainment level higher than the 30th percentile in order to best promote quality improvement. One commenter suggested maintaining the proposed approach to score individual measures on a continuum between a threshold (lower bound) and benchmark (upper bound). One commenter suggested rewarding performance in the middle range of quality improvement more than the upper target and lower threshold by taking an average of high and low performers' scores. A couple of commenters noted that without known targets it will be difficult for ACOs to know whether they will be able to achieve the quality performance standards. These commenters requested that we publish specific thresholds in the final rule so that ACOs will know before applying for the program whether they have a reasonable likelihood of success. One commenter suggested establishing performance thresholds and rewarding those ACOs that achieve or make improvements toward those thresholds while another recommended establishing specific numerical targets for all laboratory-based measures. One commenter advocated for gradual increases in the minimum attainment level so that health care organizations are encouraged to continually improve, with clear delineation and rewards for the high performers.

Response: We are finalizing our proposal to establish the minimum attainment level for a measure at a national flat 30 percent or where applicable the national 30th percentile level of performance of FFS or MA quality rates, because we believe this level is reasonable and achievable given current levels of performance on measures in other programs and based on measure community research. As previously discussed, the first year of the agreement period will be pay for reporting only, so ACOs would earn their maximum sharing rate for completely and accurately reporting 100 percent of the required data. We plan to release performance benchmarks in sub regulatory guidance at the start of the

second year of the performance period as we phase in measures to pay for performance so that ACOs are aware of the actual performance rates they will need to achieve to earn the maximum quality points under each domain. We agree with the comment suggesting we gradually raise the minimum attainment level in order to continue to incentivize quality improvement over time and would do so through future rulemaking after providing sufficient advance notice with a comment period to first gain industry input. We note that performance will be rewarded on a scale such that levels of quality improvement between an upper and lower threshold are rewarded. This scale also rewards higher improvement over time, since higher performance translates to higher shared savings. For example, an ACO that performs at 80 percent/80th percentile one year and then at 90 percent/90th percentile the next year, would receive a higher level of shared savings in their second year than in their first year, based on their improved quality performance.

Comment: One commenter suggested using the first 2 years of ACO performance data to establish performance benchmarks, rather than the first year only, since the first year will require ACOs to develop infrastructure and reporting systems. A couple of commenters suggested calculating regional benchmarks so ACOs have a similar chance of achieving success regardless of geographic location. One of these commenters recommended benchmarking at the geographic unit level MedPAC has recommended for MA payments and thought benchmarks should not be based on ACO providers/suppliers alone. One commenter recommended that the benchmark should be based on comparable, local, non-assigned, FFS beneficiaries. However, another commenter thought benchmarks should be based on a comparison of ACOs to other ACOs or Medicare FFS but not MA. The commenter thought it would be inequitable to compare ACOs to the MA program, since patients are locked-in to providers under MA and cannot change providers, unlike an ACO model under which patients are free to seek care outside of the ACO. One commenter suggested an evidence-based approach to any benchmark changes. One commenter recommended CMS specify in the final rule whether FFS or MA data would serve as the basis for benchmarks. This commenter advocated for use of FFS data since these data are more directly relevant to the target population from which the ACO population is derived. One commenter stated that relying on existing data sources for measures would have the advantage of allowing benchmarks to be determined from program onset. This commenter also believed that having a fixed set of performance targets around which the ACO can plan its work is essential to the program's success and that targets should not vary from year to year although the commenter did suggest a range (for example, good to great) be established and incentives set accordingly. One commenter asked for clarification about how benchmarks would be developed for proposed measures that do not have historical data. One commenter requested alignment of the scoring methodology with value-based purchasing.

Response: We are finalizing our proposal to establish national benchmarks for quality measures using a national sample of Medicare FFS claims data, M A quality data, or a flat percentage if FFS claims/MA quality data are not available. We believe national benchmarks are more appropriate than regional benchmarks, since Medicare FFS is a national program and we would like to measure quality improvement and make comparisons over time between FFS and ACO populations on a national basis. Regarding the comment asking how we would develop benchmarks for measures in which claims or MA quality data are not available, we would use a flat national percent establishing the minimum at 30 percent and the maximum at 90 percent as indicated in Table 3. We plan to release benchmarking data in subregulatory guidance and expect to align with other pay for performance program benchmarking methodologies over time. At this time, we are not proposing to compare an ACO's quality performance to the performance of other ACOs for purposes of determining an ACO's overall quality score and final sharing rate. We agree that we should seek to incorporate actual ACO performance on quality scores into the quality benchmark, however, we would do so in future rulemaking and then only after seeking industry input. In addition, we do expect to update the benchmarks over time, consistent with section 1899(d)(3)(C) of the Act, which requires CMS to seek to improve the quality of care over time.

Comment: Several commenters recommended a sliding scale in lieu of complete and accurate reporting. One commenter recommended the standard for complete and accurate reporting should be 95 to 100 percent and the threshold should be between the 70th and 100th percentile. A few commenters suggested CMS consider the PQRS experience with reporting; one mentioned that CMS lowered the PQRS reporting threshold from 80 to 50 percent for its claims based reporting option and kept the registry reporting threshold at 80 percent. A couple of commenters requested clarification on what would constitute a ''reasonable explanation'' for an ACO not to report quality data. A number of commenters thought the proposed approach would exclude a large number of ACOs from sharing in savings even if they provided high quality care. Many commenters took issue with the notion that failing to attain the standard for one single measure should eliminate the possibility of sharing in any savings. One commenter recommended CMS give ACOs credit for measures on which the ACO scored well, even if it does not meet the threshold for other measures within the domain, perhaps by setting the threshold at the domain level rather than the measure level. This commenter stated this was particularly important early in the program, when ACOs may not have experience with the measures, the specifications may have been modified, and the thresholds setting methodology is new and untested.

Response: While it is our intent that ACOs raise the bar in terms of quality of care improvement and performance, and although we believe 100 percent complete and accurate reporting can be achieved for the measures we are finalizing, we are sensitive to comments suggesting we have modified this final rule to allow ACOs more time to ramp up. As a result, we have modified this final rule to provide a longer phase in to pay for performance. All 33 measures used for scoring purposes will be pay for reporting in year 1 of the agreement. In year 2, 8 measures will continue to be pay for reporting, while 25 measures will be used for pay for performance. In year 3 (and 4 if applicable), 32 measures will be pay for performance and 1 measure, the health status/functional status module will be pay for reporting.

Final Decision: We recognize that achieving the quality performance standard on 33 out of 33 measures may be difficult especially in the early years. Accordingly, we have modified this final rule to require that ACOs achieve the quality performance standard on 70 percent of the measures in each domain. If an ACO fails to achieve the quality performance standard on at least 70 percent of the measures in each domain we will place the ACO on a corrective action plan and re-evaluate the following year. If the ACO continues to

underperform in the following year, the agreement would be terminated. We believe requiring ACOs to achieve the quality performance standard on 70 percent of the measures in each of the 4 domains establishes a feasible standard, while signaling to providers that they need to devote significant focus to performance in each domain.

This approach also means that an ACO could fail one or more individual measures in each domain measure and still earn shared savings. ACOs must achieve the minimum attainment level on at least 70 percent of the measures in each domain in order to continue in the program. As described in section II.H. of this final rule, if an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in each domain, we will give the ACO a warning, an opportunity to resubmit and re-evaluate the following year. If the ACO continues to underperform in the following year, the agreement would be terminated. However, in any year that an ACO scores a zero for an entire measure domain, it would not be eligible to share in any savings generated. It should also be noted that if an ACO fails to completely and accurately report the EHR measure, the ACO would miss the 70 percent cut-off for the Care Coordination domain, since this measure is double-weighted for both scoring purposes and for purposes of determining poor performance.

We are also finalizing our proposal that if an ACO fails to report one or more measures, we will send the ACO a written request to submit the required data by a specified date and to provide reasonable explanation for its delay in reporting the required information. If the ACO fails to report by the requested deadline or does not provide a reasonable explanation for delayed reporting, we would immediately terminate the ACO for failing to report quality measures. ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit may be terminated from the program. An ACO that has been terminated from the program is disqualified from sharing in savings.

TABLE 3—SLIDING SCALE MEASURE SCORING APPROACH

ACO performance level	Quality points (all measures except EHR)	EHR measure quality points
90+ percentile FFS/MA Rate or 90+ percent	2 points	4 points.
80+ percentile FFS/MA Rate or 80+ percent	1.85 points	3.7 points.
70+ percentile FFS/MA Rate or 70+ percent	1.7 points	3.4 points.
60+ percentile FFS/MA Rate or 60+ percent	1.55 points	3.1 points.
50+ percentile FFS/MA Rate or 50+ percent	1.4 points	2.8 points.
40+ percentile FFS/MA Rate or 40+ percent	1.25 points	2.5 points.
30+ percentile FFS/MA Rate or 30+ percent	1.10 point	2.2 points.
<30 percentile FFS/MA Rate or <30 percent	No points	No points.

TABLE 4—TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Total individual measures (Table F1)	Total measures for scoring purposes	Total potential points per domain	Domain weight (percent)
Patient/Caregiver Experience	7	1 measure with 6 survey module measures combined, plus 1 individual measure.	4	25
Care Coordination/Patient Safety.	6	6 measures, plus the EHR measure double-weighted (4 points).	14	25
Preventative Health	8	8 measures	16	25
At Risk Population	12	7 measures, including 5 component diabetes composite measure and 2 component CAD composite measure.	14	25
Total	33	23	48	100

As illustrated in Table 4, a maximum of 2 points per measure could be earned under both the one-sided and two-sided model based on the ACO's performance, except on the EHR measure, which is weighted double any other measure and would be worth 4 points. We believe EHR adoption is important for ACOs to be successful in the Shared Savings Program and are double weighting this measure as a way to signal this and provide incentive for greater levels of EHR adoption.

However, the total potential for shared savings will be higher under the two-sided model, since the maximum potential shareable savings based on quality performance is 60 percent of the savings generated, compared to 50 percent under the one-sided model, as discussed in section II.G. of this final rule. That is, 100 percent reporting of the quality measures in the first year of the Shared Savings Program will result in an ACO earning 50 or 60 percent of shareable savings, depending on whether the ACO is in the one-sided or two-sided model. For future performance periods, the percent of potential shareable savings will vary based on the ACO's performance on the measures as compared with the measure benchmarks as we phase in the pay for performance measures, as shown in Table 2.

We are establishing the minimum attainment level for each measure at a national flat 30 percent or the national Medicare FFS or MA 30th percentile level of performance, as proposed. We believe this level is reasonable and achievable given current levels of performance on measures in other programs and based on measure community research. ACOs will have to score at or above the minimum attainment level in order to receive any credit for reporting the quality measure. We will release corresponding national benchmarks, based on Medicare FFS claims data, Medicare Advantage quality data, or a flat percentage if claims/quality data are not available in

subregulatory guidance at the start of the second performance period and, when certain measures move to pay for performance.

We are also finalizing our proposal for scoring individual measures in each domain in pay for performance years. Based on their level of performance on each measure an ACO would earn the corresponding number of points as outlined in Table 3. The total points earned for measures in each domain would be summed up and divided by the total points available for that domain to produce an overall domain score of the percentage of points earned versus points available.

We are finalizing our proposal to weight each of the 4 measure domains (patient/caregiver experience, care coordination/patient safety, preventive health, and at-risk population) equally at 25 percent for purposes of determining an ACO's overall quality performance score. We believe giving equal weight to the domains will signal the equal importance of each of these areas and to encourage ACOs to focus on all domains in order to maximize their sharing rate. Accordingly, the percentage score for each domain, calculated using the methodology described previously, will be summed and divided by 4 to reflect the equal weighting of the domains. The resulting percentage will then be applied to the maximum sharing rate under either the one-sided or two-sided model to determine the ACOs final sharing rate for purposes of determining its shared savings payment or share of losses.

5. Incorporation of Other Reporting Requirements Related to the PQRS and Electronic Health Records Technology Under Section 1848 of the Act

The Affordable Care Act gives the Secretary authority to incorporate reporting requirements and incentive payments from these programs into the Shared Savings Program, and to use alternative criteria to determine if payments are warranted. Specifically, section 1899(b)(3)(D) of the Act affords the Secretary discretion to ''* * * incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI), under section 1848 of the Act, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1848 * * *'' and permits the Secretary to ''use alternative criteria than would otherwise apply [under section 1848 of the Act] for determining whether to make such payments.'' Under this authority, we proposed to incorporate certain reporting requirements and payments related to the PQRS into the Shared Savings Program for ''eligible professionals'' within an ACO (76 FR 19598). Under section 1848(k)(3)(B) of the Act, the term ''eligible professional'' means any of the following: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of the Act; (3) a physical or occupational therapist or a qualified speech pathologist; or (4) a qualified audiologist.

We proposed to incorporate a PQRS GPRO under the Shared Savings Program and further proposed that EPs that are ACO participant providers/suppliers would constitute a group practice for purposes of qualifying for a PQRS incentive under the Shared Savings Program (76 FR 19599). Specifically, we proposed that EPs would be required to submit data through the ACO on the quality measures we proposed (76 FR 19571) to qualify for the PQRS incentive under the Shared Savings Program. We proposed that the ACO would report and submit data on behalf of the EPs in an effort to qualify for the PQRS incentive as a group practice; that is, EPs within an ACO would qualify for the PQRS incentive as a group practice, and not as individuals. In addition, we proposed a calendar year reporting period from January 1 through December 31, for purposes of the PQRS incentive under the Shared Savings Program. With regard to the incorporation of criteria for satisfactory reporting for purposes of the PQRS incentive for the first performance period under the Shared Savings Program, we proposed that:

- An ACO, on behalf of its EPs, would need to report on all measures included in the data collection tool;
- Beneficiaries would be assigned to the ACO using the methodology described in the Assignment section of the proposed rule. As a result, the GPRO tool would be populated based on a sample of the ACO-assigned beneficiary population. ACOs would need to complete the tool for the first 411 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each domain, measures set, or individual measure if a separate denominator is required such as in the case of preventive care measures which may be specific to one sex. If the pool of eligible assigned beneficiaries is less than 411, the ACO would report on 100 percent of assigned beneficiaries for the domain, measure set, or individual measure.
- The GPRO tool would need to be completed for all domains, measure sets, and measures described in Table 1 of the proposed rule.

Accordingly, we proposed that EPs within an ACO that satisfactorily report the proposed measures during the reporting period would qualify under the Shared Savings Program for a PQRS incentive equal to 0.5 percent of the Secretary's estimate of total Medicare Part B PFS allowed charges for covered professional services furnished by the ACO's EPs during the first performance period. ''Covered professional services'' are services for which payment is made under, or based on, the physician fee schedule and which are furnished by an eligible professional under the ACO participant's TINs.

We proposed to align the incorporated PQRS requirements with the general Shared Savings Program reporting requirements, such that no extra reporting would actually be required in order for EPs or the ACO to earn the PQRS incentive under the Shared Savings Program. Thus, for ACOs that meet the quality performance standard under the Shared Savings Program for the first performance period, we proposed that the PQRS EPs within such ACOs will be considered eligible for the PQRS incentive under the Shared Savings Program for that year. In the proposed rule, we stated that this means ACOs would need to report on all measures proposed (76 FR 19571) in order to receive both the Shared Savings Program shared savings and PQRS incentive (76 FR 19599). We also stated that failure to meet the Shared Savings Program quality performance standard would result in failure to be considered eligible for shared savings, as well as failure for the EPs within the ACO to receive a PQRS incentive under the Shared Savings Program for that year. ACO participant provider/suppliers who meet the quality performance standard but do not generate shareable savings would still be eligible for PQRS incentive payments. We also indicated that we intended to discuss the policy for incorporating the PQRS incentive under the Shared Savings Program for subsequent years in future rulemaking (76 FR 19599).

We noted in the proposed rule that ACOs would be eligible for the PQRS incentive under the Shared Savings Program to the extent that they contain EPs as defined under § 414.90(b). As a result, not all ACOs would necessarily be eligible for the PQRS incentive under the Shared Savings Program. A complete list of PQRS EPs (EP) is available at: *http://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf.* In addition, similar to traditional PQRS, we indicated that an EP could not

qualify for the PQRS incentive as both a group that is part of an ACO and as an individual. Furthermore, EPs could not qualify for a PQRS incentive under both the PQRS under the Shared Savings Program and the traditional PQRS under the same TIN. For purposes of PQRS incentive analysis and payment, we stated that we intended to use TINs and NPI numbers similar to what we have done in the traditional PQRS (75 FR 40169), and we would provide such details in guidance (76 FR 19599). We invited comment on our proposal to incorporate PQRS requirements and payments under the Shared Savings Program.

We did not propose to incorporate payments for the EHR Incentive Program or eRx Incentive Program under the Shared Savings Program. Professionals in ACOs may still separately participate in the EHR Incentive Program or Electronic Prescribing Incentive Program. However, we proposed to require for the Shared Savings Program measures also included in the EHR Incentive Program and metrics related to successful participation in the Medicare and Medicaid EHR Incentive Programs for EPs and hospitals and the eRx Incentive Program.

In addition, as a Shared Savings Program requirement separate from the quality measures reporting, we proposed requiring that at least 50 percent of an ACO's primary care physicians be determined to be ''meaningful EHR users'' as that term is defined in 42 CFR 495.4 by the start of the second performance year in order to continue participation in the Shared Savings Program. The EHR Incentive regulations, including the definition of meaningful EHR user and certified EHR technology can be found at 42 CFR part 495, as published on July 28, 2010 (75 FR 44314). The preamble to the July 28, 2010 final rule also describes the stages of meaningful use. We also sought comment on whether we should also specify a percentage-based requirement for hospitals. Such a requirement would be similar to the previous proposal for primary care physicians and would require 50 percent of eligible hospitals that are ACO providers/suppliers achieve meaningful use of certified EHR technology by the start of the second performance year in order for the ACO to continue participation in the Shared Savings Program. We also requested public comment related to circumstances where the ACO may include only one eligible hospital or no hospital and whether we would need to provide an exclusion or exemption in such a circumstance.

Comment: A few commenters specifically commended CMS's alignment of the ACO quality reporting requirements with PQRS reporting requirements. A few commenters recommended a single reporting process for the measures common to PQRS, ACO, and the EHR Incentive programs to reduce burden and duplication of effort. However, one commenter recommended separate reporting for the Shared Savings Program quality performance standard and the PQRS satisfactory reporting requirement initially until experience with the measures ACOs report for shared savings eligibility purposes demonstrates reliability for both ACO and PQRS needs. One commenter suggested individual PQRS reporting for providers who may be in more than one ACO. One commenter supported alignment with traditional PQRS GPRO reporting and suggested a financial disincentive for non-compliance. One commenter believed that individual EPs should be allowed to submit quality measures data to the traditional PQRS without participating in ACOs. Another commenter expressed concern that professionals could be confused by reporting ACO PQRS measures via GPRO for their ACO patients if they are also reporting PQRS measures via claims or a registry for patients not in the ACO under the traditional PQRS program.

Response: We agree with the recommendations to streamline reporting as much as possible and are finalizing a set of measures aligned with other programs, such as the PQRS, EHR Incentive Program, and PGP Transition Demonstration. In order to reduce reporting burden and decrease operational complexity for purposes of earning the PQRS incentive under the Shared Savings Program, we are modifying our proposal. Although we are requiring that EPs in ACOs meet the criteria for satisfactory reporting by reporting data on all of the final ACO GPRO measures, we are not finalizing our proposal to condition the PQRS incentive payment on the reporting of all of the other ACO quality measures (that is from claims, CAHPS, and CMS administrative data) under the Shared Savings. That is, if an ACO, on behalf of its EPs, satisfactorily reports ACO GPRO measures, the EP's ACO participant TIN will receive the PQRS incentive even if the ACO does not meet the quality performance standards and lower growth in costs requirements to share in savings under the Shared Savings Program. EPs in an ACO that starts its agreement in April or July 2012 will also qualify for the 2012 PQRS incentive under the Shared Savings Program by satisfactorily reporting the ACO GPRO measures for the full 2012 PQRS calendar year reporting period.

We believe only requiring EPs in ACOs to meet the criteria for satisfactory reporting by reporting data on all of the final ACO GPRO measures reduces reporting burden, since we are simplifying the requirements EPs in ACOs must meet to earn a PQRS incentive under the Shared Savings Program. It also increases the probability that an EP would receive some level of incentive under the Shared Savings Program. We believe requiring ACOs to report the final GPRO measures, as opposed to all of the final ACO quality measures, to earn a PQRS incentive under the Shared Savings Program also reduces operational complexity because CMS can calculate the incentive payment under the Shared Savings Program based on the GPRO quality data after the ACO completes the GPRO quality data submission. That is, the calculation and distribution of the PQRS incentive will not be contingent on our analysis of other ACO quality data from claims, CAHPS and CMS administrative data under the Shared Savings Program. Requiring ACOs to report a full 12 months of GPRO quality data also aligns the reporting period for earning a PQRS incentive under the Shared Savings Program with the traditional PQRS. In addition, we believe groups that are currently participating under the traditional PQRS GPRO, but are considering participating in the Shared Savings Program, would have greater assurance they could earn a PQRS incentive under the Shared Savings Program, given that we are not finalizing our proposal that ACOs comprised of such group practices must also meet other Shared Savings Program requirements for a shared savings payment for purposes of earning a PQRS incentive.

We also wish to clarify that ACO participant TINs that wish to qualify for PQRS would need to participate as group practices in the PQRS under the Shared Savings Program and may not separately participate in or earn a PQRS incentive under the traditional PQRS, outside of the Shared Savings Program. In addition, individual ACO providers/suppliers who are EPs in an ACO participant TIN may not seek to qualify for an individual PQRS incentive under the traditional PQRS. We do not agree with the suggestion that ACO providers/suppliers, who are EPs in one or more ACOs, be allowed to do individual PQRS reporting—in either the traditional PQRS or the PQRS under the

Shared Savings Program—for two main reasons. First, the Shared Savings Program is concerned with measuring the quality of care furnished by the ACO as a whole, and not that of individual ACO providers/suppliers. Second, allowing provider/suppliers to earn more than one PQRS incentive goes against the rules of traditional PQRS. We do not agree with the comment that disincentives for non-participation are necessary at this point. Rather, we believe positive rewards for successful Shared Savings Program and PQRS participation will be more instrumental in achieving the desired outcomes.

Comment: A few commenters recommended CMS assure that attestation through the EHR Incentive Programs will serve as reporting for the ACO program or that participation in ACO electronic quality measurement reporting as one avenue of fulfilling meaningful use criteria under the EHR Incentive Program. One of these commenters also suggested that CMS should facilitate one-time data extraction to fulfill multiple programs' reporting requirements.

Response: At this time, the EHR Incentive Program does not have a mechanism for group reporting, so we are unable to translate quality data that ACOs will report as a group under the Shared Savings Program to individual EHR incentives for EPs. The PQRS does allow for group reporting, which is why we are able to incorporate and align such reporting and incentive payments under the Shared Savings Program.

Comment: While one commenter supported the proposal that 50 percent of an ACO's primary care providers be meaningful EHR users by the start of the second performance year, many commenters stated that the initial 50 percent bar is too high given the lack of experience with the EHR Incentive Programs, especially for smaller, less integrated practices and those in rural areas. One commenter did not believe that the Shared Savings Program should serve to increase the rigor of other CMS programs or that lack of participation in the EHR incentive programs should preclude participation in the Shared Savings Program. Some commenters noted that CMS already is providing incentives for meaningful use of certified EHR technology, making inclusion of such a requirement under the Shared Savings Program redundant and unnecessary. Several commenters suggested phasing in this requirement, potentially over a 5-year period, or through certain annual percentages starting in year two. Other commenters suggested delaying or lowering the threshold, creating exceptions (such as hardship exceptions) or opportunities for corrective action, excluding from the requirement professionals who are ineligible for the EHR Incentives, expanding the scope more broadly than primary care physicians, including hospitals in the final rule, or generally allowing ACOs to establish their own goals for meaningful use. Commenters expressed concern about the stages of meaningful use and which stage would have to be met by the second year of a given ACO's agreement with CMS, particularly if the second year began on January 1, 2014.

Response: We have modified our proposal such that EHR participation is no longer a condition of participation but remains one of our quality measures. In addition, we have clarified that the measure will include any PCP who successfully qualifies for an EHR Incentive Program incentive. We believe this change is consistent with industry comments, recognizes ACOs providers' current levels of EHR Incentive Program participation, rewards higher adoption with higher sharing rates, and signals the importance of EHR adoption to ACOs. To further signal the importance of EHRs we will score the EHR quality measure with higher weight than the other quality measures. Although we are not finalizing the requirement that 50 percent of PCPs in ACOs be meaningful users in order for the ACO to be eligible to continue to participate for a second year in the Shared Savings Program, we recognize that ACOs with more IT infrastructure integrated into clinical practice will likely find it easier to be successful under the Shared Savings Program. As providers gain more experience with EHR technology, we will reconsider using certified EHR technology as an additional reporting mechanism used by ACOs under the Shared Savings Program, which we would address in rulemaking for future program years.

In the proposed rule, we also indicated that ACOs would need to participate separately in the eRx Incentive Program (76 FR 19599). We strongly recommend that potential ACOs review the CY 2012 Physician Fee Schedule eRx Incentive Program proposed and final rules carefully, for details about participation requirements, self-nomination timeframes, incentive payments and penalties. The CY 2012 Physician Fee Schedule eRx Incentive Program proposed rule is available at: *http://www.gpo.gov/fdsys/pkg/FR-2011-07-19/pdf/2011-16972.pdf.*

Final Decision: After considering the issues raised in the public comments and for the reasons we previously discussed, we are finalizing our proposal to incorporate PQRS reporting requirements and incentive payment under the Shared Savings Program. Specifically, in this final rule we are finalizing the use of the GPRO web interface, as proposed, as well as our proposal that EPs that are ACO providers/suppliers constitute a group practice under their ACO participant TIN for purposes of qualifying for a PQRS incentive under the Shared Savings Program. Therefore, an ACO, on behalf of its EPs, is required to satisfactorily submit quality data on the GPRO quality measures we are finalizing in Table 1 of this final rule. Such EPs within an ACO may qualify for a PQRS incentive under the Shared Savings Program only as a group practice and not individuals. ACO participants and ACO providers/suppliers also may not seek to qualify for the PQRS incentive under traditional PQRS, outside of the Shared Savings Program. We are also finalizing the calendar year reporting period of January 1 through December 31 for purposes of the PQRS incentive under the Shared Savings Program.

Furthermore, we intend that reporting on the GPRO quality measures under the Shared Savings Program will also fulfill the reporting requirements for purposes of avoiding the payment adjustment under section 1848(a) of the Act that begins in 2015. We plan to address this issue in more detail in future rulemaking.

With regard to the GPRO quality measures applicable for the PQRS incentive under the Shared Savings Program, we are finalizing the PQRS GPRO criteria for satisfactory reporting as described previously.

Accordingly, EPs within an ACO participant TIN that satisfactorily report the ACO GPRO measures during the reporting period will qualify under the Shared Savings Program for a PQRS incentive equal to 0.5 percent of the Secretary's estimate of total Medicare Part B PFS allowed charges for covered professional services furnished by the ACO's EPs during the first reporting period. ''Covered professional services'' are services for which payment is made under, or based on, the physician fee schedule and which are furnished by EPs (under the ACO participant's TINs).

By satisfactorily reporting the ACO GPRO measures on behalf of the EPs in the group practice, we note that the ACO participant TIN will meet the requirements for the PQRS incentive payment and also fulfill a portion of the quality performance standard requirements for purposes of Shared Savings Program shared savings

eligibility. However, ACOs must also completely and accurately report all of the measures in Table 1, as well as meet the lower growth in costs criteria, described in section II.G. of this final rule, to be considered eligible for shared savings.

As we indicated previously, we are not finalizing our proposal regarding an ACO's failure to report all required ACO quality measures. That is, if an ACO fails to meet the Shared Savings Program quality performance standard and is not eligible for shared savings, EPs in a group practice that is an ACO participant TIN may nevertheless earn the PQRS incentive under the Shared Savings Program, as long as the ACO satisfactorily reports, on behalf of its EPs, the ACO GPRO quality measures for the reporting period. Thus, ACO participant TINs in ACOs that meet the satisfactory reporting requirements will still be eligible for a PQRS incentive payment under the Shared Savings Program, even if the ACO does not generate shareable savings for the Shared Savings Program.

As we indicated, ACOs are eligible to qualify for the PQRS incentive under the Shared Savings Program to the extent that they contain EPs as defined under § 414.90(b). As a result, not all ACO participants will necessarily be eligible for the PQRS incentive under the Shared Savings Program. A complete list of PQRS EPs is available at: *http://www.cms.gov/PQRI/Downloads/EligibleProfessionals.pdf.* In addition, similar to traditional PQRS, an EP cannot qualify for the PQRS incentive as both a group and as an individual under the same TIN. For purposes of PQRS incentive analysis and payment, we will use TINs and NPI numbers similar to what we have done in the traditional PQRS (75 FR 40169), and we will provide such details in guidance (76 FR 19599).

As we noted previously, we did not propose to incorporate the EHR Incentive Program or eRx Incentive Program reporting requirements or incentives under the Shared Savings Program. EPs in ACOs may still separately participate in the EHR Incentive Program or eRx Incentive Program, and we encourage potential ACOs to follow the applicable requirements for those programs.

We are also modifying our proposal regarding the EHR Incentive Program participation criteria as a condition of continued Shared Savings Program. We are not finalizing the proposal to require that at least 50 percent of an ACO's primary care physicians be determined to be ''meaningful EHR users'' as that term is defined in 42 CFR 495.4 by the start of the second performance year in order to continue participation in the Shared Savings Program. Instead we will double weight the quality measure ''Percent of PCPs who Successfully Qualify for an EHR Incentive Program Payment,'' as described previously in section II.F, to stress the importance of EHR adoption among ACOs.

6. Aligning ACO Quality Measures With Other Laws and Regulations

As we stated in the proposed rule, different quality frameworks and rewards may add to confusion and administrative burdens for affected parties, and mitigate efforts to focus on the highest-quality care. Therefore, we sought comment from affected parties and other stakeholders on the best and most appropriate way to align quality domains, categories, specific measures, and rewards across these and other Federal healthcare programs, to ensure the highest-possible quality of care. Specifically, we sought comment on whether quality standards in different Affordable Care Act programs should use the same definition of domains, categories, specific measures, and rewards for performance across all programs to the greatest extent possible, taking into account meaningful differences in affected parties.

Comment: A number of commenters supported aligning ACO quality measures with other CMS programs such as PQRS, eRx, Hospital Compare, Medicare Advantage, the upcoming physician fee schedule value modifier, and the EHR Incentive Programs to avoid burden, confusion duplicative reporting. One commenter suggested the EHR Incentive Program requirements are not aligned with ACO requirements, missing the opportunity to incentivize adoption and interoperability to lower costs and improve care. This commenter suggested that ACO standards be supported in the EHR Incentive Program. One commenter noted 'alignment' does not necessarily mean using exactly the same set of measures across programs, since ACOs may have data collection capabilities and needs that are broader than those applicable to the EHR incentive program, and the pools of provider participants in the two programs will be different. A few commenters recommended CMS make public its overall quality measurement strategy including the synergy between measures for ACOs, hospital IQR, and other initiatives. One commenter supported alignment with other programs but raised concerns about the fairness of resultant double jeopardy or double incentives. A few commenters expressed concern that the lack of complete alignment with MA 5 Star measures would result in increased burden of reporting and decreased performance, greater start-up costs, and hinder consumers' ability to make informed coverage choices. While one commenter believed measures reported through other programs should be excluded from this program, a number of commenters recommended that only those measures currently being reported in other CMS programs should be used initially although there were varying recommendations about with which program to align. One commenter recommended using the Hospital Quality Incentive Demonstration model as had succeeded in improving quality and decreasing cost. One commenter specifically recommended the ACO program begin exclusively with measures used in the PGP demonstration.

A few commenters believed it would be desirable to have a single set of quality measures across payers, including Medicaid, Medicare, and commercial payers; one noted this would benefit vendors, providers, and patients. A few commenters suggested alignment with non-federal programs. One commenter suggested ACO quality reports should explain differences in measures reported by CMS and those reported by Regional Health Improvement Collaboratives (RHICs). One commenter recommended CMS align measures with the goals and domains of the National Quality Strategy.

Response: We agree, in principle, with alignment across programs. To that end, we have chosen a final measure set that is closely aligned with PQRS as discussed previously. At this point in time and for this particular program, the ambulatory PQRS set was the natural choice compared with other proposed measurement sets focused on the inpatient setting or MA plans. However, we will revisit this issue and continue to work toward alignment with those and other programs in future rulemaking. We also do intend to further align the Shared Savings Program with the EHR Incentive Programs as we develop experience with both programs and EHRs become more widespread. We do not share the one commenter's concern about ''double jeopardy'' or ''double incentives'' by including measures under more than one program. Rather, we believe including a measure in more than one program and aligning the measures specifications signals CMS' desire for better performance in that area and serves to increase the motivation for such improved performance. While we

agree with the principle of alignment across a variety of programs, it is beyond the purview of this program to align fully with external programs or to explain differences between our measurement set and the numerous other measurement sets in existence. However, our final measurement set is aligned with the National Quality Strategy. In response to the commenters that recommended we make public our overall quality measurement strategy, we agree that it is important that we make our quality strategy publicly available and have done so through our Web site and a large number of public events.

Final Decision: We will finalize our proposal to align the Shared Savings Program quality measures reporting requirements with those in other programs, to the extent possible, as previously discussed.

G. Shared Savings and Losses

1. Authority For and Selection of Shared Savings/Losses Model

Section 1899 of the Act, as added by section 3022 of the Affordable Care Act, establishes the general requirements for payments to participating ACOs. Specifically, section 1899(d)(1)(A) of the Act provides that ACO participants will continue to receive payment ''under the original Medicare fee-for-service program under Parts A and B in the same manner as they would otherwise be made.'' However, section 1899(d)(1)(A) of the Act also provides for an ACO to receive payment for shared Medicare savings provided that the ACO meets both the quality performance standards established by the Secretary, as discussed in section II.F. of this final rule, and demonstrates that it has achieved savings against a benchmark of expected average per capita Medicare FFS expenditures. Additionally, section 1899(i) of the Act authorizes the Secretary to use other payment models in place of the one-sided model outlined in section 1899(d) of the Act. This provision authorizes the Secretary to select a partial capitation model or any other payment model that the Secretary determines will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

In the November 17, 2010 **Federal Register**, we solicited public comment on a number of issues regarding ACOs and the Shared Savings Program, including the types of additional payment models we should consider in addition to the model laid out in section 1899(d) of the Act, either under the authority provided in section 1899(i) of the Act or using the Innovation Center authority under section 1115A of the Act. We further asked about the relative advantages and disadvantages of any such alternative payment models.

In the proposed rule, we described and sought comment on several options for structuring the Shared Savings Program. One option we considered was to offer a pure one-sided shared savings approach using the calculation and payment methodology under section 1899(d) of the Act. This option would have the potential to attract a large number of participants to the program and introduce value-based purchasing broadly to providers and suppliers, many of whom may never have participated in a value-based purchasing initiative. Another reason we considered this option was that a one-sided model with no downside performance risk might be more accessible and attract smaller group participation. However, as some RFI commenters suggested, while such a model may provide incentive for participants to improve quality, it may not be enough of an incentive for participants to improve the efficiency and cost of health care delivery. Therefore, we considered a second option to use our authority under section 1899(i) of the Act to create a performance risk-based option in the Shared Savings Program. Such a model would have the advantage of providing an opportunity for more experienced ACOs that are ready to share in losses to enter a sharing arrangement that provides greater reward for greater responsibility.

Another approach we considered would be to offer a hybrid approach. A hybrid approach would combine many of the elements of the one-sided model under section 1899(d) of the Act with a performance risk-based approach under section 1899(i) of the Act.

Based on the input of commenters on the November 17, 2010 RFI, other stakeholders and policy experts we proposed to implement a hybrid approach. Specifically, we proposed that ACOs participating in the Shared Savings Program would have an option between two tracks:

Track 1: Under Track 1, shared savings would be reconciled annually for the first 2 years of the 3-year agreement using a one-sided shared savings approach, with ACOs not being responsible for any portion of the losses above the expenditure target. However, for the third year of the 3-year agreement, we proposed to use our authority under section 1899(i) of the Act to establish an alternative two-sided payment model. Under this model, an ACO would be required to agree to share losses generated as well as savings. ACOs that enter the Shared Savings Program under Track 1 would be automatically transitioned to the two-sided model in the third year of their agreement period. In that year, the ACO's payments would be reconciled as if it was in the first year of the two-sided model. However, quality scoring would still be based on the methods for the third year (that is, it would not revert back to the first year standard of full and accurate reporting). Thereafter, those ACOs that wish to continue participating in the Shared Savings Program would only have the option of participating in Track 2, that is, under the two-sided model. As proposed, we envisioned that this track would provide an entry point for organizations with less experience with risk models, such as some physician driven organizations or smaller ACOs, to gain experience with population management before transitioning to a risk-based model.

Track 2: More experienced ACOs that are ready to share in losses with greater opportunity for reward could elect to immediately enter the two-sided model). An ACO participating in Track 2 would be under the two-sided model for all 3 years of its agreement period. Under this model, the ACO would be eligible for higher sharing rates than would be available under the one-sided model. We proposed that this track would provide an opportunity for organizations more experienced with care coordination and risk models that are ready to accept performance-based risk, to enter a sharing arrangement that provides greater reward for greater responsibility.

In general, we proposed the same eligibility requirements and methodologies for the two tracks. That is, we proposed to use the same eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements for ACOs under the one-sided and two-sided models. We also explained our belief that the proposed monitoring procedures in combination with our proposed use of a retrospective beneficiary assignment methodology and proposed beneficiary notification requirements were sufficient to guard against the prospects that two-sided model ACOs might try to avoid at-risk beneficiaries in order to minimize the possibilities of realizing losses against

their benchmarks. However, we invited comments on the sufficiency of the proposed monitoring procedures as well as additional areas and mechanisms for monitoring two-sided model ACOs.

We proposed adding some requirements to the program in order to provide further assurance about the ability of an ACO operating under the two-sided model to repay the Medicare program in the event of incurred losses. We proposed requiring all ACOs to demonstrate, as part of their application and in advance of entering the two-sided model, the establishment of a repayment mechanism to ensure repayment of losses to the Medicare program. We stated our belief that the proposed eligibility requirements for ACOs in addition to the requirement that ACOs demonstrate an adequate repayment mechanism were sufficient to ensure the ability of ACOs to repay CMS in the event they incur losses. We sought comment on whether additional eligibility requirements were necessary for ensuring that ACOs entering the two-sided model would be capable of repaying CMS if actual expenditures exceeded their benchmark.

Further, we proposed to provide greater financial incentives to ACOs that participate under the program's two-sided model to encourage ACOs to enter the two-sided model, which we believe has a greater potential than the one-sided model to induce meaningful and systematic change in providers' and suppliers' behavior.

In the proposed rule, we described our intention to design and test partial capitation models in the Innovation Center first in order to gain more experience with such models, introduce them to providers of services and suppliers, and refine them, before applying them more widely in the Shared Savings Program.

Comment: Many comments indicated general support for our proposal to base the Shared Savings Program on a framework of existing FFS payments. However, some commenters urged CMS not to confine its payment method to the current, traditional Medicare fee-for-service payments to ACO participants but instead to employ a variety of alternative payment approaches. In some cases, commenters recommended these alternatives to facilitate participation by specific provider types or the inclusion of specific types of services. One commenter suggested this is necessary to ensure the success of the program. Another commenter, generally, supported testing of various payment and care delivery models through the Innovation Center.

Of those who recommended alternative payment models, commenters most commonly recommended inclusion of the following payment models in the Shared Savings Program: blended fee-for-service payments; prospective payments; episode/case rate payments; bundled payments; patient-centered medical homes and surgical homes payment models; payments based on global budgets; full capitation; partial capitation such as condition-specific capitation; and enhanced FFS payments for care management, such as care coordination fees. Several others suggested CMS allow ACOs to use incentives to ensure beneficiaries adhere to treatment regimens or seek care within the ACO.

In the case of enhanced FFS payments, commenters offered a variety of suggestions on the form for such payments. Most commonly, commenters suggested CMS pay for physicians' consultative or coordination services provided via e-mail or telephone, such as self-management support for patients with chronic diseases, or through a per-member per-month (PMPM) care management fee (for example, in the range of $10–$50 PMPM). One commenter offered a specific proposal for incorporating enhanced FFS payments. Specifically, CMS should use its authority under section 1899(i) of the Act to authorize payment for CPT codes for telephone calls and other non-face-to-face services used by ACOs that accept downside risk to improve care management and hold ACOs accountable for repaying a portion of these payments should they bill for these codes but fail to achieve savings. CMS should then collect data on the impact of paying for these services to determine if this payment policy should be expanded to FFS Medicare. Another suggested example would be for CMS to authorize payment for telemedicine codes reported by ACOs. Another commenter suggested using a budget neutral way to provide these payments by reallocating dollars from inpatient and specialty reimbursement.

Some commenters recommended CMS offer other targeted payment models to facilitate participation by certain types of ACOs, such as small physician-only ACOs, and ACO participants, namely small- and medium-sized physician practices, especially those in rural areas; or to support care for particular types of patients, such as dual eligible beneficiaries.

Several comments related to the overall design of the proposed program. One commenter suggested the Shared Savings Program is an overly complex approach to cost management and urged CMS to find a simpler solution. The commenter suggested setting expenditure benchmarks relative to geographic areas, allowing ACOs that meet quality thresholds to keep FFS payments received, and penalizing ACOs that do not reduce expenditures. Another commenter suggested allowing ACOs to share in first dollar savings for all Medicare beneficiaries seen by the ACO, not just those assigned to the ACO. A third commenter urged CMS to ensure a consistent approach and level playing field as between the Shared Savings Program and Medicare Advantage.

Response: We appreciate commenters' interest in and support for adopting other payment models in the Shared Savings Program, but disagree with suggestions that CMS use its authority under section 1899(i) of the Act to include additional alternative payment models in the program at this time. We believe many of the suggested payment models remain untested. We are concerned that immediately adopting models on a national scale with which we have no experience could lead to unintended consequences. However, as discussed in section II.B.6. of this final rule, it is the Innovation Center's task to test novel payment models under its demonstration authority. We anticipate that as we gain experience through the Innovation Center with novel payment models what we learn could be more widely adopted in the Shared Savings Program. We would note that a number of commenters expressed support for testing alternative models through the Innovation Center.

Comment: Several comments reflected confusion about the proposed payment model under the Shared Savings Program. For instance, some commenters asserted that the program will, in fact, make partial capitation payments, or questioned if providers electing not to participate in the program will continue to receive payment as usual.

Response: We would like to clarify that consistent with section 1899(d)(1)(A) of the Act, fee-for-service providers will continue to receive payments ''under the original Medicare fee-for-service program under Parts A and B in the same manner as they would otherwise be made'' regardless of whether they participate in the Shared Savings Program. Also, as indicated previously, we do not plan to adopt partial capitation (or other such payment methodologies) at this time, but may do so in the future through

appropriate rule-making, depending on lessons learned through demonstrations.

Comment: A few commenters noted concerns that uncertainty about the Sustainable Growth Rate (SGR) for FY 2012 could undermine the program, as doctors could be subject to lower reimbursement rates and also be potentially subject to shared losses under the Shared Savings Program. One commenter suggested that CMS delay publication of the final rule for the Shared Savings Program until clarification of the FY 2012 SGR. Further, one commenter suggested that physician reimbursement rates are already too low to cover costs, and the ''flawed'' SGR formula needs to be addressed to allow physicians to adapt new care delivery models. Another commenter suggested that the SGR and the Shared Savings Program are redundant mechanisms to control utilization and focus on prevention, quality and efficiency, and as such CMS should develop a process for waiving SGR requirements for physicians participating in ACOs.

Response: We decline to use our authority under section 1899(f) of the Act to waive the requirements of the SGR methodology for ACO participants as it is not necessary to waive these requirements in order to carry out the provisions of section 1899 and implement the Shared Savings Program. Rather, the statute at section 1899(d)(1)(A) expressly provides that we continue to make payments to the providers and suppliers participating in an ACO ''* * * in the same manner as they would otherwise be made * * *.'' Accordingly, addressing concerns about the SGR methodology is beyond the scope of this rule for the Shared Savings Program. We note, however, the publication of the proposed rule for the 2012 Medicare Physician Fee Schedule on July 1, 2011, and the publication of the final rule, to include the Secretary's initial estimate of the SGR for 2012, later this year.

Comment: The comments reflected a variety of opinions on the proposed two track approach. Several commenters supported retaining the proposed two track approach in the final rule. As one commenter explained, a shared savings only track may be appropriate for newly formed organizations to gain experience with accountable care models, but a model that includes shared performance-based risk is necessary to drive meaningful change. A few commenters strongly favored the proposal to transition ACOs under the one-sided model to a shared savings and risk model in the third year while offering more mature ACOs the option to enter into a shared savings and risk model in the first year; indicating the importance of shared performance-based risk in the delivery transformation necessary to achieve the three-part aim and for ''good stewardship'' of Medicare Trust Fund dollars.

However, most commenters expressed concerns with requiring ACOs to quickly accept performance risk for the costs of their patients, or even to accept risk at all, and suggested this proposal could diminish participation. Several comments noted that for organizations (particularly small- and medium-sized practices) that do not have any experience with care management or managing performance-based risk, a shared savings only option would better enable them to feel comfortable making the significant investments necessary to transition to the accountable care model. Along these lines, commenters suggested that including a shared savings only model would encourage participation by certain groups, such as: small- and medium-sized physician practices, loosely formed physician networks, safety net providers, small ACOs, and rural ACOs.

Some commenters expressed reservations about the proposed inclusion of the two-sided model. Some commenters were concerned that a downside risk payment model could jeopardize the financial health of ACOs and may ultimately result in market dynamics similar to those precipitating the managed care backlash in the 1990s; although, several commenters noted the additional proposed program protections would safeguard against these problems. One commenter cautioned that absent sufficient care coordination systems, blame for losses might lie with certain groups of physicians (such as emergency medicine physicians). Another commenter explained that risk emphasizes financial outcomes over patient-centered care. Further, several commenters questioned the authority for including shared losses in the program. For example, commenters suggested that Congress intended only a shared savings program, or expressed concern that a requirement for ACOs to repay shared losses would constitute an unlicensed quota share reinsurance arrangement.

Commenters offered the following specific reasons for why ACOs entering Track 1 should not automatically transition to the two-sided model in their third performance year:

- Insufficient time exists for ACOs to gain necessary experience with population management to generate savings prior to being required to accept risk.
- The risk for substantial loss already exists for new ACOs because of the unknowns about the potential for ACOs to generate savings given the significant upfront investments needed to build ACO infrastructure and the anticipated high operational costs.
- Potential ACOs may lack access to Medicare claims data that would enable them to evaluate the nature or magnitude of the downside risks they would be accepting.
- When beneficiaries retain freedom to see any provider and when assignment is retrospective, Medicare ACOs may lack the ability to have certainty over identification of their assigned population and even when identified, there is a possibility for significant turnover or lack of cooperation with an ACO's efforts to control expenditures.
- The proposed cap on risk adjustment may increase ACO risk for losses or reduced savings.
- The potential for increased costs that are beyond the ACO's control exists.
- Risk may incent ACOs to cherry pick patients, for example, by excluding from the ACO physicians which treat high cost patients.

Hence, commenters suggested a variety of alternatives to our proposal, for example, that we—

- Establish a one-sided, shared savings only track—the most commonly made recommendation.
- Remove the two-sided model as an option for ACOs.
- Remove the one-sided model as an option for ACOs.
- Extend the length of time available in a one-sided shared savings model by extending an agreement period or allowing ACOs to participate in a one-sided model for additional performance years or agreement periods.
- Exempt some ACOs from downside risk, such as small, rural and physician-only ACOs. For instance, extend an exemption from the two-sided model to those ACOs exempted from the 2 percent net sharing requirement, or develop additional tracks tailored for smaller medical practices or rural providers and suppliers. Other commenters suggested exempting ACOs in low cost States and those in areas where high hospital readmission rates result from a lack of access to community-based services beyond the ACO's control.
- Make the ACO's population the determinant of the applicable model, for instance, beneficiaries with high cost

conditions would be under the one-sided model and the remainder of the beneficiary population would be under two-sided model.

• Develop a 4-tiered approach to hold organizations at different stages of development to different standards.

However, some patient advocate groups generally cautioned against amending policies to make the program more attractive to providers at the expense of clinical or financial benefits which could accrue from ACOs.

Response: We believe that maintaining a two track approach is important for attracting broad participation, including providers and suppliers new to value-based purchasing and more experienced ACOs that are ready to share in losses. Commenters supported our belief that models where ACOs bear a degree of financial risk hold the potential to induce more meaningful systematic change, which underscores the importance of transitioning ACOs from the one-sided model to risk-based arrangements. However, the commenters also persuaded us that ACOs new to the accountable care model—and particularly small, rural, safety net, and physician-only ACOs—would benefit from additional time under the one-sided model before being required to accept risk. Commenters persuaded us further that revising Track 1 to be a shared savings only option, while retaining Track 2 as a shared savings/losses model, would be the most appropriate means to achieve this objective. Accordingly, we will finalize our proposal to offer the two-sided model under Track 2 to ACOs willing and able to take on performance-based risk in exchange for higher reward, but will offer Track 1 as a shared savings only track for the duration of the first agreement period for ACOs needing more experience before taking on risk. We believe this modification will increase interest in the Shared Savings Program by providing a gentler ''on ramp'' while maintaining the flexibility for more advanced ACOs to take on greater performance-based risk for greater reward immediately. However, we continue to believe that models that hold a degree of financial risk have the potential to induce more meaningful changes. As such, an ACO will be eligible for no more than one agreement period under the shared savings only model.

We were also encouraged by commenters' interest in including alternative payment models in the Shared Savings Program. As indicated in the proposed rule, it is our intent to gain experience with several alternative payment models through the Innovation Center before potentially adopting them more widely in the Shared Savings Program.

Comment: We received a few comments on the alignment of the one- and two-sided models on eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements. Several commenters suggested that retrospective assignment could be particularly problematic for ACOs under the two-sided model, expressing concern that ACOs would be accountable for losses from assigned beneficiaries whom they could not identify and whose care they could not influence.

Response: Unless stated otherwise elsewhere in this final rule, we decline to further differentiate the program's two models on the basis of eligibility criteria, beneficiary assignment methodology, benchmark and update methodology, quality performance standards, data reporting requirements, data sharing provisions, monitoring for avoidance of at-risk beneficiaries, and transparency requirements for ACOs because we believe the policies being adopted in this final rule are appropriate for all ACOs, regardless of whether they are participating in a one-sided or two-sided model. In addition, we believe that the preliminary prospective assignment methodology that we are adopting in this final rule will sufficiently address commenters' concerns about the ability of an ACO to identify its potential assigned beneficiaries in order to allow for effective care management.

Accordingly, we are finalizing our proposal to offer ACOs a choice of two tracks, but modify our proposal for Track 1. Track 1 will be a shared savings only model (under the one-sided model) for the duration of the ACO's first agreement period. We will make final our proposal that ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period.

In the proposed rule we discussed several options about how to incorporate a two-sided model into the Shared Savings Program. The major options we considered were—

• Base the program on a two-sided model, thereby requiring all participants to accept risk from the first program year.

• Allow applicants to choose between program tracks, either a one-sided model or two-sided model, for the duration of the agreement.

• Allow a choice of tracks, but require ACOs electing the one-sided model to transition to the two-sided model during their initial agreement period.

We explained that requiring all ACOs to initially take downside risk would likely inhibit the participation of some interested entities, particularly organizations which lack the experience and capital to accept significant downside risk. We further explained that allowing ACOs to choose from either a one-sided model or a two-sided model created concerns, in particular that ACOs capable of taking risk could take advantage of the option that allows for gain by realizing savings without any risk for incurring added costs. In the proposed rule, we stated that we believed it is important that all Shared Savings Program participants quickly move to taking on downside risk because payment models where ACOs bear a degree of financial risk have the potential to induce more meaningful systematic change in providers' and suppliers' behavior. We further explained our belief that, by introducing a risk model, we could elicit applicants to the program who are more serious about their commitment to achieving the program's goals around accountability for the care of Medicare beneficiaries and the three-part aim of enhancing the quality of health care, improving patient satisfaction with their care, and better controlling the growth in health care costs.

We proposed that applicants would have the option of choosing between a one-sided model and a two-sided model initially. Under Track 1, ACOs enter the program under the one-sided model and must transition to the two-sided model for the third year of their initial agreement period. Alternatively, under Track 2, an ACO may enter the two-sided model option immediately for a full 3-year agreement period. We further proposed that all ACOs, whether participating under Track 1 or Track 2, must participate in the two-sided model in subsequent agreement periods. Thus, under our proposal, an ACO could only participate for a maximum of 2 years under the one-sided model, during its first agreement period, before it must transition and participate thereafter in the Shared Savings Program under the two-sided model. We stated our belief that this approach would allow ACOs to gain experience with the accountable care model under the one-sided model, while also encouraging organizations to take on greater risk with the opportunity for greater reward by migrating them to the two-sided model. We invited

comment on this proposal and other options for incorporating a two-sided model into the Shared Savings Program, including mechanisms for transitioning ACOs to two-sided risk arrangements.

Comment: Some commenters urged CMS to allow ACOs to accept risk on a voluntary basis, ''at their own pace.'' MedPAC, among others, favored extending the time an ACO could participate under the one-sided model, but to ultimately require ACOs to accept downside risk. Those favoring transition to the two-sided model suggested it provides greater incentives for ACOs to eliminate unnecessary expenditures and improve integration and care coordination. The most common suggestion was to allow ACOs to participate under the one-sided model for an initial 3 year agreement period and thereafter require ACOs to accept risk. Others suggested extending the availability of the one-sided model to ACOs beyond the first agreement period, with suggestions ranging from 4, 5, or 6 years. Some commenters suggested allowing certain types of ACOs additional time under the one-sided model, such as small, rural and physician-only ACOs; for instance expanding the proposed exemption of these organizations from a 2 percent net sharing rate to the requirement to transition to the two-sided model. One commenter suggested making the one-sided model available only to early adopters. A hybrid approach would be to allow ACOs two agreement periods under the one-sided model with the option to voluntarily switch to the two-sided model at the beginning of any calendar year.

Other commenters recommended alternatives for transitioning Track 1 ACOs to risk in their third year, but exempting them from repaying some or all of their losses. For instance, one commenter suggested holding Track 1 ACOs harmless for the first 2 percent of losses in year 3 if they generated savings in their first two performance years, based on the idea that our compensation through the proposed 2 percent net sharing requirement for the one-sided model. Alternatively, this commenter suggested, more generally, using savings generated in a prior performance year to off-set the amount of losses owed.

Several commenters were concerned that an automatic transition to risk would result in ACOs under the two-sided model that lacked the capacity to bear risk. One commenter recommended a more measured approach, whereby CMS would evaluate an ACO's readiness to assume risk before transitioning it to the two-sided model. Commenters suggested various options for ACOs unable to accept risk at the point of required transition to the two-sided model: Termination by CMS, voluntarily withdrawal, and completion of the agreement period under the one-sided model with no opportunity to continue in the program.

Response: Earlier in this section, we specify that in this final rule we are adopting a final policy under which ACOs will have a choice of two tracks for their first agreement period: a shared savings only model (Track 1) or the two-sided model (Track 2). However, we are finalizing our proposal to require an ACO to participate under the two-sided model after its initial agreement period. We continue to believe that accountability for losses is an important motivator for providers to change their behavior and to maximize reductions in unnecessary expenditures, and that the prospect of accountability for losses will ensure that the program attracts participants that take seriously their commitment to achieving the program's goals.

We appreciate commenters' concerns about a mandatory transition to risk and their recommendations to allow ACOs to voluntarily assume risk. Because ACOs will be required to enter the two-sided model only in subsequent agreement periods, ACOs will have the option to decide whether to continue to participate. As a result, those ACOs that decide to continue participating in the program at the end of their first agreement period will be voluntarily entering the two-sided model. In selecting the length of time an ACO could remain under the one-sided model, we found support in comments for limiting the period to the first agreement period. Further, as discussed later in this final rule, we are revising our proposed policy in order to allow ACOs that have a net loss during their first agreement period to continue to participate in the program, provided they meet all other participation requirements. We believe that this policy provides further support for limiting participation under the one-sided model to an ACO's initial agreement period. Underperforming ACOs would be allowed to continue in the Shared Savings Program, but all ACOs that elect to do so would be required to be accountable for their losses. Lastly, we disagree with commenters' suggestions that we exempt some ACOs entirely from the two-sided model, or otherwise allow ACOs to participate in the one-sided model for an extended or indefinite period of time. Absent a limit on participation under the one-sided model we anticipate that ACOs capable of taking on risk would take advantage of the option that allows for gain by realizing savings without any risk for incurring losses by remaining in the one-sided model.

We appreciate commenters' concerns about the transition of ACOs to the two-sided model when they lack the financial reserves necessary to safely assume risk. We believe the repayment mechanism in this final rule, is sufficient to safeguard against ACOs entering the two-sided model when they lack the capacity to bear risk.

Additionally, we proposed that an ACO may not reapply to participate in the Shared Savings Program if it previously experienced a net loss during its first agreement period. We explained that this proposed policy would ensure that under-performing organizations would not get a second chance. We sought comment on this proposal and whether denying participation to ACOs that previously underperformed would create disincentives for the formation of ACOs, particularly among smaller entities.

Comment: Commenters expressed concern about the proposal to disallow continued participation by financially under-performing ACOs. Commenters suggested this policy could serve as a disincentive to participation, particularly by small ACOs. They believed organizations may be reluctant to make the necessary investments to form ACOs given the uncertainty over their ability to produce shared savings during the initial agreement period and their ability to continue in the program beyond 3 years. Some commenters suggested it may take several years for an ACO to demonstrate shared savings, indicating that some well-intentioned ACOs may not be able to do so by the end of their initial agreement period. Several commenters suggested eliminating the proposed policy. Others suggested adopting a more flexible approach to avoid penalizing well-meaning ACOs, such as:

- Allowing continued participation for ACOs that, despite experiencing a net loss, demonstrate a consistent decrease in the net loss over the initial 3 years of the agreement.
- Judging ACOs' readiness to continue in the program based on quality, not cost, performance. For instance, allow continued participation for ACOs which meet the program's quality performance requirements.

Response: We are modifying our proposal to allow continued participation by ACOs electing to do so who experience a net loss during their first agreement period. We recognize that it may take longer than the term of

an ACO's initial agreement period for an ACO to achieve shared savings, particularly ACOs new to the accountable care model. Commenters have persuaded us that barring ACOs that demonstrate a net loss from continuing in the program could serve as a disincentive for ACO formation given the anticipated high startup and operational costs of ACOs. Our policies on monitoring and termination will help to ensure that ACOs that underperform on the quality standards do not continue in the program. Further, continued participation by previously underperforming ACOs could benefit the Trust Funds– as compared to FFS providers not engaged in the Shared Savings Program—as these ACOs will participate under the two-sided model and therefore will have an even greater incentive to improve the quality and efficiency of the care they provide in order to avoid being accountable for shared losses. While there appear to be a number of benefits to allowing financially underperforming ACOs to continue to participate in the program, we believe this policy could be cause for concern, as it may allow ongoing participation by organizations that are not dedicated to the accomplishment of the program's goals but that reap the benefits from participation, such as legal protections under the waivers. Therefore we are further requiring ACOs which experience a net loss in their initial agreement period, applying to participate in a subsequent agreement period, to identify in their application the cause(s) for the net loss and to specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. Further, we will monitor closely this aspect of the program, and may revise our policy in future rulemaking.

We are modifying our proposal to allow an ACO which experiences a net loss during its first agreement period to reapply to participate in the Shared Savings Program.

Final Decision: As provided in § 425.600, we will establish the Shared Savings Program on existing FFS payments, using both shared savings only (Track 1) and shared savings and losses models (Track 2). While making final our proposal to offer ACOs a choice of two tracks, we are modifying our proposal for Track 1 so that it will be a shared savings only model for the duration of the ACO's first agreement period. We will make final our proposal that ACOs electing Track 2 will be under the two-sided model for the duration of their first agreement period. We are also finalizing our proposal to require all ACOs to participate in the two-sided model in agreement periods subsequent to the initial agreement period. We are modifying our proposal to allow continued participation by ACOs electing to do so who experience a net loss during their first agreement period. Specifically, we are requiring ACOs, which experience a net loss in their initial agreement period and apply to participate in a subsequent agreement period, to identify in their application the cause(s) for the net loss and to specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period. Further, we will monitor closely this aspect of the program, and may revise our policy future rulemaking.

2. Shared Savings and Losses Determination

a. Overview of Shared Savings and Losses Determination

We proposed that the shared savings model (one-sided model) and a shared savings/losses model (two-sided model) would share many program elements in common, including a similar methodology for determining whether an ACO has achieved savings against the benchmark. Unless specifically noted, the elements discussed in the rest of this section will apply to both the one-sided and two-sided models. However, we also explained the necessity to develop some policies for the two-sided model that would not be necessary under a one-sided model, including, for example, a methodology for determining shared losses. The following table provides an overview of our final decisions on elements of the program's financial models.

TABLE 5—SHARED SAVINGS PROGRAM OVERVIEW

	One-sided model		Two-sided model	
Issue	Proposed	Final	Proposed	Final
Transition to Two-Sided Model.	Transition in third year of first agreement period.	First agreement period under one-sided model. Subsequent agreement periods under two-sided model.	Not Applicable	Not Applicable.
Benchmark	Option 1 reset at the start of each agreement period.	Finalizing proposal	Option 1 reset at the start of each agreement period.	Finalizing proposal.
Adjustments for health status and demographic changes.	Benchmark expenditures adjusted based on CMS–HCC model.	Historical benchmark expenditures adjusted based on CMS–HCC model. Performance year: Newly assigned beneficiaries adjusted using CMS–HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS–HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year.	Benchmark expenditures adjusted based on CMS–HCC model.	Historical benchmark expenditures adjusted based on CMS–HCC model. Performance year: Newly assigned beneficiaries adjusted using CMS–HCC model; continuously assigned beneficiaries (using demographic factors alone unless CMS–HCC risk scores result in a lower risk score). Updated benchmark adjusted relative to the risk profile of the performance year.
Adjustments for IME and DSH.	Include IME and DSH payments.	IME and DSH excluded from benchmark and performance expenditures.	Include IME and DSH payments.	IME and DSH excluded from benchmark and performance expenditures.

TABLE 5—SHARED SAVINGS PROGRAM OVERVIEW—Continued

	One-sided model		Two-sided model	
Issue	Proposed	Final	Proposed	Final
Payments outside Part A and B claims excluded from benchmark and performance year expenditures;	Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals.	Finalize proposal	Exclude GME, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals.	Finalize proposal.
Other adjustments	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments.	Finalize proposal	Include other adjustment based in Part A and B claims such as geographic payment adjustments and HVBP payments.	Finalize proposal.
Maximum Sharing Rate	Up to 52.5 percent based on the maximum quality score plus incentives for FQHC/RHC participation.	Up to 50 percent based on the maximum quality score.	Up to 65 percent based on the maximum quality score plus incentives for FQHC/RHC participation.	Up to 60 percent based on the maximum quality score.
Quality Sharing Rate	Up to 50 percent based on quality performance.	Finalizing proposal	Up to 60 percent based on quality performance.	Finalizing proposal.
Participation Incentives	Up to 2.5 percentage points for inclusion of FQHCs and RHCs.	No additional incentives	Up to 5 percentage points for inclusion of FQHCs and RHCs.	No additional incentives.
Minimum Savings Rate	2.0 percent to 3.9 percent depending on number of assigned beneficiaries.	Finalizing proposal based on number of assigned beneficiaries.	Flat 2 percent	Finalizing proposal: Flat 2 percent.
Minimum Loss Rate	2.0 percent	Shared losses removed from Track 1.	2.0 percent	Finalizing proposal.
Performance Payment Limit.	7.5 percent	10 percent	10 percent	15 percent.
Performance payment withhold.	25 percent	No withhold	25 percent	No withhold.
Shared Savings	Sharing above 2 percent threshold once MSR is exceeded.	First dollar sharing once MSR is met or exceeded.	First dollar sharing once MSR is exceeded.	First dollar sharing once MSR is met or exceeded.
Shared Loss Rate	One minus final sharing rate.	Shared losses removed from Track 1.	One minus final sharing rate.	One minus final sharing rate applied to first dollar losses once minimum loss rate is met or exceeded; shared loss rate not to exceed 60 percent.
Loss Sharing Limit	5 percent in first risk bearing year (year 3).	Shared losses removed from Track 1.	Limit on the amount of losses to be shared phased in over 3 years starting at 5 percent in year 1; 7.5 percent in year 2; and 10 percent in year 3. Losses in excess of the annual limit would not be shared.	Finalizing proposal.

The basic requirements for establishing and updating the benchmark, as well as determining whether an ACO has achieved savings against the benchmark, are outlined in section 1899(d)(1)(B) of the Act. Section 1899(d)(1)(B)(i) of the Act establishes that an ACO shall be eligible for payment of shared savings ''only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark * * *.'' Consistent with the statute, we proposed to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including payments made under a demonstration, pilot or time limited program when computing average per capita Medicare expenditures under the ACO. The statute further requires the Secretary to establish the percentage that expenditures must be below the applicable benchmark ''to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.'' We will refer to

this percentage as the ''minimum savings rate'' (MSR).

Section 1899(d)(1)(B)(ii) of the Act requires the Secretary to establish and update the ''* * * benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO.'' This section also requires the benchmark to ''be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service service program, as estimated by the Secretary.'' A new benchmark is to be established consistent with these requirements at the beginning of each new agreement period.

Section 1899(d)(2) of the Act provides that, if the ACO meets the quality performance standards established by the Secretary, as discussed in section II.F. of this final rule ''a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title.'' We will refer to this percentage as the ''sharing rate.'' This section also requires the Secretary to ''establish limits on the total amount of shared savings that may be paid to an ACO.'' We will refer to this limit as the ''sharing cap''.

Thus, in order to implement the provisions of section 1899(d) of the Act for determining and appropriately sharing savings, we must make a number of determinations about the specific design of the shared savings methodology described by the statute.

First, we must establish an expenditure benchmark, which involves determining: (1) The patient population for whom the benchmark is calculated; (2) appropriate adjustments for beneficiary characteristics such as demographic factors and/or health status that should be taken into account in the benchmark; (3) whether any other adjustments to the 3-year benchmark are warranted, so as to provide a level playing field for all participants; and (4) appropriate methods for trending the 3-year benchmark forward to the start of the agreement period, and subsequently for updating the benchmark for each performance year during the term of the agreement with the ACO.

Second, we must compare the benchmark to the assigned beneficiary per capita Medicare expenditures in each performance year during the term of the agreement in order to determine the amount of any savings.

Third, we must establish the appropriate MSR, as required by the statute ''to account for normal variation in expenditures… based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO'' and we must determine the appropriate sharing rate for ACOs that have realized savings against the benchmark and meeting or exceeding the MSR.

Finally, we must determine the required sharing cap on the total amount of shared savings that may be paid to an ACO. We discuss all these issues, and our final policies for addressing them, in this section.

In light of the greater potential for a two-sided model to bring about positive changes in the operation of the FFS system by improving both the quality and efficiency of medical practice, we believe that it is appropriate to provide greater incentives for organizations that participate in the two-sided model. For example, as we described in the proposed rule, we believe that it is appropriate to provide a higher sharing rate for organizations participating in the Shared Savings Program under the two-sided model than for those organizations participating under the one-sided model.

In addition to a methodology for determining shared savings, the two-sided model requires a methodology for determining shared losses in those cases where an ACO realizes a loss as opposed to a savings against its benchmark in any performance year. We proposed to mirror the structure and features of the shared savings methodology as much as possible in the determination of loss sharing. As discussed later in this final rule, for purposes of the loss-sharing methodology, we proposed adopting a similar structure of minimum loss rate (the equivalent of minimum savings rate on the savings side), shared loss limit, and loss sharing rate.

We address the methodological steps for determining shared savings and losses, related comments, responses, and our final policy decisions, in the sections discussed later in this final rule.

Comment: We received a wide range of comments requesting or suggesting adjustments to specific policies so that an ACO could share in a higher level of savings or lower amount of losses than what was proposed. Generally, commenters expressed the view that the reward to risk ratio for participating in the program as proposed is unattractive to providers, and commenters favored policies that would attract broad participation by providers. Commenters explained that financial rewards must be sufficient to offset provider risks and startup-costs. According to one commenter ''the program as envisioned under the proposed rule places inordinate investment pressure on medical providers for an insufficient return that carries a significant amount of risk, regardless of the type of ACO.'' Comments reflected concern that this pressure is increased for small ACOs, such as those comprised largely of small and medium sized physician practices; small hospitals and safety net providers, particularly those serving rural areas; and providers serving high risk patients (for example, dual eligibles and oncology patients). Commenters suggested that participation in the proposed program will be effectively limited to those few large entities already organized under an ACO-like structure; entities that already have ready access to capital, substantial infrastructure development, and experience operating under an integrated service/payment model (for example, MA). Even entities which might meet these criteria questioned the ''business case'' for adoption of the ACO model as outlined in the proposed rule. Further, some commenters expressed concern that the cost of ACO formation may foster the development of large health system-based or hospital-based ACOs thereby financially undermining small, independent physician practices.

Several commenters questioned the adequacy of the program's incentives for primary care physicians, on which the program focuses. These commenters highlighted primary care physicians' critical role in coordinating care across care settings from the home to the hospital and ensuring that beneficiaries see the appropriate specialists. They indicated that primary care physicians will have to incur additional costs for case management and coordination of patient care to achieve the program's goals with what will be a potentially insufficient and uncertain incentive—the chance that there will be a cost savings disbursed to them. Further, commenters suggested that to the extent these physicians experience financial failure as a result of assuming risk, the program could exacerbate the primary care physician shortage, for example by discouraging physicians from specializing in primary care practice.

Typically, recommendations we received for improving the value

proposition of program participation included the following:

- Revise the methodology for establishing the benchmark to encourage participation by organizations that are already efficient or in low cost areas.
- Risk adjust expenditures with the CMS–HCC model during both the benchmark and performance periods to account for changes in acuity and movement in the assigned beneficiary population.
- Standardize the benchmark and performance year expenditures by excluding payments made in pursuit of policy goals, such as IME and DSH payments.
- Make it easier for ACOs that perform well on quality to receive savings, by increasing the sharing rate based on quality performance and reducing or eliminating the MSR and the 2 percent net sharing requirement.
- Allow ACOs to receive a larger share of savings achieved by lowering or eliminating the 25 percent payment withhold and performance payment limit.
- Include a non-risk option, so that ACOs may participate under a shared savings-only model while they gain experience with the accountable care model.

Commenters' specific concerns about particular aspects of the shared savings and losses methodology are further detailed in this section of this final rule.

Response: Commenters' arguments persuaded us of the need to improve the financial attractiveness of the program to encourage broad participation by providers and suppliers, particularly those likely to comprise smaller ACOs, such as small and medium sized physician practices, rural and safety net providers. One particularly compelling argument suggested that allowing ACOs to receive a greater share of savings would support ongoing investment in and achievement of the program's goals. Further, we agree with commenters' suggestions on the need to adjust policies related to determining shared savings/losses to avoid unintended consequences for certain groups of beneficiaries and providers or suppliers. For instance, updating ACOs' risk scores to better reflect changes in their assigned populations could remove incentives for ACOs to avoid beneficiaries with high cost or complex conditions. Excluding IME and DSH payments may allay concerns that inclusion of these payments could incent ACOs to avoid certain types of providers, such as Academic Medical Centers. Accordingly, as described in the later sections of this final rule, we are revising several of our proposed policies to make the program, overall, more financially rewarding to ACOs, to better adjust for changes in assigned beneficiaries' health status, and to ensure ACOs include providers and suppliers that can provide the high quality care for Medicare beneficiaries. Underlying our decisions regarding the policies we are adopting in this final rule is the need to address the (sometimes competing) interests of ACOs, beneficiaries, the Medicare Trust Funds, and the goal of achieving the intended transformative effects. We believe the financial models presented in the final rule offer an appropriate balance of payment incentives, while still furthering the purpose and intent of the program.

b. Establishing the Benchmark

Section 1899(d)(1)(B)(ii) of the Act specifies several requirements with regard to establishing an ACO's benchmark. These requirements are as follows:

- First, the law requires the Secretary ''to estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO.''
- Second, the law requires that ''[s]uch benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate.''
- Third, the law requires that the benchmark be ''updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary.''
- Finally, the law requires that ''[s]uch benchmark shall be reset at the start of each agreement period.''

In the proposed rule, we considered two legally permissible approaches to implementing the statutory language for estimating the benchmark, which we called Option 1 and Option 2. Both approaches involved benchmarks derived from prior expenditures of assigned beneficiaries and adjusted for certain beneficiary characteristics, and other factors, the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures. Under both approaches, we proposed to reset the benchmark at the start of each agreement period. However, a key difference between these two approaches was the beneficiary population used to determine expenditures for purposes of the benchmark. Specifically, under Option 1, we proposed estimating an ACO's benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in each of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs. As such, this methodology would generate benchmark expenditures based on the average population cared for by the ACO participants during the preceding 3 years. In contrast, under Option 2, we proposed basing the benchmark on the Parts A and B FFS expenditures of individual beneficiaries assigned to the ACO during each performance year, with the benchmark expenditures being those incurred in the 3 years immediately preceding the ACO's agreement period for each of those assigned beneficiaries. Under both Option 1 and Option 2, the benchmark would be reset (or rebased) the start of each agreement period. In the proposed rule, we proposed to adopt Option 1 to establish each ACO's benchmark; however, we solicited comments on both options. For a detailed description of Options 1 and 2, please see our April 7, 2011 proposed rule (76 FR 19604 through 19606).

Comment: We received numerous comments related to our proposal to base the benchmark on an ACO's own past cost experience. One commenter commended us for establishing the benchmark based on an ACO's historical per capita expenditures. This commenter noted that a similar approach has proven successful in a private sector value based purchasing initiative, and that this methodology offers important confidence to groups that the starting budgets represent a fair and appropriate allocation of resources.

The majority of comments, however, expressed concern with our proposal to establish the benchmark based on ACOs' historical per capita expenditures, regardless of whether Option 1 or Option 2 was implemented. In most cases, commenters expressed concern that the proposed benchmarking methodology would disadvantage efficient providers or those in low-spending areas and reward poor performers in high cost areas. Thus, commenters suggested that efficient organizations may be less willing to participate in the program because they have already invested in the systems and infrastructure to produce high-quality, low cost care, and will have difficulty achieving additional efficiencies, and hence savings, given the proposed benchmark methodology. In particular, some commenters suggested the proposed policy would

deter participation by rural providers, asserting they already operate at or near the lowest cost possible. Another commenter suggested that providers operating in the Indian Health System may have difficulty reaching savings requirements and other benchmarks because of the current funding and delivery system structure. One commenter suggested that further cost control in already efficient areas may lead to undesirable results, including, for example, limited ACO interest in participation or reduced beneficiary access to needed care. However, one commenter suggested effort will be needed by providers in both higher cost and lower cost areas to reduce costs, and it may not necessarily be 'easier' for providers in higher cost markets to achieve this transformation.

Relative to their concerns, as an alternative, some commenters suggested that CMS exercise its authority under section 1899(i) of the Act to develop and implement an alternative benchmarking methodology. Commenters suggested alternatives such as using local, regional or national experience to establish the ACOs' benchmarks; however, opinions varied as to which approach among these would be most appropriate. Some commenters suggested a blended approach based on local and national spending, for instance use of a combination of local and national averages or a phased approach to transition from initial use of local averages to a national average over time.

Other suggestions for establishing the initial benchmark included applying alternatives including the following:

- A prospective benchmark based on burden of illness with bonus payments that reflect quality care through better clinical and patient-reported outcomes.
- A peer-to-peer benchmarking methodology. For instance, one commenter suggested that existing high cost ACOs should be required to achieve a higher percentage of improvement in order to share in savings while ACOs with historically lower costs should be rewarded for smaller improvements over the threshold.
- A matched cohort of Medicare fee-for-service beneficiaries as a basis for comparison for those beneficiaries being treated under an ACO.
- A fixed percentage of total operating funds for all ACO providers, such as 85 percent of geographic-adjusted expenditure per capita. The difference between this benchmark and the medical loss ratio incurred by any ACO would be shared savings.
- Methodologies specifically for ACOs in low-cost regions, such that these ACOs would have the opportunity to earn greater rewards.
- A menu of benchmarking methodologies from which the organization can choose, similar to the methodology used in the Hospital Value-Based Purchasing program.
- A rolling 3 year look-back.
- A benchmark established by determining which beneficiaries would have been assigned to the ACO, determining their actual utilization during the relevant 3-year period, and re-pricing the cost of those services using the ACO's fee schedule for the relevant performance year being compared.

Response: We understand concerns raised by commenters on basing benchmarks on ACO's historical per capita expenditures. Section 1899(d)(1)(B)(ii) of the Act is clear, however, that ''The Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO.'' Thus, consistent with statute, we plan to make final our proposal to establish ACO benchmarks using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO.

Comment: As mentioned previously, very few comments addressed the specific methodology that we should use for establishing ACO benchmarks—that is, Option 1 or Option 2—although a few commenters, including MedPAC, suggested CMS adopt a benchmarking methodology similar or identical to that proposed for the Innovation Center's Pioneer Model ACOs, which tends to align with Option 2. For instance, MedPAC, among others, recommended calculating ACOs' benchmarks based on expenditures of individual beneficiaries assigned to the ACO. A number of commenters raised concerns about the accuracy of the benchmark and performance year expenditures in circumstances when we have only partial data for an assigned beneficiary—issues that would more typically occur under Option 2 than Option 1. For instance, several commenters suggested that using Option 2 would require an additional adjustment to account for beneficiaries who cross over to or from another payer, such as Medicaid or Medicare Advantage, and to account for decedents and beneficiaries treated in an institutional setting where their costs may not be attributable to an ACO under the proposed assignment methodology. Moreover, when adjusting expenditures for decedents, commenters tended to oppose the methods we discussed under Option 2 for adjusting for decedents, specifically the method of excluding the expenditures of deceased beneficiaries from actual expenditures during the agreement period. Several commenters suggested that while excluding these expenditure data would protect ACOs from catastrophic costs incurred in the patient's last year of life, it would have unintended consequences such as discouraging better end of life care management, and one commenter suggested CMS consider a method to risk adjust for expected costs in a beneficiary's final year of life. Another commenter favored the second method we discussed under Option 2: Comparing average expenditures for each deceased beneficiary during the agreement year to the average expenditures for beneficiaries included in the benchmark. Under this option, we would make no adjustment if the agreement year expenditures were 5 percent or less above the benchmark, but would make adjustments if expenditures were greater than 5 percent above the benchmark.

Response: On balance, we believe Option 1 is the most appropriate approach for establishing ACO benchmarks for at least initial use in the program, and plan to make final this proposal. We believe Option 1 establishes a statistically stable benchmarking methodology based on the ACO's average population by which we can assess improvements the ACO makes in the quality and efficiency of care delivery for its average population. We also acknowledge there are drawbacks to this benchmark methodology, including that it provides incentives for ACOs to seek and/or avoid specific beneficiaries during the agreement period so that their average expenditures would likely be less than for their historical beneficiaries included in the benchmark. For this reason we favor a benchmarking methodology based on an ACO's actual assigned population, such as Option 2, MedPAC's suggested approach, or as proposed for Pioneer Model ACOs. However, we lack experience with this model of benchmarking and the related need to adjust for decedents, sudden increases in individual costs, and incomplete expenditure data on some assigned beneficiaries. We support the Innovation Center's testing of this benchmarking approach through the Pioneer Model ACO initiative, and look forward to applying lessons learned from the Pioneer experience towards

developing a robust benchmarking methodology for possible use within the Shared Savings Program. We intend to revisit use of a benchmarking methodology based on the ACO's assigned population in future rule making, as soon as practicable, once we gain more experience with this benchmarking approach through the Pioneer Model.

Comment: Some commenters expressed concerns that the proposed assignment methodology would exclude some of Medicare FFS beneficiaries' costs from the ACOs' benchmark and thereby disadvantage certain providers and the populations they serve. One commenter expressed concern that assignment of beneficiaries based on primary care services rendered by physicians with primary care specializations could exclude beneficiaries with disabilities and those needing medical rehabilitation services which rely on care by specialists. This commenter favored a step-wise approach to assignment in which beneficiaries are assigned first on the basis of care by primary care physicians followed by a second ''sweep'' of assignment based on specialists would help ensure that these beneficiaries' costs would be counted.

Many commenters expressed concern that Medicare FFS beneficiaries treated by FQHCs and RHCs would not be assigned to an ACO or have their costs reflected in an ACO's benchmark under the proposed assignment and benchmarking methodologies. A commenter stated: ''The statute does not appear to require the specific methodology that has been proposed by CMS to determine the benchmark, and certainly does not require a single uniform methodology for all primary care providers. Under the wording of this provision, CMS appears to have the flexibility to apply a methodology to 'estimate a benchmark' specifically for FQHCs.'' This commenter and some others suggested various ways to compute the benchmark for FQHCs absent 3 years of benchmark data: (1) CMS could use the data and claims it will have from FQHCs for 2011 and assume similar and comparable data and claims for the two years prior with some adjustments as appropriate relating to inflation, etc.; (2) CMS could assign beneficiaries utilizing the 2011 data and recover billing data from the prior 2 years with use of health center office visit revenue codes to determine the 3 year benchmark; (3) CMS could further investigate the methods that are being used to create benchmarks for demonstrations, such as the methods that were considered for the Pioneer ACO Model Request for Applications; (4) a number of FQHCs have been recording HCPCS codes for all of their patients and have this information stored in their practice management systems, dating back prior to the requirement to report to CMS starting on January 1, 2011. Those centers that are able to provide CMS with the data it requires to establish the 3-year benchmark should be allowed to do so; and (5) CMS could allow each health center to voluntarily choose whether it would provide any specific requested information. Further, commenters suggested that section 1899(i), if not section 1899(d) of the Act, provides CMS flexibility to estimate a benchmark specifically for FQHCs.

One commenter advocated allowing those RHCs and FQHCs who wish to participate in ACOs the opportunity to provide the requisite data so that they may fully participate in the program. However, another commenter appreciated the Department's reluctance to impose reporting requirements in this rule for both FQHCs and RHCs and other entities without either a statutory requirement or clear support for such a regulatory change from the community at large.

Response: In the section II.E. of this final rule, we establish a step-wise approach to beneficiary assignment that simultaneously maintains the primary care-centric approach to assignment and recognizes the necessary and appropriate role of specialists in providing primary care services. Through this assignment methodology we will be able to attribute to ACOs expenditures for beneficiaries who predominantly rely on care from specialists.

Based on the assignment process that we are adopting in this final rule (see section II.E. of this final rule), we are able to compute a benchmark for ACOs that include FQHCs and RHCs, in the same manner as we would for any other ACO. For ACOs that consist of FQHCs and/or RHCs (either independently or in partnership with other eligible entities), we will establish such ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period.

Comment: As described in section II.G. of this final rule, several commenters recommended that we trend and update the benchmark and risk adjust by categories of beneficiaries, including aged, disabled and ESRD beneficiaries, among others.

Response: We agree with commenters' suggestions for taking a categorical approach to establishing the benchmark and are adopting this approach for calculating expenditures for the historical benchmark. In this final rule, we are adopting a policy whereby the historical benchmark expenditures will be calculated for cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries. We will sort beneficiaries according to these categories in the order in which they are stated. We will make a distinction between the aged/dual eligible and aged/non-dual eligible populations since modeling has suggested the expected expenditures for these populations is significantly different. The ESRD and disabled categories include both dual eligible and non-dual eligible beneficiaries, however, since modeling has indicated expenditures are less divergent for these populations. As described in section II.G. of this final rule, we are adopting this categorical approach to establishing the benchmark, updating the benchmark and calculating performance year expenditures.

Comment: We received a number of comments on our proposal to minimize variation from catastrophically large claims by truncating an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare FFS expenditures as determined for each benchmark year and performance year. Mostly commenters were supportive of the proposal to adjust for outliers. Some commenters suggested that the proposed limitations may provide ACOs inadequate protections from high-cost beneficiaries, and suggested a variety of additional or alternate limitations including the following:

- Remove outliers altogether from the assigned populations used to establish the benchmark and performance year expenditures. For instance, one commenter suggested excluding all costs incurred by patients with rare and extreme diagnoses or for care received in the tertiary care setting, while another recommended CMS use in the Shared Savings Program an approach similar to what was proposed for the Pioneer Model ACOs, in which ACOs have the option to exclude from benchmark and performance year expenditures claims above the 99th percentile for national per capita expenditures.
- Reduce the outlier threshold from the 99th percentile to the 75th or 95th percentile, for instance, to help ensure

that ACOs are not penalized for using innovative technologies.

• Use a flat dollar amount, such as $100,000 per year, instead of a percentile as a basis for truncating claims.

• Use ''alternate windsoring techniques'' for adjusting a distribution for outliers; for example, calculating separate savings among different cost categories of beneficiaries, such as the top 5 percent of beneficiaries by cost versus the remaining 95 percent of beneficiaries.

• Exclude claims for high cost treatments demanded by the patient that have a negative result, in part as a means of addressing higher medical costs in States with high rates of medical malpractice litigation.

One commenter expressed concern that under the proposed policy, ACOs would have little incentive to effectively coordinate care for high cost beneficiaries. This commenter explained that the proposed policy may negatively impact dialysis patients because these patients' costs may be close to the 99th percentile threshold. If an ACO knows its risk exposure is limited for what may be a small portion of its assigned population, such as ESRD beneficiaries, the ACO may have little incentive to spend time and money needed to provide high quality care to these beneficiaries.

Several commenters asked for clarification about the proposed truncation methodology, including whether the same 99th percentile will be applied to the benchmark or performance year expenditures or if it will be determined within each performance year. Several commenters asked for clarification as to whether the expenditure amount includes hospital outlier payments, or otherwise how outlier payments to inpatient facilities will be handled. One commenter asked generally how CMS will ensure providers with high cost patients are able to receive savings.

Response: We are finalizing our proposal to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year and performance year. We disagree with those commenters that suggested placing greater limitations on ACOs' accountability for the cost of outliers, such as by completely removing outliers from ACO benchmark and performance year expenditures or lowering the threshold (such as the 95th percentile). Doing so would give ACOs less incentive to coordinate care and services for high-cost beneficiaries, for whom improved care coordination could be especially valuable, to improve outcomes and control unnecessary costs.

The 99th percentile represents a dollar amount (roughly $100,000) that matches in dollar terms an attachment point that is fairly common in the reinsurance market. The important reason for its inclusion is that it reduces variation in expenditure growth, thereby lowering the risk of paying ACOs savings or requiring ACOs to pay losses that result from random variation. A lower percentile might have been chosen, but the incremental benefit in terms of lowered variation would be offset by further reduction in the incentive for ACOs to increase efficiency for high-cost patients. Therefore, we believe that truncating claims at the 99th percentile achieves an appropriate balance between limiting catastrophic costs and continuing to hold ACOs accountable for those costs that are likely to be within their control.

We appreciate commenters' concerns that by limiting ACO's accountability for catastrophic costs, ACOs may have an incentive to avoid managing the care for the select few very high-cost beneficiaries. However, we believe that truncating claims at the 99th percentile in conjunction with the opportunity to receive shared savings, as well as monitoring protections, help assure ACOs will not avoid treating at-risk beneficiaries. We also note, in response to the commenter who expressed concern that an ACO could not achieve savings for high cost beneficiaries, that one of the purposes of risk adjustment is to make it possible for ACOs that improve the quality and efficiency of the care they provide to achieve savings in the cost of care for both high and low cost beneficiaries.

Accordingly, as specified in the proposed rule, we will truncate all Parts A and B FFS per capita expenditures at the 99th percentile for each beneficiary in each benchmark year and for each assigned beneficiary in each performance year. Further, we will truncate for outliers in the ACO's assigned population as opposed to accounting for outlier payments made to hospitals (potential ACO participants) which will be included in the calculation of actual expenditures during the performance year.

Comment: Several comments generally suggested that the proposed policy for weighting benchmark expenditures at 60 percent for BY3, 30 percent for BY2 and 10 percent for BY1 was appropriate. Several others recommended alternative approaches to weighting benchmark expenditures. For instance, one commenter recommended that CMS weight the most expensive benchmark year the highest, followed by the second highest and finally the least expensive. Another commenter suggested, relative to Option 2 for establishing the benchmark, to weight BY3 at 60 percent and BY2 at 40 percent.

Response: We thank the commenters for their support of our proposed policy. We continue to believe that our proposed approach to weighting base year expenditures, compared to the alternatives suggested by commenters, will result in a more accurate benchmark. This approach recognizes that the ACO's financial performance in the most recent base year is the most current of the three base years and therefore reflects more accurately the latest expenditures and health status of the ACO's assigned beneficiary population. Further, weighting BY1 at zero, as suggested by one commenter, would not meet the statutory requirement under section 1899(d)(1)(B)(ii) of the Act to establish the benchmark using the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. Accordingly, we are finalizing our proposal to weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent.

Comment: Many commenters urged CMS not to reset the benchmark for ACOs that continue in the program after the first agreement period, or to limit how far the baseline could be moved from one agreement period to the next. They indicated that rebasing the benchmark each agreement period will make savings more difficult to attain and eventually make savings unattainable. They further suggested this could discourage initial participation in the program, as organizations will have little incentive to make the needed investment in ACO formation. Commenters recommended a number of alternatives to mitigate these anticipated effects which included the following:

• Never rebasing.

• Delayed rebasing, for example apply the original baseline for longer than 3 years, such as 6 or 9 years (covering a second and third agreement period).

• Apply partial, as opposed to full, rebasing.

• Rewarding ACOs for maintaining, rather than further decreasing, their expenditures.

• Using rebasing as a mechanism to facilitate ACOs' transition from FFS to capitated payments.

On the other hand, several commenters favored resetting the benchmark more frequently than we proposed, stating their preference for a rolling 3 year look back to reset the ACO's benchmark annually.

Further, some commenters provided technical suggestions on how to reset the benchmark. One commenter suggested that we take inflation into consideration when resetting the benchmark as to not penalize ACOs for market increases beyond their control. Another commenter suggested that reset benchmarks must include payments for care management and coordination services and urged CMS to establish rates that ACOs could bill for such services. This commenter further suggested that such rates should vary based on the beneficiary's number of chronic conditions and the acuity of these conditions (such as severe mental illness and/or chemical dependence), as well as socio-economic or environmental risk factors that would require additional social services.

Response: We are finalizing our proposal to reset the benchmark at the start of each agreement period, as required under section 1899(d)(1)(B)(ii) of the Act. Moreover, we believe that resetting the benchmark at the beginning of each agreement period will most accurately account for changes in an ACO's beneficiary population over time. As we indicated in the proposed rule, turnover in assigned beneficiaries could be approximately 25 percent year to year. By the end of the agreement period, an ACO's assigned population may be significantly different from the historically assigned beneficiary population used to calculate the ACO's initial benchmark. Resetting the benchmark at the beginning of subsequent agreement periods will allow the benchmark to more accurately reflect the composition of an ACO's population, and therefore will protect both the Trust Funds and ACOs. We appreciate commenters' concerns that resetting the benchmark after 3 years could ultimately make it more challenging for ACOs to achieve savings, particularly for low-cost ACOs; however, we believe that one of the fundamental purposes of the Shared Savings Program is to provide incentives for ACOs to strive continually to make further advances in the quality and efficiency of the care they provide. We also appreciate commenters' technical suggestions on resetting the benchmark in relation to beneficiary health status, and socio-economic and environmental factors. While at this time we decline to use authority under section 1899(i) of the Act to adopt an alternate approach to resetting the benchmark, we may reconsider the issue in future rulemaking.

Final Decision: We are making final our proposed methodology under § 425.602 for establishing an ACO's initial benchmark based on the Parts A and B FFS expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 years prior to the start of an ACO's agreement period using the ACO participants' TINs identified at the start of the agreement period. We will calculate benchmark expenditures by categorizing beneficiaries in the following cost categories, in the order in which they appear: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This benchmarking methodology will apply to all ACOs, including those consisting of FQHCs and/or RHCs (either independently or in partnership with other eligible entities). We are also making final our proposals to truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark and performance year; weight the most recent year of the benchmark, BY3, at 60 percent, BY2 at 30 percent and BY1 at 10 percent; and reset the benchmark at the start of each agreement period. Further, as specified in section II.C. of this final rule, we will use a 3-month run-out of claims data and a completion factor to calculate benchmark expenditures.

c. Adjusting the Benchmark and Actual Expenditures

(1) Adjusting Benchmark and Performance Year Average per Capita Expenditures for Beneficiary Characteristics

Section 1899(d)(1)(B)(i) of the Act stipulates that an ACO is eligible for shared savings ''only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics'' is below the applicable benchmark. Likewise, section 1899(d)(1)(B)(ii) of the Act specifies that the benchmark ''shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate * * *'' This requirement to adjust for ''beneficiary characteristics'' implicitly recognizes that, under a shared savings model, the realization of savings against a benchmark could be a function of two factors. One factor is reduced expenditure growth as a result of greater quality and efficiency in the delivery of health care services. The other factor could be changes in the characteristics of the beneficiaries who are under the care of the ACO. Thus, in the absence of risk adjustment, some organizations may realize savings merely because they are treating a patient mix with better health status than the patient population reflected in their benchmark. On the other hand, some organizations may share in savings on a risk adjusted basis that would not have shared in savings if expenditures were not risk adjusted.

When applying a risk adjustment model, it is necessary to guard against changes that result from more specific or comprehensive coding as opposed to improvements in the coordination and quality of health care. An ACO's ability to share in savings can be affected not only by changes in the health status of the ACO's assigned population but also by changes in coding intensity and changes in the mix of specialists and other providers within an ACO, which in turn could affect the characteristics of its assigned beneficiary population, relative to the benchmark period. As we stated in the proposed rule, our goal is to measure improvements in care delivery of an ACO and to make appropriate adjustments to reflect the health status of assigned patients as well as changes in the ACO's organizational structure that could affect the case mix of assigned patients rather than apparent changes arising from the manner in which ACO providers/suppliers code diagnoses.

To address these concerns, in the proposed rule, we considered 3 options for risk adjusting the initial benchmark. One option was to employ a method that considered only patient demographic factors, such as age, sex, Medicaid status, and the basis for Medicare entitlement (that is, age, disability or ESRD), without incorporating diagnostic information. The second option was to employ a methodology that incorporates diagnostic information, in addition to demographic variables, specifically the CMS–HCC prospective risk adjustment model that has been used under the Medicare Advantage (MA) program. The third option was to implement the MA ''new enrollee'' demographic risk adjustment model: a model that includes adjustments for age, sex, Medicaid enrollment status, and

originally disabled status, but would not take into account the health status of the assigned beneficiaries.

We proposed to adjust Medicare expenditure amounts using the CMS–HCC model because it more accurately predicts health care expenditures than the demographic-only model as it accounts for variation in case complexity and severity. We also noted that incorporating diagnosis data in the risk adjustment model would encourage ACOs to code more fully or intensely for purposes of population management and quality reporting, and to optimize their risk scores to achieve shared savings. We elected not to propose the MA new enrollee model because it could have an adverse effect on ACOs that include providers and suppliers that typically treat a comparatively sick beneficiary population, including academic medical centers and tertiary care centers.

We also considered, and sought comment on, several approaches to account for the upward trend in risk scores which may result from coding changes alone, without improved methods of beneficiary care, such as the following:

- Use of normalization factors and coding intensity adjustments, as is done for the MA program.
- Use of an annual cap in the amount of risk score growth we would allow for each ACO. For instance, we considered setting a fixed growth percentage for all ACOs and negating any risk score growth over the cap. Alternatively, we could establish a risk score for the ACO's assigned population during the agreement period based on the calculated risk score of beneficiaries who were used to calculate the ACO's benchmark.
- Use of a methodology similar to the MA methodology that would reduce the amount of growth in the risk scores for beneficiaries assigned to ACOs, but continue to allow increases.

We further explained our expectation that the ACO's average population risk scores would remain stable over time, given that there is expected to be stability in ACO participants and therefore case mix and we will have calculated the benchmark risk adjustment score for the ACO's historically assigned beneficiary population under conditions when the ACO providers/suppliers would not have had the same incentive to increase coding. We stated that we considered the benchmark risk adjustment score for the ACO's historically assigned beneficiary population to be a reasonable approximation of the actual risk score for the beneficiary population assigned to the ACO during the agreement period, while avoiding any distortion due to changes in coding practices. Therefore, we proposed a cap of zero percent growth on risk adjustment by calculating a single benchmark risk score for each ACO and applying this same risk score throughout the agreement period to the annual assigned patient population's per capita expenditures for assigned beneficiaries.

We specified our intent to monitor and evaluate the issue of more complete and accurate coding as we gained experience with the Shared Savings Program, and that we would consider making revisions and adaptations to the final risk adjustment model through future rulemaking if warranted. Further, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we proposed to retain the option to audit ACOs, especially those ACOs with high levels of risk score growth relative to their peers, and to adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. We sought comment on these proposals.

Comment: Commenters typically expressed support for adjusting benchmark expenditures based on the CMS–HCC model; although, some commenters raised technical concerns about the accuracy of HCC risk adjustment. For example, one commenter suggested that CMS needs to improve the accuracy of the HCC risk adjustment model. Other commenters expressed concern that the proposed risk adjuster lacks the capacity to account for socioeconomic status. Another commenter suggested the need for physician input into risk adjustment factors, for example, to be able to identify patients with multiple chronic conditions. Commenters also made a number of recommendations about the proposed risk adjustment methodology, including the need to define other ''beneficiary characteristics'' that might be used to risk adjust, modify the HCC model to exclude zero spend beneficiaries (while these beneficiaries are included in the HCC model as used in MA, it could disadvantage ACOs whose assigned populations would by definition exclude zero spend beneficiaries), and risk adjust for including safety net providers, such as RHCs, FQHCs and Method I CAHs.

While commenters supported use of the CMS–HCC model for adjusting benchmark expenditures, they also expressed concern that benchmark and performance expenditures would not also be annually updated for risk using this same mechanism. Numerous commenters expressed concern that a cap on risk adjustment in cases where care furnished to a patient is documented and appropriate would diminish the level of shared savings, and serve as a disincentive to manage patients with complex health care needs who can most benefit from better care coordination. MedPAC, among other commenters, expressed concern that this approach would create incentives for ACO providers to encourage existing patients who are costly to seek care elsewhere and to avoid taking on new patients that could be costly. Another commenter suggested that accurate risk adjustment is especially important for providers, such as academic medical centers, that disproportionately treat the sickest and most complex patients.

Some commenters were concerned that the proposed cap on risk adjustment would not adequately capture changing severity of disease in the ACO's assigned population. For example, one commenter encouraged CMS to allow for timely and appropriate risk adjustment for cancer patients, particularly to address the circumstance under which a patient has not been diagnosed with cancer when the benchmark is set, but is later diagnosed with and treated for cancer. Another commenter noted that individuals with multiple health conditions will still need more services than other beneficiaries with lower acuity. Another commenter expressed concern that the proposed risk adjustment methodology would not account for changes in beneficiaries' health status which result from aging.

Others were concerned that the proposed cap on risk adjustment would not address changes in the ACO's population as beneficiaries move to different providers during the agreement period. For instance, some commenters pointed to our experience with the PGP demonstration, which showed approximately a 25 percent variation in assignment from year to year. One commenter suggested, based on its own experience in the demonstration, that the turnover rate may be higher.

Accordingly, several commenters encouraged CMS to adopt policies that would encourage ACOs to care for high-risk and high-cost beneficiaries. The alternative most often recommended by commenters is for CMS to annually update performance expenditures for risk. In their view, these annual updates would help keep pace with a changing patient population, for example in terms of beneficiary age, acuity or severity of health status and movement of beneficiaries into and out of the ACO's assigned patient population. As one

commenter recommended, the ACO's risk adjustment score should be determined by the population the ACO is actually treating, and should therefore be recalculated for each year of the agreement period. This commenter further suggested that the potential for, and presumably consequences of, increased coding intensity are far outweighed by concerns about creating incentives to avoid complex patients or penalizing institutions that treat patients in their performance period who are more complex compared to their benchmark population. One commenter noted the importance of adjusting the ACO's benchmark for changes in risk scores during the agreement period, indicating that doing so could limit incentives for ACOs to avoid high-cost and high-risk beneficiaries.

Among the alternatives offered by comments, some commenters recommended a narrower approach, suggesting that CMS annually update ACOs' risk scores for select populations of beneficiaries, such as the aged, disabled and ESRD populations, and beneficiaries with chronic disease codes, or create exceptions for safety net providers. One commenter suggested CMS apply a cap of 10 percent on any annual increase in risk scores, based on coding severity, unless an ACO can provide a satisfactory sampling of assigned beneficiaries audited to support the use of proper coding and therefore higher risk adjustments. Another commenter recommended that risk adjustment be made retrospectively, on an annual basis, based on the ACO's assigned patients.

A number of commenters specifically addressed the relationship between coding accuracy and coding intensity. One commenter viewed the concept of coding intensity as synonymous with coding accuracy. Several commenters suggested that improvements in coding will likely occur over time as a result of ACO formation, for example, as more providers adopt EHR and can code more completely. One commenter pointed out that this improvement in coding should be viewed positively, and suggested that the issue of disproportionate relative risk growth for a subpopulation due only to improved coding accuracy will self-correct. One commenter encouraged CMS to educate physicians and other providers in preparation for the implementation of ICD–10 in 2013, which could result in a significant change in coding. Another commenter noted their agreement with the proposal to address coding accuracy by the proposed audit process.

Commenters suggested a number of alternatives to mitigate the effects of increased coding intensity which included the following:

- Adjust for increased coding intensity as is done for the MA program.
- Do not subject new enrollees or those transitioning from MA to the risk score change limitations.
- Allow ACOs to request a one-time benchmark recalculation during the agreement period.

One commenter suggested CMS investigate, on an ongoing basis, risk adjustment methods that could capture the unexplained variation in spending or risk of a population.

Response: We continue to believe that risk adjusting benchmark expenditures based on the CMS–HCC model accounts for variation in case complexity and severity and therefore more accurately predicts health care expenditures compared to a demographic-only model or other alternatives suggested by commenters. We did not intend for our proposed risk adjustment methodology to discourage ACOs from accepting responsibility for beneficiaries that might present higher than average risk, but commenters have persuaded us of the need to better account for risk associated with changes in the ACO's beneficiary population, for instance in terms of acuity and beneficiary movement, during the agreement period. However, we remain concerned that liberally adjusting for changes in risk scores for beneficiaries assigned to the ACO for the entire agreement period could create an incentive for ACOs to use coding practices intended to optimize their risk scores to achieve shared savings. Thus, we are modifying our initial proposal so that ACO benchmarks will better reflect the risk associated with their assigned beneficiaries. We will adjust expenditures to account for changes in severity and case mix for beneficiaries newly assigned in the current performance year (''newly assigned''), and those who are continuously assigned to the ACO year-to-year (''continuously assigned''). A newly assigned beneficiary is a beneficiary assigned in the current performance year who was neither assigned nor received a primary care service from any of the ACO's participants during the most recent prior calendar year. A continuously assigned beneficiary is a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO's participant during the most recent prior calendar year.

First, for newly assigned beneficiaries we will annually update an ACO's CMS–HCC prospective risk scores to adjust for changes in severity and case mix in this population. Second, each year, we will recalculate the ACO's CMS–HCC prospective risk scores for continuously assigned beneficiaries. If the continuously assigned population shows a decline in its CMS–HCC prospective risk scores, we will adjust for health status changes for this population using this lower risk score. If the continuously assigned population shows no decline, this population will be adjusted using demographic factors only. We believe that this approach to risk adjustment strikes a fair balance between accounting for changes in the health status of an ACO's population while not incenting changes in coding practices for care provided to beneficiaries who remain continuously assigned to the ACO, nor encouraging ACOs to avoid high risk beneficiaries. This methodology implicitly adjusts for beneficiaries who are assigned in the prior year but not the current performance year (patients which leave the ACO), as these beneficiaries will be excluded from the continuously assigned population. We will monitor HCC scores for beneficiaries which are assigned in the prior year who are not assigned in the current performance year, to determine if there is trend in changes in health status for this population. Based on our findings, in future rule making, we may make a more explicit adjustment for beneficiaries assigned to the ACO in the prior year who are not assigned in the current performance year. Further, we agree with the commenter's suggestion on the need for benchmark expenditures to be adjusted relative to the risk profile of the performance year assigned beneficiaries. Therefore the ACO's updated benchmark will be restated in the appropriate performance year risk to ensure fairness recognizing changes in the level of risk among the ACO's assigned beneficiaries.

Additionally, we agree with commenters' suggestions about the need to take account of variations in risk scores across categories of beneficiaries to reflect differences in disease severity across subpopulations. Therefore, in adjusting for health status and demographic changes, we will make adjustments for separate categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid

beneficiaries as described in section II.G.2.b. of this final rule.

Also, we agree with the comment recommending that we use the audit process to address coding inaccuracies. Therefore, to assure the appropriateness of ACO coding practices and our methodology for risk adjusting, we are finalizing our proposal to retain the option to audit ACOs, especially those ACOs with high levels or risk score growth relative to their peers, and to adjust the risk scores used for purposes of establishing the 3-year benchmark accordingly. In addition, as we stated in the proposed rule, we intend to monitor and evaluate the issue of more complete and accurate coding and, as we gain experience with the program, we may consider making further revisions through future rulemaking.

Final Decision: We are making final our proposal under § 425.602 to risk adjust an ACO's historical benchmark expenditures using the CMS–HCC model. We are modifying our proposal under § 425.604 and § 425.606 to make additional risk adjustments to performance year assigned beneficiaries instead of capping growth in risk adjustments during the term of the agreement at zero percent. For newly assigned beneficiaries, we will annually update an ACO's CMS–HCC prospective risk scores, to take into account changes in severity and case mix for this population. We will use demographic factors to adjust for severity and case mix for the continuously assigned population relative to the historical benchmark. However, if the continuously assigned population shows a decline in its CMS–HCC prospective risk scores, we will lower the risk score for this population. An ACO's updated benchmark will be restated in the appropriate performance year risk relative to the risk profile of the performance year assigned beneficiaries. Further, we will make adjustments for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. We are also making final our proposal to monitor and evaluate the issue of more complete and accurate coding for future rule making and to use an audit process to assure the appropriateness of ACO coding practices and to adjust ACO risk scores. We will also monitor HCC scores for beneficiaries assigned in the prior year that are not assigned in the current performance year, and may make a more explicit adjustment for this population in future rule making.

(2) Technical Adjustments to the Benchmark and Performance Year Expenditures

Consistent with the statute, we proposed to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including payments made under a demonstration, pilot or time limited program when computing average per capita Medicare expenditures for an ACO during both the benchmark period and performance years.

In the proposed rule, we stated our belief that all relevant Medicare costs should be included in an ACO's benchmark to maintain sufficient incentives for ACOs to ensure their assigned beneficiaries receive care in the most appropriate settings. We noted that payment adjustments achieve policy goals such as supporting teaching hospitals and hospitals that serve a disproportionate share of low income beneficiaries, adjusting for local wage differences, or accounting for providers' performance on quality initiatives. We further explained that adjustments to payment rates can affect both expenditures during the benchmark period and also during each subsequent performance year. Additionally, changes in these payment factors, between the benchmark and performance years could also influence whether an ACO realizes savings or incurs losses under the program.

In the proposed rule, we addressed the issue of whether to exclude some adjustments to Parts A and B payments when determining ACOs' benchmark and performance year expenditures. We considered a number of specific claims-based payment adjustments in the proposed rule, including: IME and DSH payments, geographic payment adjustments, and some bonus payments and penalties. We also discussed some payment adjustments which are outside the payments for Parts A and B services and therefore would not be included in our calculation of ACOs' expenditures.

We explained that section 1899(d) of the Act provides a way of adjusting for such payments in the benchmark. Section 1899(d)(1)(B)(ii) of the Act states, among other things, that the benchmark must be adjusted for "* * * beneficiary characteristics and such other factors as the Secretary determines appropriate * * *." However, when it comes to performance year expenditures, section 1899(d)(1)(B)(i) of the Act provides authority to adjust expenditures in the performance period for beneficiary characteristics, but does not provide authority to adjust for "other factors." Therefore, we noted that while we could make some adjustments to the benchmark, to exclude certain payments, we could not make similar adjustments in our calculation of performance year expenditures. We did not discuss the possible use of our authority under section 1899(i) of the Act, which authorizes use of other payment models, to adjust performance year expenditures for "other factors."

Comment: We received a number of comments on adjusting for payments and policies not mentioned in the proposed rule. Commenters requested clarification, or made recommendations, on the treatment of a number of payments or costs. Among these, commenters recommended that we exclude the following:

- Costs of preventive services from an ACO's benchmark and spending calculations to avoid incentives to withhold preventive care.
- Costs of urgent care center visits from ACO's benchmark and performance year expenditures to avoid creating incentives for ACOs to refer their non-emergent patients to their own emergency departments instead of to urgent care centers in the community.
- Costs of beneficiaries who seek care outside the ACO.
- New technology payments under the Inpatient Prospective Payment System and transitional pass through payment expenditures under the Outpatient Prospective Payment System for drugs, biological and devices. Commenters believed exclusion of these payments would avoid incentives for ACOs to underuse new technologies and therapies. One commenter, for example, suggested that CMS' exclusions keep pace with the latest recommended treatments.
- Rural health payment adjustments under which CMS reimburses some providers under alternative, specialized methodologies due to their designation as rural or critical access facilities.
- Low cost county payments.
- Primary care incentive payments under the primary care incentive program established by the Affordable Care Act.
- Federal hospital insurance trust fund payments.
- TEFRA relief payments, the inclusion of which could provide incentives for ACOs to avoid forming joint ventures with and including cancer centers.

Commenters offered differing opinions on the treatment of Part D costs. One commenter urged us to include Part D costs, suggesting this could maximize ACO's opportunity for success because of the opportunities for

cost savings and improved quality associated with drug benefits. Several commenters expressed concern that in some clinical areas (such as cancer care and cardiac ablation for atrial fibrillation) ACOs may have an incentive to move patients from appropriate treatments or procedures reimbursed through Parts A or B to Part D therapies which are excluded from the shared savings calculation. Commenters suggested safeguards may be needed for certain clinical areas. One commenter outlined a process for CMS to exclude the costs of certain Part A and B drugs/biologics or medical procedures from the shared savings calculation, but to account for use of Part D drugs as an alternative to procedures paid under Parts A and B. One commenter identified a seemingly countervailing effect resulting from the proposed additional incentive for ACOs to include FQHCs and RHCs, which may be entities eligible for the 340B Drug Pricing Program. The commenter explained that the incentive for including FQHCs and RHCs may prompt ACOs to shift treatment protocols and patients from an inpatient setting to an outpatient setting in order to have access to 340B pricing discounts.

Several commenters expressed the need for CMS to take into consideration payment policies and causes for payment changes which could affect ACO financial performance. One commenter noted that some payment rules can run counter to the goals of the Shared Savings Program, for instance post-acute care transfer policies that reduce payments if the beneficiary is moved to certain other types of providers prior to reaching the geometric mean average length of stay for that diagnosis-related group. ACOs will be mindful these types of payment adjustments, which could result in higher Medicare spending. This commenter suggested the need to align payment policies to be consistent with the goals of the Shared Savings Program, and recommended that CMS not apply payment policies that penalize providers for directing the setting of care. Several other commenters suggested that we consider adjustments to the benchmark and performance year expenditures to account for changes in the structure of ACO providers and suppliers which may have a significant impact on annual payment rates, such as a hospital receiving the status of ''sole community provider,'' or a hospital incorporating a provider-based billing clinic that was previously freestanding. Another commenter suggested CMS develop a method to account for the defensive practice of medicine which results in higher medical costs, particularly in States with higher rates of medical malpractice litigation.

One commenter recommended that CMS offer a process where individual ACOs could petition for specific benchmark adjustments that might be relevant to their providers or beneficiaries, but would not be relevant to all ACOs.

As described section II.G. of this final rule, several commenters recommended that we trend and update the benchmark and risk adjust by categories of beneficiaries, including aged, disabled, and ESRD beneficiaries, among others.

Response: We disagree with commenters' suggestions that we adjust ACO benchmark and performance year expenditures to account for various differences in cost and payment among providers and suppliers. We believe that making such extensive adjustments, or allowing for benchmark adjustments on a case-by-case basis, would create an inaccurate and inconsistent picture of ACO spending and may limit innovations in ACOs' redesign of care processes or cost reduction strategies. Similarly, we do not believe it is appropriate to consider Part D spending in our calculation of benchmark and performance year expenditures. The statute is clear in requiring that we take into account only payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, when computing average per capita Medicare expenditures under the ACO. Although commenters pointed out important concerns about the potential for inappropriate cost shifting to Part D therapies and unintended shifts in the site of care for beneficiaries with high cost therapies, we believe that the program's quality measurement and program monitoring activities will help us to prevent and detect any avoidance of appropriately treating at-risk beneficiaries. Furthermore to the extent that these lower cost therapies are not the most appropriate and lead to subsequent visits or hospitalizations under Parts A and B, then any costs associated with not choosing the most appropriate treatment for the patient would be reflected in the ACO's per capita expenditures.

As we indicated in the discussion of establishing and updating the benchmark and risk adjusting ACO expenditures, we agree with commenters' suggestions for taking a categorical approach to calculating ACO expenditures. Consistent with our policies stated elsewhere in section II.G. of this final rule, we are adopting a policy whereby performance year expenditures will be calculated for cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries, as described in section II.G.2.b. of this final rule.

Final Decision: We are finalizing our proposal under § 425.602, § 425.604, and § 425.606 to take into account payments made from the Medicare Trust Fund for Parts A and B services, for assigned Medicare FFS beneficiaries, including individual beneficiary identifiable payments made under a demonstration, pilot, or time limited program, when computing average per capita Medicare expenditures under the ACO. Further, we will calculate ACO expenditures for each of the following categories of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. Lastly, as specified in section II.C. of this final rule, we will use a 3-month run-out of claims data and a completion factor to calculate performance year expenditures.

(a) Impact of IME and DSH

In the proposed rule, we explained that teaching hospitals receive additional payment to support medical education through an IME adjustment. In addition, hospitals that serve a disproportionate share of low-income beneficiaries also receive additional payments, referred to as the Medicare DSH adjustment. Many hospitals, especially academic medical centers, receive both adjustments, which can provide substantial increases in their Medicare payments compared to hospitals that do not qualify for these adjustments. We stated our belief that the higher payments provided to these types of hospitals could provide ACOs with a strong incentive to realize savings simply by avoiding referrals to hospitals that receive IME and DSH payments.

In developing the proposed rule, we considered whether it would be appropriate to remove IME and DSH payments or a portion of these payments from the benchmark and the calculation of actual expenditures for an ACO. However, we explained that because of our limited statutory authority under section 1899(d) of the Act, we could adjust the benchmark under this provision by removing IME and DSH payments, but we could not also do so in our calculation of performance year

expenditures. We further noted reasons for including these payments in the calculation of both the benchmark and performance year expenditures. First, if we were to remove IME and DSH payments from the benchmark, the benchmark would be set artificially low relative to the performance period, thus making it more difficult for an ACO to achieve savings under this program. Second, excluding these payments could result in an artificial and incomplete representation of actual spending of Medicare Trust Fund dollars. Third, section 1899(d)(1)(B)(ii) of the Act requires that we update an ACO's benchmark during each year of the agreement period based on ''the projected absolute amount of growth in national per capita expenditures for parts A and B under the original Medicare fee-for-service program* * *.,'' which would necessarily include the effects of these payments. Lastly, including all relevant Medicare costs in an ACO's benchmark would maintain sufficient incentives for ACOs to ensure their assigned beneficiaries receive care in the most appropriate settings. We indicated, for example, that this could advantage ACOs which include teaching hospitals or DSH hospitals because their benchmarks would be set higher, and they could potentially earn shared savings when they refer patients to a more appropriate, less intensive care setting. We proposed not to remove IME and DSH payments from the per capita costs included in an ACO's benchmark. We invited comment on this proposal.

Comment: While a few comments supported our proposal not to remove IME and DSH payments from the benchmark, most comments urged us to use our authority under section 1899(i) of the Act to remove IME and DSH from both the benchmark and performance year expenditures. Others suggested that section 1899(d) of the Act provides implicit authority to adjust the performance year expenditures for ''other factors,'' such as IME and DSH payments. Many commenters favoring exclusion of IME and DSH payments also recommended that CMS exclude direct graduate medical education (DGME) payments.

Commenters explained that our proposed policy would incentivize ACOs to avoid referring beneficiaries to higher-cost academic medical centers, thus limiting beneficiary access to high quality, medically necessary care. One commenter pointed out that the inclusion of IME and DSH payments to teaching hospitals in establishing the benchmark may be attractive to ACOs because it would generate a higher benchmark against which an ACO could work to achieve savings. However, on the performance side, ACOs may see the cost structure of teaching hospitals as too prohibitive to achieve the desired savings during the performance years. Or, as another commenter suggested, ACOs may be motivated to shift their referrals away from academic centers so as to achieve apparent savings due to avoiding education-related payments, and not due to achieving actual efficiencies. Commenters expressed concern that the proposed policy could ultimately decrease support for the societal benefits provided by teaching hospitals, including the training of health professionals, discovery of advanced treatments, and ensuring the presence of the highest level of clinical care in a community. Several commenters also suggested that the proposed policy disadvantages hospitals serving low income populations, including those which serve a large number of Medicare and Medicaid patients.

Other comments supported inclusion of teaching hospitals in ACOs participating in the Shared Savings Program because of their potential to achieve the program's goals. One commenter noted that teaching hospitals tend to offer a wider variety of technologically sophisticated services, such as transplant services, compared to what is available at other hospitals, and, as a result, attract sicker patients, requiring more complex and costly treatments. This commenter further suggested that teaching hospitals are well positioned to generate savings and improve quality through better care coordination under the Shared Savings Program.

One commenter noted that certain State policies may lead to a discrepancy between Federal DSH payments to hospitals and the amount actually received by DSH hospitals. The commenter described a policy in the Texas under which a portion of a hospital's Federal DSH payment accrues to the State general revenue fund instead of the institution.

Several commenters suggested alternatives to excluding IME and DSH payments. One commenter recommended that CMS exclude teaching and DSH payments from the benchmark and savings calculations except for ACOs that include at least one major teaching hospital and one hospital that receives high DSH payments, or a single hospital that satisfies both criteria. This commenter further recommended that we account for other reforms under the Affordable Care Act that relate to hospitals that receive high DSH payments. Other commenters suggested that, in the longer term, CMS use risk adjustment methodologies or additional metrics to assess savings and quality improvements specific to hospitals receiving IME and DSH payments. In the event that CMS decides to favor including IME and DSH costs in the calculation of the benchmark and performance year expenditures, one commenter suggested that ACOs that include hospitals receiving IME and DSH adjustments should have an opportunity to receive additional shared savings payments, as we proposed for ACOs including FQHCs and RHCs as participants.

Response: We are modifying our proposal in order to adopt an alternate payment methodology that excludes IME and DSH payments from ACO benchmark and performance year expenditures, as authorized by section 1899(i) of the Act. We believe that care should be provided in the most appropriate setting whether it be a physician office, outpatient clinic, community hospital or teaching hospital. We further recognize the role of teaching hospitals in providing high quality, medically necessary care to Medicare beneficiaries. Commenters have persuaded us that including IME and DSH payments in determining ACO cost performance could create incentives for ACOs to avoid appropriate referrals to teaching hospitals in an effort to demonstrate savings. We remain committed to the societal benefits supported through IME and DSH payments, such as educating the nation's medical workforce, advancing the state of medical science, and ensuring access to care by vulnerable populations.

To exercise our authority under section 1899(i) of the Act, we must demonstrate that this policy (1) ''* * * does not result in spending more for such ACO for such beneficiaries than would otherwise be expended * * * if the model were not implemented * * *.'' and (2) ''* * * will improve the quality and efficiency of items and services furnished under this title.'' First, we believe that the intent of the program is to reward the prevention of unnecessary services and redundancies in care. By removing IME and DSH payments from benchmark and performance year expenditures we can reward more accurately actual decreases in unnecessary utilization of health care services. Second, excluding IME and DSH payments from determinations of ACO financial performance could help ensure participation of hospitals receiving IME and DSH payments in

ACOs, and their engagement in the accountable care model. We believe that removing the disincentive for ACOs to refer patients to teaching hospitals will help ensure beneficiaries continue to be referred to the most appropriate place of service for their care. In combination, these factors could result in Medicare beneficiaries receiving higher quality, better coordinated and more cost-efficient care in these settings. For these reasons, we do not expect that excluding IME and DSH payments from the determinations of ACO financial performance will result in greater payments to ACOs than would otherwise have been made if these payments were included. However, we intend to monitor this issue and will revisit it if we determine that excluding these payments has resulted in additional program expenditures.

Compared to other alternatives suggested by commenters, we believe that excluding IME and DSH payments from the determination of an ACO's eligibility for shared savings is presently the most effective approach to ensure participation by hospitals that receive IME and DSH payments. We plan to monitor this issue to help us determine whether these adjustments should be maintained and may revisit it in future rulemaking as we gain more experience with the Shared Savings Program.

DGME payments are made outside of the payments of Parts A and B claims. By virtue of this fact, under the methodology in either our proposed or final rules, DGME payments would not be included in an ACO's benchmark and performance year expenditures. Therefore, we do not need to make adjustments to individual claims for these payments.

Final Decision: We are modifying our proposal under § 425.602, § 425.604, and § 425.606 so as to exclude IME and DSH payments from ACO benchmark and performance year expenditures.

(b) Geographic and Other Payment Adjustments

In addition to IME and DSH payments, in the proposed rule we also considered whether to include or exclude a number of other payments from ACO benchmark and performance year expenditures.

In the proposed rule we explained that another factor in the Medicare FFS payment systems that could affect an ACO's ability to realize savings is the geographic payment adjustment applied under Medicare payment systems (for example, the IPPS wage index adjustments and the physician fee schedule geographic practice cost index (GPCI) adjustments). These adjustments increase and decrease payments under these systems to account for the different costs of providing care in different areas of the country. We further noted that there have been a number of temporary legislative adjustments to the wage indexes for various parts of the country during recent years. In some cases these have been extended on virtually an annual basis while others have been updated more intermittently. The timing of these adjustments could result in changes being made during an ACO's agreement period and between the benchmark and the performance years, thus influencing an ACO's ability to realize savings under the program.

We explained that, as in the case of IME and DSH adjustments, under section 1899(d)(1)(B)(i) and (ii) of the Act, we could adjust the benchmark by removing geographic payment adjustments, but we could not make a similar adjustment to performance year expenditures. Consistent with our proposed treatment of IME and DSH payments, we proposed not to remove geographic payment adjustments from the calculation of benchmark expenditures. We welcomed comment on this issue, and in particular the likely impact of this proposal in areas that are affected by temporary geographic adjustments.

Further, we addressed bonus payments and penalties for eligible professionals and hospitals. We proposed to exclude from ACO benchmark and performance year expenditures incentive payments for eligible professionals under section 1848 of the Act for the Physician Quality Reporting System, eRx, and EHR. We explained that section 1899(b)(3)(D) of the Act provides authority for the Secretary to incorporate these incentive payments into the Shared Savings Program, as the Secretary determines appropriate. The statute further provides that these incentive payments ''shall not be taken into consideration when calculating any payments otherwise made under subsection (d).'' We reasoned that section 1899(b)(3)(D) of the Act does not, however, provide authority for the Secretary to exclude Medicare expenditures or savings for incentive payments and penalties under other provisions of the Act from benchmark and actual expenditures. Therefore, we proposed to include in both the computation of actual expenditures and benchmark expenditures for Part A and B services any incentive payments not made under section 1848 of the Act that are reflected in Part A and B claims for services furnished to assigned FFS beneficiaries, such as EHR incentive payments to hospitals and payments under the Hospital Inpatient Value-Based Purchasing Program, which are made under section 1886 of the Act, and EHR incentive payments to CAHs, which are made under section 1814 of the Act.

We explained that incentive payments for programs such as these can affect actual expenditures and the benchmark, and thus an ACO's ability to realize savings. For example, an ACO's chances to share in savings or the level of savings that would be shared with the ACO would be reduced when an ACO professional or hospital participating in the ACO fails to receive an incentive payment (or is penalized with a payment reduction) under one of these programs during a benchmark year and subsequently receives an incentive payment from that program in an ACO performance year. This is because, all else being equal—(1) the ACO's expenditures in the performance year would be higher than they would have been in the absence of the incentive; and (2) the ACO's expenditures during the benchmark year would be relatively lower than they would have been had an incentive been received. Conversely, an ACO would be more likely to share in savings if it received an incentive payment under one of these other programs in a benchmark year and received no incentive or was penalized during a performance year. We stated our belief that the effect of including these incentive payments in the calculation of the benchmark and actual expenditures could create perverse incentives with the result that participation in the Shared Savings Program has the potential to adversely affect the performance of providers of services and suppliers with respect to other important Medicare efforts. We further stated that excluding these costs and savings would reduce the chances that incentives that were intended to encourage and reward participation in one Medicare program would discourage full participation in another.

Comment: MedPAC, among other commenters, suggested standardizing costs for ACOs, so that ACOs would be judged based on their success in controlling the growth in service use by their patients isolated from payments unrelated to resource use or changes in prices (such as input prices in their markets) that may be outside of ACOs' control. These commenters were among those that urged CMS to use its implicit authority under section 1899(d) of the Act or its authority under section 1899(i) of the Act to make additional adjustments to exclude certain claims-

based payments including: IME and DSH payments, geographic adjusters (such as payments based on the area wage index), GPCI, HVBP bonuses, hospital EHR incentive payments, transitional pass-through payments for new technologies, primary care incentive payments, and low cost county payments. Absent existing statutory authority to make these adjustments, some commenters suggested that CMS request that Congress amend the statute to allow for this possibility. The focus of other comments was on ensuring that any adjustments, or the lack thereof, to the benchmark be applied consistently to the calculation of performance year expenditures. One commenter cautioned that the data used for some cost-based incentive payments may be flawed.

Of the comments received, most favored excluding geographic payments from benchmark and performance year expenditures. In particular, commenters specified the exclusion of payments based on the following: area wage index, low cost county payment adjustments, GPCI, and the frontier States policy adjustment. Several commenters expressed concerns about including geographic payment adjustments in the benchmark calculations. One commenter, capturing the concerns indicated by several others, explained their view that variations in cost growth across geographic areas as well as inaccuracies in current CMS methods for accounting for differences in local input and practice costs (recently reviewed by the Institute of Medicine) may create incentives that reward ACO formation in some markets compared to others. For instance, some commenters were especially concerned that the GPCI, which differentially advantages providers based on location, is based on outdated payment location definitions. Another commenter suggested that inclusion of these geographic payment adjustments could have unintended consequences for referral patterns by ACOs, such as driving referrals based on geographic wage adjustments rather than performance. Others were generally concerned about including geographic payment adjustments that would disadvantage some ACOs more than others. Several commenters urged CMS to consider the findings from the Institute of Medicine's study on the impact of geographic adjustment factors on Medicare payment policy before addressing geographic payment adjustments in the Shared Savings Program.

Commenters agreed with the proposed exclusion of bonus payments for eligible professionals, in particular PQRS, eRx, and EHR incentives from benchmark and performance year expenditure calculations. Many commenters urged exclusion of all incentive bonus payments and penalties from calculations of the benchmark or the performance year expenditures.

Many commenters expressed concern that inclusion of Hospital EHR incentives and HVBP payments in ACO cost calculations could send mixed messages to hospitals, and could result in misaligned incentives. For example, several commenters suggested that by including VBP incentive payments in the cost of patient care, the proposed methodology for determining average per beneficiary costs would penalize ACOs with high quality hospitals. Similarly, as another commenter noted, ACOs could be penalized for including hospitals that earn EHR incentives during their agreement periods. Commenters described the consequences of including hospital EHR incentives and HVBP payments in calculating ACO financial performance, namely the proposed policy could force hospitals to choose between participating in the Shared Savings Program and other Medicare initiatives, which could result in discouraging hospital participation in ACOs. One commenter noted the importance of ensuring that incentives of the various programs are properly aligned so that their interactions support rather than impede each of the programs' goals. To this end, most commenters favored excluding EHR incentive payments to hospitals and CAHs as well as payments under the HVBP program from ACO benchmark and performance year expenditures. Further, one commenter suggested excluding EHR incentive payments for hospitals because the EHR bonus payments are not calculated on a per beneficiary basis and therefore will be difficult to apportion among assigned beneficiaries, and also because reductions in expenditures when the EHR incentives expire in future years will not be due to any change in the quality of patient care furnished by the hospitals.

Response: Some incentive payments and penalties discussed in the proposed rule are included in payments for Parts A and B services, for example, payments to hospitals through the Hospital Inpatient Value-Based Purchasing Program, which will be made under section 1886 of the Act. Other incentives we discussed, such as PQRS, eRx, and EHR incentives to eligible professionals, hospitals and CAHs are paid outside of payments for Parts A and B services. We wish to clarify that some bonus payments and penalties paid outside of Part A and B claims would be effectively excluded from the benchmark and performance year expenditures because of our proposal to take into account payments made from the Medicare Trust Fund for Parts A and B services furnished to assigned Medicare FFS beneficiaries when determining ACO's historical and actual costs. This is because bonus payments made outside of Parts A and B claims would not be captured in either the benchmark and performance year expenditures.

We are encouraged by the comments supporting our proposed methodology which would exclude payments that fall outside of Part A and B claims in calculating the benchmark and performance year expenditures; for example, DGME payments, PQRS, eRx, and EHR incentive payments for eligible professionals, and EHR incentive payments for hospitals.

We believe it is appropriate to finalize our proposal to include all Part A and B expenditures with the exception of the IME and DSH adjustments, as previously discussed, in the calculation of the benchmark and shared savings payments (that is, we would not standardize payments for example, by making adjustments for geographic or HVBP payments). We have experience with the PGP demonstration which calculated all Part A and B expenditures without such adjustments. Unlike the IME/DSH adjustments, we do not believe these other payments that are included in Part A and B expenditures (such as geographic payment adjustments, and HVBP payments) would result in a significant incentive to steer patients away from particular hospitals or providers since ACOs will be compared to their own historical expenditure benchmark as updated. Additionally, we are concerned about the complexity resulting from standardizing payments, given its relatively minor impact under our benchmarking methodology. However, we intend to evaluate this issue and may address it in future rule-making.

Final Decision: We are making final our proposal under § 425.602, § 425.604, and § 425.606 to include all Parts A and B expenditures, with the exception of IME and DSH adjustments, in the calculation of the benchmark and performance year expenditures. However, we intend to evaluate this issue and may address it in future rulemaking.

(3) Trending Forward Prior Year's Experience To Obtain an Initial Benchmark

Section 1899(d)(1)(B)(ii) of the Act requires the use of ''* * * the most recent available 3 years of per-beneficiary expenditures for parts A and B services * * *.'' to estimate a benchmark for each ACO. As the statute requires the use of historical expenditures, the per capita costs for each year must be trended forward to current year dollars and then averaged using the weights previously described to obtain the benchmark for the first agreement period. The statute further requires that we update the benchmark for each year of the agreement period based on the ''* * * projected absolute amount of growth in national per capita expenditures for parts A and B services * * *.'' under the FFS program, as estimated by the Secretary.

(a) Growth Rate as a Benchmark Trending Factor

The statute does not specify the trending factor to be used in estimating the initial benchmark. In the proposed rule we considered two options for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. We considered trending these expenditures forward using growth rates in expenditures for Parts A and B services for FFS beneficiaries. We also considered trending these expenditures forward using a flat dollar amount equivalent to the absolute amount of growth in per capita expenditures for Medicare Parts A and B under the FFS program.

We explained that a growth rate would more accurately reflect each ACO's historical experience. That is, in contrast to a flat dollar amount, a growth rate would neither raise the bar for ACOs in historically higher growth rate areas nor lower it for ACOs in lower growth areas. We also noted that use of a growth rate could perpetuate current regional differences in medical expenditures. We explained our belief that use of a flat dollar amount for a trending factor was more consistent with the method designated by the under section 1899(d)(1)(B)(ii) of the Act for updating the benchmark during the agreement period. Further, we indicated that use of a flat dollar trending factor could provide a stronger incentive for ACO development in areas with historically lower expenditures and growth rates. Conversely, potential ACOs in areas with historically higher growth rates could be reluctant to participate in the program because the challenge to reduce their growth rate would be greater in these areas relative to low expenditure, low growth ones.

We explained that, on balance, we believed that for purposes of establishing an initial expenditure benchmark, expenditures should be trended forward in a relatively neutral and comparable way across geographic areas. Therefore, we proposed to trend forward the most recent 3 years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services. We provided an example of how an ACO's historical experience would be trended forward. We would use 2009, 2010, and 2011 claims year data to set the benchmark for an ACO starting its agreement period January 1, 2012. The 2009 and 2010 data would be trended forward using the factor described later in this final rule so that all benchmark dollars would be in 2011 dollars. We welcomed comment on this proposal, and especially on whether use of a flat dollar amount to trend the benchmark would be more consistent with our proposal to update the benchmark as specified under section 1899(d)(1)(B)(ii) of the Act.

Comment: Commenters generally agreed with the proposed use of a growth rate, as opposed to a flat dollar amount, to trend forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. One commenter expressed concerns that a flat dollar trending factor would not account for either high cost geographic areas or annual growth in payments to hospitals (such as IME and DSH payments) outside the ACO's control, and that the flat dollar amount would be based on growth rates across all Medicare beneficiaries (those assigned to and not assigned to ACOs). Based on CMS' experience with the PGP demonstration and the benchmarking methodology for the PGP Transition demonstration, one commenter generally recommended that we use separate benchmarks for specific groups of beneficiaries—specifically the aged, disabled and ESRD populations—to account for significant variations in the costs of these beneficiaries. Another commenter suggested that we weight the concentration of Medicaid spending by categorizing patients into tiers based on their level of Medicaid spending.

Response: We are finalizing our proposal to use a growth rate as a trending factor. Further, we were persuaded by comments pointing to the need to account for variation in costs between different populations of Medicare beneficiaries. We believe that trending forward the benchmark expenditures, and updating the benchmark (as explained later in this final rule), for several categories of beneficiaries would provide a more accurate benchmark compared to the methodology we proposed. Expanding upon the commenter's suggestions, we are finalizing our proposal and clarifying that we will add to our methodology for trending the benchmark the calculation of separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries, as specified in section II.G.2.b. of this final rule. We believe that trending historical expenditures for these four categories provides a more complete and accurate benchmark for an ACO since it captures more accurately the proportion of ACO assigned patients that make up these categories, their expenditure growth patterns, and changes in the health status of these patients over time. It will also enable us to provide a more accurate risk adjustment as described in section II.G.2.c.1. of this final rule for an ACO's patient population, by capturing changes in the composition of the patient population over time, while reducing the impact of changes in the health status of an ACO's population due to more complete and accurate coding.

Final Decision: In establishing an ACO's benchmark, we are finalizing our proposal under § 425.602 to trend forward the most recent 3 years of per-beneficiary expenditures using growth rates in per beneficiary expenditures for Parts A and B services. That is, we will trend BY1 and BY2 forward, based on a growth rate, to BY3 dollars. Further, to trend forward the benchmark, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(b) National Growth Rate as a Benchmark Trending Factor

In the proposed rule, we considered use of national, State or local growth factors for trending the benchmark. We explained that using the national growth rate in Medicare A and B FFS expenditures appeared to be more consistent with the methodology that was specified in statute for updating each ACO's benchmark. Further, a national growth rate would allow a single growth factor to be applied to all

ACOs regardless of their size or geographic area. However, a national rate could also disproportionately encourage the development of ACOs in areas with historical growth rates below the national average that would benefit from having a relatively higher base, which increases the chances for shared saving, while discouraging the development of ACOs in areas with historically higher growth rates above the national average that would have a relatively lower base.

In contrast, we explained that trending expenditures based on State or local area growth rates in Medicare A and B expenditures may more accurately reflect the experience in an ACO's area and mitigate differential incentives for participation based on location. Therefore, we considered an option to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate. This option balanced providing a more accurate reflection of local experience with not rewarding historical growth higher than the national average. We believed this method would instill strong saving incentives for ACOs in both high-cost growth and low-cost growth areas.

We proposed to employ the national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. We believed this approach would help to ensure that ACOs in both high spending, high growth and low spending, low growth areas would have appropriate incentives to participate in the Shared Savings Program. We further indicated that this approach would allow us to move toward establishing a national standard to calculate and measure ACO financial performance. We sought comment on this proposal and on the alternatives to using a national growth rate.

Comment: Some commenters supported the proposal to employ a national growth rate, however many more favored use of either local, regional, or State growth rates. Commenters expressed concerns that the use of a national growth rate would discourage participation of ACOs in higher cost areas, including areas where many academic medical centers are located, where there is a high prevalence of chronic illness, or in States (such as Vermont) that have increased health care spending due to initiatives to expand health insurance coverage. These commenters suggested that benchmarking using more localized growth rates could reflect the experience of ACOs in different geographic settings, as well as local economies and local populations, and thereby encourage ACOs to participate nationwide, instead of only in certain pockets of the country. Others urged CMS to adopt policies which would not disadvantage already efficient providers or those operating in lower cost areas of the country.

Several commenters recognized the importance of using national growth rates, for rationalizing overall spending across regions nationwide, but thought it premature to introduce this approach to benchmarking at the outset of the program: suggesting instead that we begin with a local or regional growth rate and migrate to a national growth rate over time. One commenter favored the alternate option we considered, to trend the benchmark by the lower of the national projected growth rate or the State or the local growth rate, whereas several others suggested using the lower of either the national or local growth rates. In addition, commenters offered a number of alternative approaches for trending benchmark expenditures, including the following:

- Use a blend of national average growth and absolute dollar growth, such as that planned for the Pioneer Model ACOs.
- Use the ACO's own percentage growth rate to trend forward the historical benchmark data.
- Account for local variation after analyzing national and local growth rates.
- Account for adjustments for new technology costs.

Response: We believe that implementing a historical benchmark trending factor using the national growth rate for Parts A and B FFS expenditures appropriately balances commenters' concerns that benchmark trending should encourage participation among providers that are already efficient or operating in low cost regions without unduly rewarding ACOs in high-cost areas. The net effect of using the same trending factor for all ACOs will be to provide a relatively higher expenditure benchmark for low-growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. ACOs in high cost high growth areas have an incentive to reduce their rate of growth more to bring their costs more in line with the national average; while ACOs in low cost low growth areas have an incentive to continue to maintain or improve their overall lower spending levels. Therefore we are finalizing our proposal to use a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO.

As we proposed, using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, we will determine the national growth rates for the first and second benchmark years and trend expenditures for these benchmark years forward to the third benchmark year (BY3) dollars. Further, to trend forward the benchmark, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

Final Decision: We are finalizing our proposal under § 425.602 to use a national growth rate in Medicare Parts A and B expenditures for FFS beneficiaries for trending forward the most recent 3 years of per beneficiary expenditures for Parts A and B services in order to estimate the benchmark for each ACO. In doing so, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

d. Updating the Benchmark During the Agreement Period

Section 1899(d)(1)(B)(ii) of the Act states that the benchmark shall be ''updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary.'' We considered two options for updating the benchmark during the agreement period, but proposed to use a flat dollar amount equivalent of the absolute amount of growth in the national FFS expenditures. We explained our view that in enacting section 1899(d)(1)(B)(ii) of the Act, Congress demonstrated interest in mitigating some of the regional differences in Medicare spending among ACOs and that this approach would help to ensure that ACOs in both high spending/high growth and low spending/low growth areas would have appropriate incentives to participate in the Shared Savings Program. We described the effect this update methodology might have in the second and third years of an agreement period: using a flat dollar increase, which would be the same for all ACOs, provides a relatively higher expenditure benchmark for low growth, low spending ACOs and a relatively lower benchmark for high growth, high

spending ACOs. All else being equal, an ACO can more likely share in savings when its actual expenditures are judged against a higher, rather than a lower benchmark. Thus, with a flat dollar increase to the benchmark, ACOs in high cost/high growth areas must reduce their rate of growth more to bring their costs more in line with the national average. We acknowledged that this approach to updating the benchmark could contribute to selective program participation by participants in low growth areas that could result in Medicare costs due to an increase in the amount of bonus payments for unearned savings.

We also considered and sought comment on a second option which would be to use our authority under section 1899(i) of the Act to update the benchmark by the lower of the national projected absolute amount of growth in national per capita expenditures or the local/State projected absolute amount of growth in per capita expenditures. This option could instill strong saving incentives for ACOs in low-cost areas, as well as for those in high-cost areas. Incorporating more localized growth factors reflects the expenditure and growth patterns within the geographic area served by ACO participants, potentially providing a more accurate estimate of the updated benchmark based on the area from which the ACO derives its patient population. Capping the update at the projected absolute amount of growth in national per capita expenditures, however, can advantage ACOs in low cost/low growth areas that have already achieved greater efficiencies, while still offering a strong incentive for those in high cost/high growth areas to reduce their spending.

Comment: Commenters were mixed in their preference for either the proposed policy of updating benchmark by absolute growth in national FFS expenditures, or use of the lower of the national projected absolute amount or the local/State projected absolute amount. For example, one commenter disagreed with the option to use the lower of the national projected absolute amount or the local/State projected absolute amount, suggesting it negatively prejudges all high growth sectors without regard to the underlying clinical or quality issues. However, another commenter favored this approach because this adjustment would afford ACOs the greatest potential for achieving shared savings and minimize the threat of an ACO being disadvantaged by virtue of pricing within its geographic location. Along these lines, one commenter felt the proposed approach offered insufficient incentives for efficient providers to form an ACO. More generally, many commenters urged CMS to adopt policies to encourage participation by organizations that are already efficient or in low cost areas.

Several commenters urged use of regional or market-specific expense data for calculating the benchmark update. One commenter questioned whether the update would occur in the first performance year, as we specifically mentioned the potential effect resulting from the update in the second and third performance years.

Response: We considered commenters' suggested alternatives, but on the whole we believe our proposed method for updating the benchmark could best address the program's goals and commenters' overall concerns about the participation of efficient/low cost ACOs. The net effect of using the same update for all ACOs is to provide a relatively higher expenditure benchmark for low growth/low spending ACOs and a relatively lower benchmark for high growth/high spending ACOs. Further, with a flat dollar increase to the benchmark equivalent of the absolute amount of growth in the national FFS expenditures, ACOs in high cost, high growth areas must reduce their rate of growth more (compared to ACOs in low cost, low growth areas) to bring their costs in line with the national average.

In light of the alternatives we considered, we disagree with the commenter who indicated that the proposed updating methodology offers insufficient incentives for efficient providers to form ACOs. Benchmarks for efficient/low cost providers updated to account for growth in regional or local expenditures would be comparatively lower, and therefore less advantageous, than benchmarks updated based on national experience. Thus, under the proposed update methodology, low cost ACOs could achieve a greater amount of savings, based on the same performance, than a comparable ACO in a higher cost area. Moreover, we believe that a benchmark methodology which encourages providers in higher cost areas to bring their spending more in line with the national average is a desirable outcome in furtherance of the program's goal of lowering Medicare expenditures. Lastly, updating the benchmark during the agreement period using a national growth factor aligns with our approach of using a national growth rate to trend forward base year expenditures to obtain the initial benchmark. This could facilitate analysis of trends in ACO financial performance relative to national trends in Medicare expenditures. For these reasons, we are finalizing our proposal to use the flat dollar amount equivalent of the projected absolute amount of growth in the national FFS expenditures to update the benchmark. Also, to clarify, the proposed update to the benchmark will occur in each year of the agreement period.

Comment: Based on CMS' experience with the PGP demonstration and the benchmarking methodology for the PGP Transition demonstration, one commenter generally recommended that we use separate benchmarks for specific groups of beneficiaries—specifically the aged, disabled and ESRD populations—to account for significant variations in the costs of these beneficiaries. Another commenter suggested that we weight the concentration of Medicaid spending by categorizing patients into tiers based on their level of Medicaid spending. Another commenter asked whether the projected absolute amount of growth in national per capita expenditures for Parts A and B would be scaled to reflect risk differences between the ACO and the Medicare average.

Response: To clarify, we will not risk adjust (that is, based on the CMS–HCC model) the flat dollar amount used to update the benchmark. However, as discussed in section II.G.2.c.(1). of this final rule, the updated benchmark will be adjusted relative to the risk profile of the performance year assigned beneficiaries. We agree with commenter's concerns about the need to account for variation in costs between different populations of Medicare beneficiaries. To align with our modified methodology for trending the benchmark, we will also make category-specific adjustments when updating the benchmark. We believe that updating the benchmark for several categories of beneficiaries would provide a more accurate benchmark compared to what we proposed, as applying national growth dollars to each of the benchmark strata separately reflects the different expected growth rates for these types of beneficiaries. Consistent with our policies stated elsewhere in section II.G. of this final rule, we are modifying our proposal to incorporate into the methodology for updating the benchmark the calculation of separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

Final Decision: We are finalizing our proposal under § 425.602 to update the benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services

under the original Medicare fee-for-service program using data from CMS' Office of the Actuary. Further, in updating the benchmark, we will make calculations for separate cost categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible and aged/non-dual eligible.

e. Determining Shared Savings

(1) Minimum Savings Rate

Section 1899(d)(1)(B)(i) of the Act states that ''an ACO shall be eligible to receive payment for shared savings * * * only if the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark * * *.'' We call this percent the minimum savings rate (MSR). Section 1899(d)(1)(B)(i) of the Act further specifies that the ''Secretary shall determine the appropriate percent * * * to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.'' Section 1899(d)(2) of the Act provides that, if an ACO has savings in excess of the MSR and meets the quality standards established by the Secretary, ''a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this title.'' We call the percent paid to the ACO the shared savings rate.

As we discussed in the proposed rule, a goal of the Shared Savings Program is to use a portion of the savings (the difference between the ACO's actual expenditures and the benchmark) to encourage and reward participating ACOs for coordinating the care for an assigned beneficiary population in a way that controls the growth in Medicare expenditures for that patient population while also meeting the established quality performance standards. However, observed savings can also occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. Thus, even if an ACO engages in no activities to improve the quality and efficiency of the services it delivers, in certain cases, differences between the benchmark expenditures (updated according to statute) and assigned patients' expenditures would be observed during some performance periods merely because of such normal variation. Consequently, under the one-sided model, the statute requires us to specify a MSR to account for the normal variations in expenditures, based upon the number of Medicare FFS beneficiaries assigned to the ACO. The MSR should be set in a way that gives us some assurance that the ACO's performance is a result of its interventions, not normal variation. However, we also do not want an outcome where savings that have been earned are not recognized.

Establishing an MSR on the basis of standard inferential statistics that take into account the size of an ACO's beneficiary population provides confidence that, once the savings achieved by the ACO exceed the MSR, the change in expenditures represents actual performance improvements by the ACO as opposed to normal variations.

Under the PGP demonstration, the MSR was initially set at a flat 2 percent of the benchmark, regardless of number of assigned beneficiaries, and PGP practices received back 80 percent of the savings achieved in excess of the MSR. However, in establishing a MSR, section 1899(d)(1)(B)(i) of the Act calls on us to take into account ''the number of Medicare fee-for-service beneficiaries assigned to an ACO.'' As such, we would need to apply statistical sampling techniques to determine a MSR based on the number of assigned beneficiaries with some level of statistical confidence.

The MSR in combination with the savings rate will determine the amount of shared savings that an ACO can receive. For example, fewer savings would be shared if the MSR were set at a higher percentage. Conversely, shared savings would be higher if the MSR were set at a lower percentage. There are several policy implications associated with the methodology used to set the MSR. A higher MSR would provide greater confidence that the shared savings amounts reflect real quality and efficiency gains, and offer greater protection to the Medicare Trust Funds. However, due to the larger barrier to achieving savings, a higher MSR could also discourage potentially successful ACOs, especially physician-organized ACOs and smaller ACOs in rural areas, from participating in the program. In contrast, a lower MSR would encourage more potential ACOs to participate in the program, but would also provide less confidence that savings are a result of improvements in quality and efficiency made by an ACO. In the proposed rule, we stated that we believed that the most appropriate policy concerning determination of the ''appropriate percent'' for the MSR would achieve a balance between the advantages of making incentives and rewards available to successful ACOs and prudent stewardship of the Medicare Trust Funds.

(a) One-Sided Model

For the one-sided model we proposed a sliding scale confidence interval (CI) based on the number of assigned beneficiaries. The MSR would be established for each ACO based on increasing nominal confidence intervals for larger ACOs so that an ACO with the minimum 5,000 assigned beneficiaries would have an MSR based on a 90 percent CI; an ACO with 20,000 assigned beneficiaries would have a MSR based on a 95 percent CI and an ACO with 50,000 assigned beneficiaries would have an MSR based on a 99 percent CI. In addition, the MSR would not be allowed to fall below 2 percent for larger ACOs. Table 6 displays the minimum savings rate an ACO would have to achieve before savings could be shared based on the number of its assigned beneficiaries. We proposed that an ACO that exceeds its MSR would be eligible to share up to 50 percent of the savings in the one-sided model (based on quality performance), as discussed in section II.F. of this final rule.

In order to improve the opportunity for groups of solo and small practices to participate in the Shared Savings Program, we proposed to vary confidence intervals by the size of the ACO, which is determined based on the number of assigned beneficiaries. In response to our November 17, 2010 RFI, many RFI commenters recognized the prevalence of solo and small practices and the importance of these providers for rural areas and for the treatment of specific patient populations, for example, individuals with mental health and substance abuse disorders or beneficiaries residing in skill nursing facilities. Many of these RFI commenters urged us to consider policies and models that encourage the participation of solo and small practices and to address barriers they face in forming ACOs, such as access to up-front capital to invest in the infrastructure and resources required to redesign care. One option that would help accomplish this would be to vary the confidence intervals used to establish MSRs so that smaller practices would have relatively lower MSRs. Conversely, in recognition that they are

likely to be already established, possess prior experience, and thus better able to achieve savings, larger ACOs would have their MSRs based on a higher confidence interval, resulting in a relatively higher MSR.

We proposed that the MSRs would be estimated to provide confidence that an ACO with a given number of beneficiaries and assumed to be of average national baseline per-capita expenditure and expenditure growth rate would be unlikely to achieve a shared savings payment by random chance alone. A specific MSR is a function of both the number of assigned beneficiaries and a chosen confidence interval. Recognizing the higher uncertainty regarding expenditures for smaller ACOs and the desire to encourage participation by smaller ACOs, for the one-sided model, we proposed to set the confidence interval at 90 percent for ACOs of 5,000 beneficiaries, resulting in an MSR of 3.9 percent. For ACOs with 20,000 and 50,000 beneficiaries, we proposed to set the confidence interval at 95 percent and 99 percent, respectively, resulting in MSRs of 2.5 percent and 2.2 percent. As ACO size increases from 5,000 to 20,000 (or similarly from 20,000 to 50,000), we proposed blending the MSRs between the two neighboring confidence intervals, resulting in the MSRs as shown later in the document in Table 6. We specified an MSR at both the high and low end of each range of ACO population size. A particular ACO would be assigned a linearly-interpolated MSR given its exact number of beneficiaries. For example, an ACO with 7,500 beneficiaries would be assigned an MSR of 3.3 percent because it lies at the midpoint between 7,000 and 7,999 beneficiaries, sizes at which the MSR would be 3.4 percent and 3.2 percent, respectively. For ACOs serving more than 60,000 assigned beneficiaries, we proposed that the MSR would not be allowed to fall below 2 percent. This lower bound was designed to protect the shared savings formula from expenditure reduction due to random chance that can occur in group claims due to factors that persist regardless of a group's size. This lower bound is also consistent with the flat 2 percent MSR we proposed to use in the two-sided model and is the minimum level that was used in the PGP Demonstration.

The proposed confidence intervals were determined assuming that the variation in the per capita expenditure growth for a particular ACO would be equal to the variation in per capita expenditure growth nationally. We acknowledged that this would not be the case for the majority of ACOs, however, as regional growth rates tend to vary from the national average due to a number of variables. Therefore, the confidence intervals generated using only the national expenditure growth variation would overstate the relative confidence associated with an increasing group size. This would be compensated for in two ways: (1) the 2 percent floor; and (2) increasing the confidence interval as group size increases.

TABLE 6—PROPOSED MINIMUM SAVINGS RATE BY NUMBER OF ASSIGNED BENEFICIARIES

[One-sided model]

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000 +	2.0	

In the proposed rule, we stated that we would welcome comment on the most appropriate means to establish the MSR for an ACO, including the appropriate confidence intervals.

Comment: Several comments supported the proposed MSRs under the one-sided model. In particular, MedPAC specified that CMS should keep the proposed MSRs if it allows for a shared savings only track in the first agreement period. Most comments on this topic, however, expressed concern that the proposed methodology for establishing the MSR on a sliding scale based on population size would disadvantage smaller ACOs and discourage participation, particularly by setting a bar that is too high to encourage participation by smaller ACOs, including ACOs likely to form in rural areas and those largely comprised of small- and medium-sized physician practices. Some commenters considered the potential long term consequences of this dynamic, indicating it could ultimately result in diminished provider competition in some markets or stifle the development of innovative care coordination strategies.

Some commenters suggested it would be unfair to hold smaller ACOs to what they perceived to be a relatively higher MSR than what exists for larger ACOs. One commenter indicated that the MSR is financially beneficial to CMS at the expense of ACOs. Further, as other commenters indicated, smaller ACOs are likely to be in greatest need of additional capital to support start-up and operational expenses. One commenter suggested our proposal could make it harder for ACOs to continue to achieve savings in excess of the MSR as they become increasingly efficient over time. Some commenters suggested the MSRs may make it impossible for smaller ACOs to ever share in savings, particularly given the program's rigorous quality standards.

Thus, commenters recommended a variety of alternatives to the proposed MSRs. Most commonly, commenters suggested that we either— (1) apply a common threshold rather than a sliding scale, such as a flat 1 or 2 percent MSR, for all ACOs; or (2) reduce the MSR that

smaller ACOs must achieve. Several comments suggested that CMS generally adjust the sliding scale to be based on lower thresholds (for example, a range of 2 to 3 percent), eliminate the MSR, or eliminate it for certain ACOs. In lieu of an MSR, commenters offered alternate suggestions to protect against random variation such as making the percent of shared savings for which a provider is eligible inversely proportional to their percentile in expenditures per Medicare beneficiary. A number of commenters offered that other aspects of the proposed program, for example, the rigorous quality performance standards or the requirement that all ACOs ultimately accept downside performance risk, are sufficient to ensure savings are a result of actions by ACOs and obviate the need for an MSR. One commenter suggested a blended approach such that if an ACO exceeds the 2 percent MSR, it would be eligible for a lower sharing rate, but would not receive the full sharing rate unless it exceeded its statistically adjusted MSR. Another commenter suggested a rolling confidence interval option for small ACOs that would allow them to cumulate cost experience (and savings) over time. Under this approach, CMS would base the ACO's MSR on the sum of its assigned beneficiaries across all 3 years of participation (for example, a 5,000 member ACO would have the CI of a 15,000 member ACO over 3 years). Further, the commenter recommended allowing ACOs to include their entire patient base, including privately insured patients for purposes of computing their MSR. Another commenter asked whether CMS would consider rewarding those ACOs who can maintain lower costs than their initial MSR for 3 years. Finally, one commenter asked that we defend our assumption that variation within an ACO is comparable to national variation.

Response: We agree with comments by MedPAC and others supporting the proposed sliding scale, based on the size of the ACO's assigned population, to establish the MSR for ACOs under the one-sided model. In particular, given our decision to allow for a shared savings only model, we are following MedPAC's advice to retain the proposed MSR methodology. Alternatives suggested by commenters that allow for lower MSRs for smaller ACOs under the one-sided model (such as a flat 1 or 2 percent MSR for all ACOs) provide insufficient protection to the Medicare Trust Funds against shared savings resulting from random variation, absent some additional protection such as accountability for shared losses. We believe the relatively lower MSR under the two-sided model is appropriate since there is a balancing of the risk of random variation because the ACO is accountable for losses. Thus, while there is some minimal risk that an ACO will achieve savings due to random variation, there is also some risk that the ACO will incur losses due to random variation. Therefore, we find it appropriate to finalize the proposal to establish MSRs for ACOs under the one-sided model to protect the Trust Fund from paying out incentives for random variations in costs rather than for real improvements made by ACOs. With respect to the comments that expressed concern that our proposed MSR methodology did not provide appropriate incentives for smaller ACOs, we believe the change to our proposed methodology to provide for a shared savings-only track, in addition to other changes to increase the financial attractiveness of the program, will be sufficient to encourage participation.

The proposed MSRs were defined to recognize variation due to the number of beneficiaries assigned to the ACO, as required by the statute. Therefore in developing the proposed MSRs, we examined variation in expenditure growth rates for groups sampled on a national basis in order to isolate variation based on group size rather than regional factors that can cause added variation relative to the national average growth rate.

Final Decision: We are finalizing our proposal under § 425.604 to use a sliding scale, based on the size of the ACO's assigned population, to establish the MSR for ACOs participating under the one-sided model.

(b) Two-Sided Model

In the proposed rule, we stated that the MSR remains important under the two-sided model to guard against normal variation in costs, so that ACOs share savings or losses with the program only under those circumstances in which we can be confident that such savings or losses are the result of the ACO's behavior rather than normal variation. At the same time, we noted that we believed it was more appropriate to employ a fixed minimum savings rate under this model than under the one-sided model. First, given the potential for shared loss, the greater predictability of a fixed MSR is more likely to attract organizations to participate under this model. Second, greater protection to the Medicare Trust Fund is afforded by ACOs accepting the risk of paying Medicare back for losses. Therefore, based on our experience with the PGP demonstration and consistent with the lowest applicable MSR under the one-sided model, we proposed to adopt a fixed 2 percent MSR for organizations operating under the two-sided model, in place of the variable minimum savings rate for organizations operating under the one-sided model.

Comment: Commenters' suggestions for revising the proposed policy for the MSR for ACOs under the two-sided model largely tracked those described previously for the one-sided model. For instance, several commenters recommended removing the MSR from the two-sided model given ACOs' accountability for shared savings and losses under this model.

Response: We are finalizing our proposal to adopt a fixed 2 percent MSR for ACOs under the two-sided model. We find support for the application of a flat 2 percent MSR to ACOs participating in the two-sided model in commenters' suggestions that we apply a common threshold of 1 or 2 percent to all ACOs. We disagree with suggestions that we reduce, or eliminate altogether, the MSR in the two-sided model. Although greater protection to the Medicare Trust Fund is afforded by ACOs accepting the risk of paying Medicare back for losses, there remains a need to protect the Trust Fund from paying out incentives for random variations in costs rather than for real improvements made by ACOs. We continue to believe that a flat 2 percent MSR is appropriate for the two-sided model. As explained previously, unlike the one-sided model, under the two-sided model there is a balancing of risk of random variation because the ACO is accountable for losses. Thus, while there is some minimal risk that an ACO will achieve savings due to random variation, there is also some risk that the ACO will incur losses due to random variation. Further, as indicated in the proposed rule, a 2 percent MSR reflects the lowest MSR under the one-sided model and is also the MSR that was used in the PGP demonstration.

Final Decision: We are finalizing our proposal under § 425.606 to apply a flat 2 percent MSR to all ACOs participating under the two-sided model.

(2) Quality Performance Sharing Rate

As discussed in section II.F. of the proposed rule (76 FR 19620 and 19621), we proposed that ACOs choosing to participate in the one-sided model could share in savings if they exceed a MSR. For those ACOs whose savings exceed the MSR in the one-sided model, we proposed a savings sharing rate of up to 50 percent of total savings, above a 2 percent savings threshold, with a payment cap of 7.5 percent of an ACO's

benchmark. We also proposed an additional increase of up to 2.5 percentage points for including FQHCs and/or RHCs as ACO participants, as discussed in section II.F of the proposed rule. Thus, under our proposal, an ACO participating in the one-sided model could realize a maximum shared savings rate of 52.5 percent. Under the two-sided model, we proposed that an ACO that realized savings against its benchmark could qualify for a final sharing rate of up to 65 percent if it was eligible for the maximum adjustments. The 65 percent final sharing rate was comprised of a savings rate of up to 60 percent for quality performance, plus 5 percentage points for including FQHCs and/or RHCs as ACO participants.

Comment: Commenters favored allowing higher sharing rates based on ACO quality performance for both the one-sided and two-sided models, and offered a variety of rationales for increasing the sharing rate. Typically, commenters suggested that higher sharing rates would better incent participation, particularly considering the costs of ACO formation. Others indicated that the proposed shared savings percentages were too low when compared with other Medicare shared savings initiatives, such as the 80 percent shared savings rate under the Physician Group Practice Demonstration, and the higher sharing rates proposed by the Innovation Center for Pioneer Model ACOs.

Commenters suggested sharing rates ranging from 50 to 95 percent (most commonly 75 percent) under the one-sided model and 66 to 95 percent (most commonly 80 percent) under the two-sided model. MedPAC recommended increasing the sharing rates for both models, suggesting, for example, offering a savings rate of up to 75 percent for the one-sided model and 95 percent for the two-sided model for the first agreement period. Several commenters suggested we initially establish higher sharing rates than what was proposed, while incrementally decreasing the maximum sharing rate over time; for instance, setting the sharing rate at 75 percent or 95 percent for the initial performance year and then gradually tapering it off in subsequent years. Several commenters suggested approaches whereby ACOs meeting a quality standard would obtain a guaranteed minimum amount of shared savings, and thereafter receive an additional percentage of shared savings on a sliding scale based on higher quality performance. For instance, creating a minimum sharing rate of 50 percent for Track 1 and 60 percent for Track 2, and using an ACO's quality score to award additional shared savings up to a maximum sharing rate of 80 percent for Track 1 and 90 percent for Track 2.

One commenter suggested the sharing rates should be the same for both models. More commonly, however, commenters supported a policy of establishing different sharing rates for the two models, to provide a greater reward to ACOs taking risk. Some commenters recommended that CMS increase the difference in sharing rates between the models. Several commenters suggested maintaining or lowering the proposed sharing rate for the one-sided model, while increasing the sharing rate for the two-sided model. One commenter suggested downwardly adjusting the sharing rate for the one-sided model over time to encourage ACOs to move to the two-sided model. Others suggested higher sharing rates for certain types of ACOs, such as early adopters of the ACO model, or ACOs in low cost areas. Overall, commenters' suggestions for the amount of difference in the sharing rates between the two models ranged from zero to 40 percent, however most commenters tended to recommend differential of between 5 and 25 percent.

Response: We carefully considered commenters' requests for a higher sharing rate based on quality performance for both the one-sided and two-sided model as a means of encouraging participation in the program.

In the proposed rule we explained that the sharing rate based on quality performance was a function of equally weighting the five proposed domains for quality measurement. As such, under the one-sided model, each domain would account for 10 percent, for a total sharing rate of 50 percent. We further specified the need to differentiate between the program's models—to incent ACOs to take risk by offering the possibility of a greater financial reward—and proposed the two-sided model would have a maximum sharing rate based on quality performance of 60 percent, equally apportioned among the five measurement domains.

As specified in section II.F. of this final rule, in the final rule we have reduced the number of quality measures, and consequently are finalizing a quality performance standard which includes 4 domains that will be equally weighted for purposes of quality scoring. As discussed elsewhere in this section of this final rule, we are modifying our proposals to provide greater opportunity for ACOs to achieve shared savings, for instance, by allowing first dollar sharing under the one-sided model and raising the payment performance limits for both models.

We considered how to address the opposing views presented in the comments on the sharing rate for the one-sided model, including recommendations that providing a higher sharing rate would encourage participation in the program, and recommendations that we maintain or lower the sharing rate to ensure a sufficient incentive for ACOs to participate in the two-sided model. Given our modifications to the quality performance standard and financial models which will make it easier for ACOs to share in a savings, we believe that maintaining the proposed sharing rate for the one-sided model offers a fair balance between commenters' suggestions that we provide greater opportunities for ACOs to share in savings while also remaining protective of the Trust Funds.

We appreciate commenters' support of the need to differentiate financially between the two models by offering a higher sharing rate to ACOs under the two-sided model. We continue to believe that risk-based arrangements are more effective in driving behavior changes by providers, and therefore we should ensure there are appropriate incentives for ACOs to enter the program's two-sided model. We agree with commenters' recommendations that support our proposal to offer ACOs under the two-sided model a higher sharing rate than those under the one-sided model, as a means of encouraging ACOs to accept downside risk. Further, our proposal to differentiate the sharing rates for the models by 10 percent aligns with commenters' preference for a difference in sharing rates in the range of 5 to 25 percent. When compared to the 50 percent sharing rate based on quality for the one-sided model, we believe that a 60 percent sharing rate for the two-sided model offers an appropriate additional incentive for ACOs to accept downside risk.

Final Decision: We are finalizing our proposal under § 425.604 and § 425.606 that ACOs under the one-sided model can earn up to 50 percent of total savings based on quality performance and ACOs under the two-sided model can earn up to 60 percent of total savings based on quality performance.

(3) Additional Shared Savings Payments

In the proposed rule, we recognized the important role that FQHCs and RHCs play as safety net providers and in improving access to primary care for Medicare and Medicaid beneficiaries. Under the proposed rule, FQHCs and RHCs were unable to participate

independently in this program by forming their own ACOs. As a result, we believed that providing incentives to ACOs that include FQHCs and/or RHCs as ACO participants was in the interest of the Shared Savings Program as including these types of entities could promote care coordination and the delivery of efficient, high-quality health care. We proposed that ACOs could be eligible to receive higher sharing rates, based on a sliding scale, for including FQHCs and RHCs as ACO participants. Under the one-sided model we proposed up to a 2.5 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. Under the two-sided model we proposed up to a 5.0 percentage point increase in the sharing rate for ACOs that include these entities as ACO participants. We proposed establishing a sliding scale payment, outlined in the Table 7, based on the number of Medicare FFS beneficiaries with one or more visit at an ACO participant FQHC or RHC during the performance year.

TABLE 7—SLIDING SCALE PAYMENT BASED ON NUMBER OF BENEFICIARY VISITS AT AN ACO PARTICIPANT FQHC OR RHC

Percentage of ACO assigned beneficiaries with 1 or more visits to an ACO participant FQHC/RHC during the performance year	Percentage point increase in shared savings rate (one-sided model)	Percentage point increase in shared savings rate (two-sided model)
1–10 percent	0.5	1.0
11–20 percent	1	2.0
21–30 percent	1.5	3.0
31–40 percent	2	4.0
41–50 percent	2.5	5.0

We also proposed that ACOs specifically identify their FQHC/RHC participant TINs in their initial and annual reporting of ACO participant TINs, and disclose other provider identifiers as requested to assure proper identification of these organizations for the purpose of awarding the payment preference. Further, we proposed to define FQHCs and RHCs, for the purpose of awarding this payment preference, as these terms are defined in 42 CFR 405.2401(b) of our regulations. We sought comment on alternate options for establishing a payment preference with a sliding scale for ACOs that include FQHCs or RHCs as ACO participants, including suggestions for the appropriate method to measure FQHC/RHC involvement and the appropriate level of incentives.

Comment: While many commenters supported the concept of the proposed incentive, others found the incentive inadequate to encourage meaningful FQHC and RHC participation in ACOs. One commenter envisioned that FQHCs and RHCs would be ''latched on'' to the ACO in an attempt to achieve a greater share of savings. Commenters were also critical of the incentive's focus on care provided to ACO beneficiaries at FQHCs and RHCs when we proposed to assign beneficiaries to ACOs based on their use of other primary care providers. As one commenter explained, the incentive assumes an unlikely scenario where non-FQHC providers will refer a patient to an FQHC for care. Others considered the incentive, based on a one visit rule, ripe for gaming: ACOs might schedule their beneficiaries to have one visit at an FQHC or RHC to obtain the incentive, which could result in ''primary care discontinuities.'' One commenter questioned whether the incentive was in line with the letter and spirit of the Affordable Care Act.

Commenters provided various suggestions for how to revise the structure of the incentive, such as the following:

- Increasing the amount of the incentive, for instance to a 10 percent bonus under both models.
- Including Method I CAHs in the incentive payment structure.
- Providing additional payments for including multiple FQHCs.

Commenters also offered alternatives. For instance, one commenter recommended that CMS create incentives for FQHCs and RHCs to participate in ACOs, rather than to reward ACOs for including these organizations.

Response: In this final rule, we are eliminating our proposal to provide an incentive for ACOs to include FQHCs and/or RHCs as participants. We proposed this incentive to address our inability to determine a statutorily satisfactory way of assigning beneficiaries to an ACO on the basis of services furnished by these entities. However, given that we have determined an appropriate methodology for assigning beneficiaries to ACOs on the basis of services furnished by FQHCs and RHCs, therefore allowing FQHCs and RHCs to more fully participate in the program, we believe the incentive is unnecessary and has the potential to cause unintended consequences as articulated by commenters.

Final Decision: The final rule will not contain a sliding scale-based increase in the shared savings rate, up to 2.5 additional percentage points under the one-sided model and up to 5 additional percentage points under the two-sided model, for ACOs that include an FQHC or RHC as an ACO participant.

In the proposed rule we also discussed our interest in encouraging providers who serve a large portion of dual eligible beneficiaries to participate in the Medicare Shared Savings Program. We explained that Medicare beneficiaries who are also eligible for Medicaid—that is, are ''dually eligible'' for these programs—are among the most vulnerable of Medicare beneficiaries. Dual eligible beneficiaries tend to have higher medical costs than other FFS beneficiaries, and, as a result, are expected to benefit even more than other beneficiaries from improvements in the quality and efficiency of their care resulting from the greater care coordination offered by an ACO.

We also stated in the proposed rule that section 1899(j) of the Act provides that ''[t]he Secretary may give preference to ACOs who are participating in similar arrangements with other payers.'' The statute prescribes neither the kind of preference that the Secretary should provide to such ACOs nor what other types of arrangements should be considered ''similar'' for purposes of such a preference. We stated our belief that the more patients an ACO sees for which it is eligible to receive performance-based incentives, such as shared savings, the more likely it is that the ACO will adopt

substantial behavior changes conducive to improved quality and cost savings.

We sought comment on methods to provide preference to ACOs that serve a large dual-eligible population or that enter into and maintain similar arrangements with other payers. Specifically, we sought suggestions to encourage accountability for dual-eligible beneficiaries and participation in similar arrangements with other types of payers.

Comment: Comments described the health needs of dual eligible beneficiaries and the potential challenges of managing this population. Some commenters saw the need for CMS to ensure participation by providers that care for dual eligible beneficiaries as part of the larger issue of the need for CMS to support safety net providers and ACOs more generally. Many commenters favored policies that financially reward ACOs whose assigned populations include a larger proportion of dual eligible beneficiaries. Commenters offered a variety of suggestions on how to structure this payment preference, including the following:

- Higher shared savings rates for ACOs that serve a high percentage of dual eligible beneficiaries, similar to the increased sharing rate proposed for ACOs which included FQHCs and RHCs. Commenters' suggestions for higher sharing rates typically ranged from 2.5 percentage points to 20 percent under the one-sided model and 5 percentage points to 25 percent under the two-sided model.
- Additional incentives coupled with alternative payment models for an ACO whose patient mix is comprised mostly of Medicaid patients, and which care for large percentages for dual eligible beneficiaries.
- Exempt ACOs that treat a larger proportion of dual eligible beneficiaries from the 2 percent net sharing rate.
- Revised benchmarking methodology (for example, a ''separate savings target'') for ACOs that serve a large population of dual eligible beneficiaries.

Several commenters raised concerns about creating incentives for ACOs to care for dual eligible beneficiaries. One commenter noted that the proposed assignment methodology, under which FQHCs would not be the basis for assignment, would exclude many dual eligible beneficiaries from ACOs. By virtue of this policy, the commenter perceived proposed monitoring for avoidance of at-risk beneficiaries and the proposed rule's emphasis on providing incentives for ACOs to include dual eligible beneficiaries to be flawed. Another commenter, pointing to the unique health care needs of dual eligible beneficiaries, cautioned that ACOs should have the capacity and ability to serve these individuals; suggesting that CMS condition any dual eligible incentive payment on an ACO not only serving a large proportion of dual eligible beneficiaries, but also having the appropriate infrastructure to coordinate care and benefits for this population. One commenter opposed the use of financial incentives to encourage ACOs to serve dual eligible beneficiaries or to encourage providers serving duals to become ACOs, based on the belief that such financial incentives in the early days of the program may distort provider behavior in ways that are detrimental to beneficiaries and costly to the program. To effectively serve this population, this commenter indicated, for example, that we should ensure that ACO providers are Medicaid participating providers, and that an ACO serving many dual eligible beneficiaries has a relationship with the State Medicaid agency in the State in which it operates. This commenter further pointed out an effort by the Innovation Center in Connecticut to develop an Integrated Care Organization to serve dual eligibles in the State.

We received few comments on our statutory authority to give preference to ACOs who are participating in similar arrangements with other payers. One commenter recommended that CMS give preference to ACOs that have contracts with private payers that include financial accountability and quality performance incentives, and avoid requirements that could have a chilling effect on the willingness of private payers to invest in and partner with ACOs. This commenter further recommended that the definition of ''similar arrangement'' be consistent across the Shared Savings Program and the Pioneer ACO Model. On a related issue, many commenters expressed their support, generally, for the Innovation Center's Pioneer ACO Model. As a condition of participation in the Pioneer Model, ACOs must commit to entering outcomes-based contracts with other purchasers (private health plans, State Medicaid agencies, and/or self-insured employers) such that the majority of the ACO's total revenues (including from Medicare) will be derived from such arrangements, by the end of the second performance period in December 2013. One commenter requested clarification on the extent to which private payers could participate in ACOs.

In addition to the payment incentives and preferences discussed in the proposed rule, commenters recommended that CMS include a variety of other incentives based on an ACO's other quality improvement activities, and the composition of the ACO's participants or the particular populations they serve. For example, commenters suggested we include the following:

- Incentives for early adopters of the accountable care model.
- Incentives for caring for particular populations, such as rewarding ACOs that serve the uninsured, care for beneficiaries in rural areas, or that have diverse patient populations.
- Incentives for including the following providers and suppliers:
  - ++ Patient centered medical homes.
  - ++ Teaching hospitals.
  - ++ Ambulatory Surgery Centers.
  - ++ Community health organizations including Community Mental Health Centers.
  - ++ Home health and hospice agencies.
  - ++ Physicians practicing in rural areas.
- Incentives for including health programs operated by the Indian Health Service, tribes or tribal organizations, and urban Indian organizations.
- Incentives to encourage participation by small, rural, and physician-led ACOs.
- Incentives to ensure some primary care services are delivered by NPs and PAs.
- Incentives to move patients from the acute care setting to appropriate post-acute or outpatient providers.
- Incentives to reward participation in other quality improvement initiatives, such as physician-led quality improvement programs.
- Incentives to use telehealth and remote patient monitoring technologies in innovative modalities extending beyond what is currently reimbursed under FFS Medicare.
- Incentives for the development of primary care training in new models of care.
- Incentives for ACOs participating in clinical trials, to encourage innovation in health care.

Response: We are finalizing our proposal, which does not give preference to ACOs engaged in similar arrangements with other payers, or provide additional incentives for ACOs which care for dual eligible beneficiaries. Similarly, we do not intend to recognize other factors, such as the ACO's other quality improvement activities, the composition of the ACO's participants or the particular populations they serve. CMS' goal is to promote complete integration of care

and align incentives whether care is provided under Medicare, Medicaid, or both. ACOs are one valuable new option to assure greater coordination of care for Medicare Parts A and B services for dual eligible beneficiaries. Additionally, there are existing demonstrations and emerging care models underway in the Innovation Center in partnership with the Medicare-Medicaid Coordination Office which will provide further opportunities for the integration of care and financing across both Medicare and Medicaid, including long term services and supports. For dually eligible individuals CMS intends to study the effect of assignment of these individuals to ACOs in the Shared Savings Program on Medicaid expenditures, and may use this information in the development of future models for testing by the Innovation Center. We believe that these demonstrations and models targeting the dual eligible population will further address and create incentives for providers to focus on serving their special needs.

Through the flexibility allowed in the governance requirements, discussed in the Section II.B. of this final rule, we have left room for ACOs to engage with private payers. In addition, we may revisit our authority to award a preference to ACOs that participate in similar arrangements with other payers as we gain more experience with such arrangements through the Pioneer ACO Model.

We decline to incorporate incentives into this national program to account for the variety of approaches that ACOs may choose for their quality improvement activities outside the Shared Savings Program, as well as their provider and supplier composition and patient mix. We believe that the flexibility allowed in the distribution of shared savings provides the opportunity for ACOs to reward ACO participants' for engaging in other quality improvement initiatives.

We may revisit the issue of incentives related to ACO activities, composition, and patient mix as we gain experience with the ACO model through the Shared Savings Program and the Pioneer ACO Model.

Final Decision: The final rule will not contain additional financial incentives, beyond those established for quality performance, for the care of dual eligible beneficiaries or other factors related to the composition of the ACO or its activities, nor will the final rule include a preference for ACOs participating in similar arrangements with other payers.

(4) Net Sharing Rate

Section 1899(d)(2) of the Act calls for us to share ''a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO.'' Section 1899(i) of the Act permits the Secretary to consider other payment models if she determines that they will ''improve the quality and efficiency of items and services furnished under this title'' and will not result in additional expenditures. Thus, in considering the amount of savings ACOs under the one-sided model and two-sided model would be eligible to receive, we considered several options in addition to the methodology outlined in section 1899(d)(2)of the Act.

The first option we considered is the one required under section 1899(d)(2) of the Act, which would permit the ACO to share on first dollar savings once it achieves savings in excess of the MSR. This option would maximize the reward that an ACO could realize. This amount could provide critical financial support for ACOs that serve a smaller population (for example, less than 10,000 assigned beneficiaries), which may be physician only and/or predominantly care for underserved populations, or ACOs whose beneficiaries rely upon safety net providers for care or ACOs which serve rural areas. However, given the normal variation in expenditures, we had concerns that sharing on first dollar savings with ACOs under the one-sided model could result in sharing on unearned savings rather than on savings achieved by the ACO for redesigned care processes. We also explained that this concern was mitigated under the two-sided model, where ACOs are assuming the risk of losses due to normal year-to-year- variations in Medicare beneficiaries' claims expenditures.

We considered another alternative which would limit the amount of savings by requiring ACOs to exceed the MSR and then share with the ACO only those savings in excess of the MSR. As discussed previously, one challenge to appropriate sharing of savings under this program is that observed savings can occur as a result of normal year-to-year variations in Medicare beneficiaries' claims expenditures in addition to the ACO's activities. This concern is heightened in the one-sided model, because absent initial accountability for losses, ACOs have less motivation to eliminate unnecessary expenses and may be more likely to be rewarded as a result of methodological requirements. Sharing only in savings which exceed the MSR is consistent with the design of the original PGP demonstration and would reduce the probability that shared savings are earned as a result of chance or lower pre-existing expenditure trends due to existing efficiencies, and not newly enhanced care coordination and/or redesigned delivery of care. Further, such a requirement would encourage ACOs to strive to generate greater levels of savings.

A third option we considered would be to require all ACOs to exceed the MSR to be eligible for savings, but only to share savings in excess of a certain threshold. ACOs meeting certain criteria could be exempted from this provision and allowed to share in first dollar savings. This option would balance the need to have assurance that savings are not a result of random variation with the need to provide critical financial support for under-funded ACOs, particularly ACOs that serve a smaller population, safety net providers, or physician-only ACOs. Additionally, we have experience with this model through the PGP demonstration.

For the one-sided model, we proposed the third option, that once an ACO has surpassed its MSR, the ACO would share in savings beyond a certain threshold. We further proposed that, unless exempted, ACOs that exceed the MSR would be eligible to share in net savings above a 2 percent threshold, calculated as 2 percent of its benchmark (updated according to statute). The sharing rate would be applied to net savings above this 2 percent threshold in order to determine the shared savings amount. We believed that this threshold would protect the program from sharing unearned savings by helping to ensure that shared savings are due to enhanced care coordination and quality of care on the part of the ACO.

As previously discussed, many smaller physician-driven ACOs and ACOs caring for underserved populations have the potential to improve the quality and efficiency of care, but may be especially challenged in accessing capital to meet their needs. We hope to encourage successful participation by these ACOs in the Shared Savings Program. Additionally, we acknowledge that providers/suppliers working in these environments face additional challenges in coordinating care and creating the infrastructure necessary to create a successful ACO, and therefore may not be equipped to assume the risk of the two-sided model right away (and be

eligible for greater reward). Accordingly, we proposed that ACOs that met certain criteria outlined in the proposed rule (76 FR 19613) would be exempt from the 2 percent net savings threshold and would instead share on first dollar savings under the one-sided model.

For the two-sided model, we proposed that ACOs which generate savings that exceed the MSR would be eligible to share in savings on a first dollar basis. We indicated that a number of factors favored allowing two-sided model ACOs to share on first dollar savings. First, savings generated by ACOs assuming risk of losses are less likely to result from random variation compared to savings generated by ACOs under the one-sided model because these ACOs have a greater incentive to make the types of changes that are necessary to achieve shared savings and avoid shared losses. Second, sharing first dollar savings with two-sided model ACOs would provide greater reward for ACOs that choose to participate in the program's two-sided model as compared to the one-sided model. Therefore, under the two-sided model, the final sharing rate would be applied to an ACO's total savings against its updated benchmark.

Comment: Overall, comments expressed concern over the proposal for ACOs under the one-sided model, other than those exempted, to share savings net a 2 percent threshold once they exceed the MSR. Many commenters requested removal of the net 2 percent sharing rate. Most recommended sharing on a first dollar basis for all ACOs. Commenters provided a variety of rationales to support eliminating this requirement, for example, that it unduly increases uncertainty that an ACO will share in savings or could impede an ACO's ability to make the kinds of up front and ongoing investments needed to better manage care. Some suggested that adequate controls are already proposed to ensure that shared savings are due to improved care coordination and quality of care. Several commenters recommended first dollar sharing indicating random variation in data can work in both directions: Setting higher thresholds may protect CMS from random variation, but does not protect against or recognize random variation that might affect providers negatively.

Others suggested that first dollar sharing for all ACOs would encourage increased participation in the program, for instance helping ensure ACOs receive a return on investments. One commenter pointed out a 2 percent net sharing requirement was not included in the PGP demonstration. Another commenter questioned whether the 2 percent savings threshold is authorized by the law.

Commenters suggested several alternatives to the proposed 2 percent net savings threshold; most commonly, to allow first dollar sharing for the entire agreement period, or as one commenter suggested, for a portion of the agreement period. Another commenter suggested allowing ACOs, not CMS, to share 100 percent of the first 2 percent of savings earned, thereafter CMS and the ACO should receive their percentage shares.

Response: We are persuaded by comments suggesting the elimination of the 2 percent net sharing rate. Commenters made it clear that the option we proposed would unlikely achieve the balance we sought between a threshold low enough to ensure participation while protecting the Trust Funds from paying ACOs for results based on random variation. Commenters persuaded us that the 2 percent net sharing threshold could deter participation. We believe sharing on a first dollar basis with all ACOs will be important for encouraging participation and ensuring ACOs receive capital to invest in achieving the program's goals and achieve a return on investment. First dollar sharing, compared to alternatives that would share on a lower threshold amount, appears the most effective way to ensure ACOs receive needed capital. At this time, we consider other program protections—in particular the minimum savings rate—should be adequate to ensure shared savings result from ACO performance rather than random variation. We will monitor this issue, however, and could consider adjustments through future rulemaking should they be found necessary.

We are revising our proposal to allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. We are finalizing our proposal to similarly allowing sharing on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

Comment: Commenters were generally supportive of the proposed exemption from the 2 percent net sharing threshold for small ACOs, particularly those in underserved and rural areas. A number of commenters suggested expanding the exemption to other types of ACOs. One, for example, recommended that the exemption include ACOs that treat a large proportion of dual eligible beneficiaries.

However, several commenters expressed concerns about the proposed exemption. One commenter explained that based on the proposed assignment methodology, ACOs that include FQHCs and RHCs would have difficulty meeting the threshold level to qualify for the exemption. Another commenter suggested the exemption may not be sufficient to encourage participation by ACOs in rural areas.

Response: Our elimination of the 2 percent net sharing rate negates the need for an exemption from this requirement. Accordingly, we are eliminating the proposed exemption from the 2 percent net sharing rate as all ACOs that achieve savings in excess of their MSR will share in savings on a first dollar basis.

Final Decision: We are revising our proposal under § 425.604 to allow for sharing on first dollar savings for ACOs under the one-sided model once savings meet or exceed the MSR. We are finalizing our proposal under § 425.606 similarly allowing sharing on a first dollar savings for ACOs under the two-sided model once savings meet or exceed the MSR.

(5) Performance Payment Limits

Section 1899(d)(2) of the Act requires the Secretary to ''establish limits on the total amount of shared savings that may be paid to an ACO * * *.'' Therefore, in the proposed rule we addressed the issue of the maximum performance payment an ACO may receive in any given performance year. In determining what would constitute an appropriate limit, we stated that it should provide a significant opportunity for ACOs to receive shared savings generated from quality improvements and better coordination and management of Part A and B services, while avoiding creating incentives for excessive reductions in utilization which could be harmful to beneficiaries. Under the PGP demonstration, the limit was set at 5 percent of the organization's Part A and Part B expenditure target.

For purposes of the Shared Savings Program, we considered an option to vary the performance payment limit by the readiness of the ACO to take on greater responsibility and performance-based risk. ACOs seeking to participate in the Shared Savings Program will vary with respect to their readiness to function under a risk model due to their organizational and systems capacity and structure. Accordingly, some ACOs might more quickly be able to demonstrate quality improvements and savings than will others. Applying differential payment limits based on an ACO's readiness to take on performance-based risk could be another means to encourage and reward successful ACO participation.

In light of our experience with the PGP demonstration, we considered a limit of 5 percent of benchmark expenditures. We also considered whether a higher limit, such as 10 percent or 15 percent, would be appropriate to provide an even stronger incentive for ACOs to develop the quality and efficiency improvements that could result in greater shared savings. Depending on an ACO's composition, shared savings payments under such higher limits could represent an even larger portion of Medicare payments to ACO participants for care furnished to assigned beneficiaries since the limit is a percentage of the ACO's benchmark for Medicare Part A and B expenditures for assigned beneficiaries, which reflects all care furnished to those beneficiaries, regardless of whether it was provided in the ACO. For example, an ACO that does not include a hospital would have the opportunity to realize a relatively higher proportion of shared savings as a percentage of its Medicare revenue by reducing Part A expenditures for its assigned beneficiaries. However, opportunities to earn greater savings could also raise questions about whether the quality of care is improving, which is as important a goal as achieving savings in the Shared Savings Program. In the proposed rule, we recognized that providing an incentive for ACOs to invest to improve quality and efficiency of care needs to be balanced against providing an overly large incentive such that an ACO may be encouraged to generate savings resulting from inappropriate limitations on necessary care. A higher limit on total shared savings could provide such an incentive to limit care. While all ACOs may have this incentive to some degree, ACOs without Part A providers could have greater incentive to do so, depending on where the limit is established.

A lower limit, such as the 5 percent limit under the PGP demonstration, would reward ACOs for improving quality and efficiency and potentially generate more savings for the Medicare program without creating incentives to limit care that is appropriate and necessary. On the other hand, a lower limit might be an insufficient incentive for some potential ACOs to participate in the program. In contrast, a higher percentage limit, such as 10 or 15 percent of an ACO's Part A and B expenditure benchmark, would provide greater incentives for organizations to participate in the program and to achieve the quality and efficiency gains that are the goals of the Shared Savings Program. Many health care researchers believe that the rate of unnecessary health care is more than the approximate 10 percent which would be implied by establishing a 5 percent limit on ACO shared savings. (Since the maximum shared savings potentially realized by an ACO under the proposed one-sided model was 52.5 percent, we noted that a 7.5 percent limit on the ACO share would imply an expectation that overall savings may be as high as approximately 14 percent; a 10 percent limit would imply a savings expectation of approximately 19 percent.) On the other hand, a higher limit might provide some incentive for ACO providers/suppliers to reduce utilization inappropriately, which could potentially be harmful to beneficiaries.

In the proposed rule, we acknowledged that the considerations in favor of both a lower (for example, 5 percent) and a higher (for example, 10 percent) limitation on shared savings with an ACO had merit. Accordingly we proposed to establish the payment limit at 7.5 percent of an ACO's benchmark for the first 2 years of the agreement under the one-sided model. Following suggestions by MedPAC, and in order to encourage ACOs to assume performance-based risk and participate in the two-sided model, we proposed, for the two-sided model, to establish the payment limit at 10 percent of an ACO's benchmark for those ACOs that either elect the two-sided model initially for all 3 years or are transitioned from the one-sided model during the third year of their agreement period. (Since the maximum shared savings potentially realized by an ACO under the proposed two-sided model was 65 percent, a 10 percent limit on the ACO share would imply an expectation that overall savings may be as high as approximately 15 percent). We solicited comment on these proposed payment limits and on whether a higher limit—for example, 10 percent for all ACOs—would be more appropriate in light of the considerations discussed in the proposed rule and other considerations that commenters might wish to raise. We also sought comments on whether differential limits should be established based on an ACO's readiness, as discussed previously, including the criteria we would apply and the methods by which we would assess readiness and how differential limits should be structured. We stated that we would consider this information and the implications for a differential limit based on ACO readiness in future rulemaking cycles.

We stated that, regardless of what limit was adopted in the final rule, we planned to monitor beneficiary access to and utilization of services, and the potential contribution of the performance limit to any inappropriate reductions in services. Our final policies related to monitoring and addressing ACO performance are discussed in section II.H. of this final rule. Furthermore, we indicated that as we gain more experience with the Shared Savings Program and are able to evaluate how well the incentive structure under the Shared Savings Program is operating to generate greater quality and efficiency without inappropriately reducing utilization of services, we may undertake additional rulemaking to revise the performance payment limits we establish in this final rule.

Comment: One commenter suggested that limiting savings is reasonable if losses are also limited, in line with our proposal. Many commenters, however, opposed the proposed limits on shared savings for both the one-sided and two-sided models stating that these policies could limit the ACO's return on investment and therefore the attractiveness of the program, particularly given the large startup and operating costs ACOs are expected to face. One commenter cited a recent New England Journal of Medicine editorial which suggested the ACO must see a 20 percent gain in order to see a return on investment and noted that the proposal limits gains to 7.5 percent. Others suggested the limits could serve as a disincentive for ACOs to invest in transformational improvements, questioning the use of limits if the opportunity for shared savings is indeed a motivator for cost management behavior. One commenter explained that CMS' rationale for the limits, to prevent providers and suppliers from inappropriately reducing utilization, is unfounded; suggesting that the proposed quality performance standards and other proposed protections will effectively prevent ACOs from attempting to improperly reduce utilization of services. Another commenter suggested removal of the limits would signal CMS' commitment to the success of the program. Commenters indicated confusion about whether the limit applies only to the savings paid to the ACO or to the total savings subject to sharing.

Commenters typically recommended eliminating the limits, to allow ACOs to share in all savings they could achieve, suggesting this change could result in increased interest and participation in the program, particularly by smaller medical practices and oncologists. Other

commenters suggested raising the limits, for instance—

- Raise the limit to 10 for the one-sided model;
- Raise the limit by 5 percent for both the one-sided and two-sided models;
- Raise the limit to 15 or 25 percent; or
- For the two-sided model, incrementally increase the limit across the agreement period from 7.5 percent in year 1, to 10 percent in year 2 and 15 percent in year 3 to incentivize formation of ACOs willing to pursue this option.

Response: To clarify, the sharing limit applies to the savings paid to the ACO, not to the total savings subject to sharing. We are, however, persuaded by comments suggesting the importance of raising the performance payment limits to encourage participation and to ensure ACOs receive capital to invest in achieving the program's goals and achieve a return on their investment. We believe retaining the performance payment limits is necessary to comply with the statute and important for ensuring against providing an overly large incentive that may encourage an ACO to generate savings through inappropriate limitations on necessary care. We believe that a modest increase in the performance payment limits balances our concerns while increasing the attractiveness of the program. Further, we believe it is important to maintain a higher limit for ACOs accepting risk for losses, to incent participation in the program's two-sided model. Accordingly, we are modifying our proposal in order to provide a 10 percent payment limit for ACOs under the one-sided model and a 15 percent payment limit to ACOs under the two-sided model.

Final Decision: We are revising our proposal under § 425.604 and § 425.606 to raise the payment limit from 7.5 percent to 10 percent of an ACO's updated benchmark for ACOs under the one-sided model and to raise the payment limit from 10 percent to 15 percent of an ACO's updated benchmark for ACOs that elect the two-sided model.

f. Calculating Sharing in Losses

The proposed rule outlined the methodology for determining shared losses. We proposed a shared losses methodology that mirrored the shared savings methodology, comprised of: a formula for calculating shared losses based on the final sharing rate (1 minus the final sharing rate), use of a minimum loss rate (MLR) to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay. We noted that under this approach, an ACO's share of losses would vary depending on its quality score. Therefore, an ACO with a higher quality score would owe a lower amount of losses compared to an ACO with an equivalent amount of losses but a lower quality score. We considered other approaches to calculating the amount of shared losses, tracking the options considered for establishing the quality standard. For instance, we considered using a threshold approach to measuring quality performance for purposes of determining the amount of shared savings and losses. Alternately we considered using a blend of these two methods, whereby we would allow ACOs to increase their share of savings with higher quality scores, but use a threshold approach when calculating losses. We sought comment on these options.

Comment: We received few comments on our methodology for calculating shared losses. One commenter explained that the elements of the shared savings and losses models need not be symmetrical.

Response: We are finalizing our proposed methodology for determining shared losses, mirroring the methodology for calculating shared savings. Our final policy on each specific issue is described in detail later in this final rule.

Final Decision: As proposed, the shared losses methodology under § 425.606 will mirror the shared savings methodology, comprised of: a formula for calculating shared losses based on the final sharing rate, use of a MLR to protect against losses resulting from random variation and a loss sharing limit to provide a ceiling on the amount of losses an ACO would be required to repay.

(1) Minimum Loss Rate

We proposed a minimum loss rate (MLR) for purposes of computing shared losses when an ACO's actual expenditures exceed its benchmark. We explained that, as with savings, losses must exceed some minimum percentage around the benchmark in order to provide sufficient confidence that the losses experienced during a given performance year are not simply the result of random variation. We proposed the MLR would be the equivalent of the MSR under the two-sided model: A flat 2 percent regardless of the size of the ACO's assigned population. ACOs with excess expenditures below the MLR would not be responsible for repaying Medicare. ACOs with expenditures exceeding the MLR would be responsible for paying a share of excess expenditures calculated by multiplying the amount of excess above the updated benchmark by one minus the final sharing rate. Further we proposed that once the MLR was exceeded, ACOs would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

Comment: Several commenters urged CMS to apply an adjustment for normal variation for losses, instead of requiring first dollar loss sharing. Some commenters favored policies that would exempt some ACOs from repaying losses, such as high quality performers. One commenter favored increasing the MLR and implementing a sliding scale so that the rate would correspond with the ACO's population size. Others favored lowering the MLR (for example, to 1 percent, as proposed for the Pioneer Model ACOs) or eliminating it altogether. One commenter explained that reducing or eliminating the MSR and the MLR recognizes that random variation works in both directions and over the course of the agreement period would likely have a net neutral effect on ACO revenues; further, this would be consistent with other inducements being offered to ACOs willing to bear risk immediately. One commenter appears to have confused the 2 percent MLR under the two-sided model with the 2 percent net sharing requirement under the one-sided model.

Response: We are finalizing our proposal to use a MLR in computing an ACO's shared losses. We believe that comments reflect confusion about the function of the MLR, which serves as a protection for ACOs. An ACO is not accountable for losses if its expenditures are lower than the MLR. This protects ACOs against being held accountable for losses that result from random variation, as opposed to their performance. If an ACO's actual expenditures are 2 percent or more above its updated benchmark, the ACO would be responsible for paying excess expenditures calculated by multiplying the amount of the excess above the updated benchmark by one minus the final sharing rate, up to the limit on shared losses. Once losses meet or exceed the MLR an ACO would be required to repay losses on a first dollar basis. To clarify, the MLR is distinct from, and unrelated to, the 2 percent net sharing threshold proposed for the one-sided model, which would have precluded ACOs from sharing savings on a first dollar basis.

The proposed 2 percent MLR appears to be an appropriate compromise between commenters' suggestions.

Exempting ACOs from accountability for losses under the two-sided model would negate the purpose of a risk-based payment arrangement. Eliminating or reducing the MLR may deter participation by some ACOs in the two-sided model, particularly those new to risk-bearing, in addition to potentially holding ACOs accountable to losses resulting from random variation.

Final Decision: We are finalizing our proposal under § 425.606 to apply a MLR for the two-sided model. To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must exceed its updated benchmark costs for the year by at least 2 percent. Once losses meet or exceed the MLR, an ACO would be responsible for paying the percentage of excess expenditures, on a first dollar basis, up to the proposed annual limit on shared losses.

(2) Shared Loss Rate

We proposed that ACOs with expenditures exceeding the MLR would be responsible for paying excess expenditures calculated by multiplying the amount of excess above the benchmark by one minus the final sharing rate. In the proposed rule we defined the final sharing rate as the quality performance sharing rate plus any percentage points for including FQHCs and/or RHCs as ACO participants.

Comment: We received a few comments on the proposed shared loss rate. One commenter suggested we allow ACOs the choice of a percentage shared loss rate (as proposed) or a fixed dollar amount of risk. Several commenters pointed out that under the proposed methodology for calculating shared savings and losses, an ACO could be accountable for a 100 percent share of losses (for example, if the ACO's quality sharing rate is zero) which is asymmetrical with the shared savings methodology. One commenter suggested that CMS ensure that the ACO's financial risk equals its potential gains in shared savings.

Response: We are maintaining our proposal to calculate the shared loss rate as one minus the final sharing rate. Given our elimination of the incentive for an ACO to include FQHCs or RHCs as ACO participants, the final sharing rate is based solely on quality performance. Therefore, under the two-sided model an ACO could achieve a maximum sharing rate of 60 percent based on quality performance. We believe that commenters identified an important concern about the shared loss rate, that an ACO could achieve a 100 percent shared loss rate, while the maximum shared savings rate is set at 60 percent. We are concerned that the prospect of a shared loss rate bounded at 100 percent could significantly deter participation by ACOs in the two-sided model, particularly ACOs that are new to the accountable care model and to risk-bearing. On the other hand, we do not want to limit the shared loss rate so much as to dampen the benefit of the program for Medicare or to remove the incentive for ACOs to strive for high quality scores. To balance these issues, we are modifying our proposal to cap the shared loss rate at 60 percent, to align with the maximum shared savings rate based on quality performance under the two-sided model.

Final Decision: As proposed, under § 425.606, the shared loss rate for an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark will be determined based on the inverse of its final sharing rate based on quality performance (that is, 1 minus the shared savings rate). However, we are modifying our original proposal to provide that an ACO's shared loss rate will be subject to a cap of 60 percent consistent with the maximum rate for sharing savings.

g. Limits on Shared Losses

We proposed an annual maximum shared loss limit measured as a percentage of the benchmark to provide a greater incentive for organizations to participate in the Shared Savings Program under the two-sided model. We proposed to phase in the limit on shared losses over a 3 year period, with limits of: 5 percent, 7.5 percent, and 10 percent, respectively across the first 3 years for Track 2 ACOs. We further proposed that an ACO in Track 1 that has entered the third year of its initial agreement period would be liable for an amount not to exceed the percentage for the first year of the two-sided model, that is, shared losses would not exceed 5 percent of its updated benchmark.

Comment: Several commenters agreed with the proposed limits on shared losses, which one commenter indicated would provide an incentive for ACOs to participate in the two-sided model. One commenter explained that the limits on shared losses need not be symmetrical with the shared savings limit. Several commenters suggested alternatives, such as use of risk corridors and capped losses similar to the MA program, or limiting shared losses to 5 percent of the benchmark in all 3 years. Another commenter suggested using a per-beneficiary cap on losses. One commenter requested that CMS provide actuarial data to justify the proposed limits on shared losses.

Response: We are maintaining our proposal to phase in limits on shared losses, measured as a percentage of the ACO's updated benchmark, over the agreement period as follows: 5 percent, 7.5 percent, and 10 percent, respectively across the first 3 performance years for Track 2 ACOs. We believe the proposed limits achieve an appropriate balance between providing ACOs with security about the limit of their accountability for losses while encouraging ACOs to take increasing responsibility for their costs and protecting the Medicare Trust Funds.

Otherwise, we believe commenters' concerns are addressed by policies discussed in other parts of this finale rule. For instance, because we will truncate an assigned beneficiary's total annual Parts A and B FFS per capita expenditures at the 99th percentile as determined for each benchmark year, we are adopting a de facto limit on the amount of shared losses an ACO can incur for care furnished to a single beneficiary.

Final Decision: We are finalizing our proposal under § 425.606 that the amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark: 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program, 7.5 percent in the second performance year, and 10 percent in the third performance year. Further, because we have eliminated the requirement for ACOs under the one-sided model to accept risk in their third performance year, we are not finalizing the proposed provision regarding the limits on shared losses for ACOs transitioning from the one-sided to two-sided model.

h. Ensuring ACO Repayment of Shared Losses

As we discussed in the proposed rule, ensuring that ACOs entering the two-sided model will be capable of repaying us for costs that exceed their benchmark is a critical program requirement. We described examples of financial protection requirements for other entities with which CMS does business.

We proposed a flat 25 percent withholding rate that would be applied annually to any shared savings payment earned by the ACO. We proposed that this withholding would serve as a component of the repayment mechanism that ACOs would need to establish to ensure their ability to repay Medicare for incurred losses. We

proposed that we would apply the withheld amount towards repayment of an ACO's losses. However, we recognized that the 25 percent withholding of shared savings may be inadequate to cover the total amount of shared losses, particularly if an ACO participating in the two-sided model experienced losses in its first year.

In order to more fully ensure that the Medicare program would be repaid in the event that an ACO incurred losses, we proposed that an ACO must demonstrate that it has established a self-executing method for repaying losses to the Medicare program. A detailed discussion of these methods is found in our April 7, 2011 proposed rule (76 FR 19622).

The intent of the proposal was to assure operational simplicity without establishing eligibility requirements that might discourage ACOs with limited risk-bearing experience from entering Track 2. Further, this option offered greater flexibility to ACOs in establishing their repayment mechanism compared to another option we considered, requiring ACOs to use only one of these repayment mechanisms. In that regard, we considered requiring ACOs to obtain a letter of credit in an amount not less than the maximum potential downside exposure for the ACO in any given performance year (for example 5 percent of the benchmark in the first performance year for an ACO entering Track 2, or for a Track 1 ACO entering its third performance year of its initial agreement period).

In the proposed rule, after considering several options for determining the adequacy of an ACO's recoupment mechanism, we proposed that the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of per capita expenditures for assigned beneficiaries from the most recent year available. We believed that requiring ACOs to demonstrate their ability to repay losses at a level below the annual loss sharing limit was potentially equally effective as requiring ACOs to demonstrate their ability to repay the maximum amount of possible losses, but less onerous and also accounted for the limited probability that an ACO would incur the maximum possible losses.

Given the anticipated variation in ACO composition and regional variations in cost, we indicated that we believed the sufficiency of the ACO's repayment mechanism would need to be periodically reassessed to ensure its adequacy.

We further proposed that we would determine the adequacy of an ACO's repayment mechanism prior to its entrance into a period of participation in the Shared Savings Program. We also proposed that an ACO must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it accepts risk, to ensure that it is adequate to cover the anticipated number of assigned Medicare beneficiaries. Under the proposal, an ACO would have been required to maintain this repayment mechanism, ensuring adequate capitalization of funds in the case of some recoupment methods (such as adequately funded escrow accounts or reinsurance coverage), for the duration of the performance year and up until the time when we would need to be reimbursed for any losses by the ACO. We proposed that we would ensure that an ACO maintains an adequate repayment mechanism through monitoring activities.

We further proposed that an ACO would be required, as part of its application, to submit documentation of such a repayment mechanism for approval by us. This documentation would include details supporting the adequacy of the mechanism for repaying the ACO's maximum potential downside risk exposure. An ACO applying for the two-sided model would be required to submit this documentation as part of its initial application. An ACO applying for the one-sided model would also be required to submit this documentation as part of its initial Shared Savings Program application because under the proposal these ACOs would have been required to transition to the two-sided model in their third performance year.

To the extent that an ACO's repayment mechanism does not enable us to fully recoup the losses for a given performance year, we proposed to carry forward unpaid losses into subsequent performance years (to be recouped either against additional financial reserves, or by offsetting shared savings earned by the ACO).

We invited comment on these proposals and on the other options that we had considered.

Comment: A number of commenters expressed concern about the proposed requirement that ACOs establish a self-executing repayment mechanism to cover potential losses. While some of these commenters acknowledged CMS' desire for assurances regarding an ACO's ability to repay losses, they believed that the proposals were too burdensome and would place the ACOs in a difficult financial position. One commenter opposed requiring ACOs to establish a self-executing method for repaying losses, particularly as it may be imposed on individual providers that may lack a choice as to whether to join an ACO based on their relationship with a hospital or health system. This commenter did not believe such physicians should be required to pay for losses. Another commenter suggested that ACO providers and suppliers should bear financial risk proportional to the efficiency of their practice (for example, psychiatrists would bear a lower level of risk). Another commenter mentioned the burden a letter of credit would create for providers and expressed distaste for the mandatory withhold. Several commenters generally expressed doubt that the proposed requirement would ensure that ACOs would be able to repay potential losses.

Others provided comments about the financial burden of the proposed repayment mechanisms, particularly for smaller ACOs that may be unable to meet the solvency requirements. They indicated that it would be very difficult, if not impossible, for ACOs, which would typically include low margin businesses, to be at risk for both the administrative costs associated with forming and operating an ACO and also be subject to underwriting losses. These commenters viewed the proposed 1 percent repayment mechanism as an additional drain on ACOs participating in the Shared Savings Program and therefore recommended that the requirement be removed.

A number of commenters expressed concern about reinsurance as a repayment option. One commenter suggested that reinsurance would be costly and would reduce or eliminate any net payment available to reward the ACO providers/suppliers. This commenter believed that a significant increase in the sharing percentage and the limit on shared savings would be required to make reinsurance a viable repayment approach. Other commenters asked that CMS clarify in the final rule the mechanisms for ACOs to obtain reinsurance. A couple of commenters encouraged CMS to specify a clear mechanism in the final rule for ACOs to obtain reinsurance, such as CMS sponsorship of reinsurance pools for ACO providers or including additional funds in the shared savings payments to ACOs. One commenter suggested that we require ACOs to obtain insurance only from highly rated, State regulated insurance carriers.

Several commenters suggested eliminating the proposed requirement for a repayment mechanism, given the proposed 25 percent withhold, believing it was unnecessary to have both

requirements. On the other hand, as described later in this final rule, a number of other commenters requesting elimination of the proposed 25 percent withhold cited the proposed repayment mechanism as providing sufficient coverage to protect CMS against losses. For example, a commenter indicated that CMS should monitor capital adequacy on an annual basis and rely on the provisions in the proposed rule regarding the requirement to adopt a self-executing repayment method, rather than a withhold, to ensure that ACOs will be able to repay losses to the program.

Some commenters suggested additional alternative approaches that CMS could consider to address concerns about an ACO's ability to pay for losses, for example:

- Allow flexibility for an ACO to determine the magnitude of financial risk it will experience and to determine the most appropriate manner of repayment.
- Allow ACOs to use existing financing mechanisms, used to participate in two-sided models outside of Medicare, to ensure repayment of shared losses under the Shared Savings Program.
- Adjust the repayment method based on the ACO's prior year performance in the Shared Savings Program, or its performance and experience with other payers. One commenter suggested that CMS consider waiving or reducing the repayment mechanism requirements for applicants to the two-sided model, particularly those who have demonstrated experience in managing risk through participation in a Medicaid, State, or private ACO or other payment reforms. In this commenter's view, a track record of managing risk under other programs should reduce CMS' uncertainty regarding the financial viability of the ACO.
- Adopt certain other approaches used by some managed care companies.
- An agreement to recoup losses from future Medicare revenue payments should be required for on-going enterprises (those in existence for 5 or more years of continuous operations). The commenter suggesting this alternative further explained that the repayment term for any losses should be set on a sliding scale of time in proportion to the amount of debt as a percentage of assigned beneficiary per capita expenditures for the most current year results available.

Several comments raised concerns about how ACOs would share losses with their participants. One commenter indicated that liability for losses creates significant operational issues for ACOs and raised questions about how losses would be shared as follows:

- If losses are incurred, how would the liability for sharing those losses be shared?
- Will physicians and other professionals have incentives to participate if they know they may have out-of-pocket liability or would be required to accept Medicare payments at less than traditional Medicare payment rates?
- May the financial obligation for losses be disparately shouldered by ACO participants or ACO providers/suppliers and would this implicate the fraud and abuse laws?

One commenter indicated that recoupment efforts should be directed against the ACO and not its individual primary care physicians.

In addition, a few comments asked us to clarify specific points in the proposal. For example, one commenter simply asked that CMS further clarify the minimum capitalization requirement. Another asked whether there was a minimum reserve requirement, and if so what the amount would be. Another asked how we will evaluate if the proposed methodology and minimum amount are sufficient. Another asked how an ACO should calculate beneficiary assignment when preparing its initial application in order to ensure that the amount of reserves is accurate.

In response to the proposal to carry forward losses into future years, one commenter suggested that this provision should depend on the success of the overall program. As an example, the commenter suggested that if 50 percent or more of the ACOs entering the program under the one-sided model in 2012 see savings in years 1 and 2, then CMS should carry forward losses because there would be a likelihood of achieving savings in a future year. In contrast, if 75 percent or more of ACOs experience losses, then CMS should undertake a review of the entire program to evaluate if there is a fatal design flaw. Further, the commenter suggested that if an actuarial review finds that there are significant deviations from initial assumptions, then CMS should consider forgiving ACOs for any net losses that occurred during the initial 3 year period. Another commenter requested that CMS use its discretion to waive repayments in full or in part and to make other arrangements to address unpaid losses (aside from carrying them forward to the next year).

A few commenters expressed support for the proposed repayment mechanism. Several commenters urged more stringent protections; for instance, one commenter noted that the requirements that ensure an ACO could meet its risk obligation appeared weak in comparison to those for Medicare Advantage plans. Another commenter expressed concern that the financial failure of ACOs could undermine the solvency of physician practices, thereby limiting patient access to care in the ACO's locality and urged additional protections to ensure both ACO solvency and to safeguard beneficiaries, as opposed to just ensuring adequate funds for CMS to recoup losses.

Several commenters expressed support for proposed policies to ensure ACOs maintain an adequate repayment mechanism over time. For example, one commenter recommended that CMS maintain the rule's strong repayment proposals and further suggested that CMS should periodically reevaluate the adequacy of the various repayment mechanisms during the agreement period, believing that it is imperative for CMS to maintain strong solvency protections to protect the Medicare program and beneficiaries, and to counter efforts to shift cost risks to private payers. Another commenter expressed support for a process whereby CMS would, on an annual basis, verify that processes specified in the ACO's application had been implemented and that other program requirements had been satisfied.

Response: We continue to believe that it is a critical program requirement to ensure that ACOs entering a two-sided model are capable of repaying us for costs that exceed their benchmark. We agree with the commenters' concern that it is desirable to protect consumers from disruption of their care due to a financial failure of an ACO. We have experience implementing protections to guard against the financial failure of providers in other parts of the Medicare program. Our proposals took into account our experiences with these other programs and requirements. We further recognize that the Shared Savings Program is a unique, new Medicare program and we want to address commenters' concerns about the burdens of participating in this program to the extent possible. However, in light of a number of other significant changes to the original proposals for the program that we are making in this final rule in order to reduce the burdens for participating ACOs, we continue to believe our proposals to ensure that ACOs are able to pay for any shared losses are reasonable.

In particular, a number of commenters objected to the repayment proposals on the grounds that they were excessive in light of the additional requirement of a

25 percent withhold from shared savings. As discussed in section II.G.2. of this final rule we are not finalizing our proposal to require a withhold of shared savings as a method for helping assure that ACOs could repay any future shared losses.

Another significant change from the proposed rule which we have included in this final rule (discussed in section II.G.1. of this final rule) is that Track 1 of the program is now a one-sided only model (that is, shared savings only) for the entire initial agreement period. During the term of the initial agreement, only those ACOs that voluntarily choose to participate in the Shared Savings Program in the two-sided model under Track 2 will be subject to the repayment rules. We would expect that during the initial stages of the program, these Track 2 ACOs would more likely be larger and/or more experienced ACOs, and thus have the experience, expertise, and/or resources to meet the repayment requirements.

After review of the comments, we are finalizing our proposal to allow ACOs flexibility to specify their preferred method for repaying potential losses, and how it would apply to the ACO participants and ACO providers/suppliers. We continue to believe our proposal provides significant flexibility for ACOs to identify the repayment method that is most appropriate for their organizations. As a result, our policy as proposed, already affords ACOs, particularly smaller ACOs, the choice of the alternative that would be least burdensome for them. For example, larger ACOs that include hospital systems may be able to repay losses from their reserves, whereas, smaller ACOs may prefer to pay for shared losses through reductions to their future FFS payments. Under the approach we are finalizing, during the application process and annually, each ACO participating in Track 2 will be required to demonstrate that it has established a repayment mechanism. As part of this, individual ACOs must specify how the liability for sharing losses would be shared among ACO participants and/or ACO providers/suppliers. We will determine the adequacy of an ACO's repayment mechanism prior to the start of each performance year under the two-sided model.

In this final rule, we are also finalizing our proposal that the minimum amount of the reserves required for an ACO is sufficient to ensure repayment of potential losses equal to at least 1 percent of per capita Medicare FFS Parts A and B expenditures for its assigned beneficiaries. Further, we are clarifying that this amount should be based either on expenditures for the most recent available performance year or benchmark year. We continue to believe this is a reasonable amount that reflects our desire to balance possible financial burden on ACOs with our need for a reasonable assurance that any shared losses could be paid. For example, Track 2 ACOs could be responsible for losses up to a maximum of 5 percent of its benchmark in performance year 1, 7.5 percent in performance year 2, and 10 percent in performance year 3. We believe requiring a reserve of 1 percent is reasonable relative to this level of liability.

We decline to finalize the proposed policy to carry forward losses into future program years (as suggested by one commenter). We believe the final rule includes sufficient protection against ACOs which fail to repay their losses, including the requirement for an ACO to establish a repayment mechanism, and program protections which would allow CMS to terminate an ACO for not fully repaying its losses with the opportunity for the ACO to enter into a corrective action plan to address this failure to meet program requirements.

In addition, as requested by a commenter, we will continue to monitor the program as it is implemented to determine whether program adjustments are needed.

Further, because we will allow ACOs to participate in a shared savings only model for their first agreement period, we are revising our proposal to require only ACOs entering the program's two-sided model (Track 2) or requesting an interim payment under the one-sided model (Track 1) to demonstrate an adequate repayment mechanism.

We are not adopting the comments that suggested a government sponsored reinsurance option, such as CMS-sponsored reinsurance pools for ACOs. ACOs that might want to pursue reinsurance as a repayment mechanism should contact insurers in their individual States to further explore this option.

We are also not adopting other comments that encouraged us to adopt approaches employed by other payers, or to adjust the repayment method based on prior year performance in the Shared Savings Program or performance and experience with private payers. At this time we do not believe such approaches would be feasible since, for example, we would not have readily available information or evaluation criteria about such performance. As explained previously, we believe the 1 percent reserve requirement provides a reasonable balance between minimizing the financial burdens on ACOs, while providing an assurance to the Medicare program that any shared losses will be repaid.

We will further clarify operational questions about the repayment requirement through the application process and other program instructions. Finally, we note that the commenters' concerns that the division of liability for losses among ACO participants and ACO providers/suppliers may implicate certain fraud and abuse laws, except to the extent that those laws are waived.

Final Decision: In this final rule we are retaining our proposed policies under § 425.204 concerning the repayment mechanism to ensure ACO repayment of shared losses. We are finalizing our proposal to allow ACOs flexibility to specify their preferred method for repaying potential losses, and how that would apply to ACO participants and ACO providers/suppliers. During the application process and annually, each ACO under the two-sided model will be required to demonstrate that it has established a repayment mechanism. One-sided model ACOs requesting interim payment must make a similar demonstration at the time of application. We will determine the adequacy of an ACO's repayment mechanism prior to the start of each year under the two-sided model. We are also finalizing our proposal that the repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of total per capita Medicare Parts A and B fee-for-service expenditures for assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. To the extent that an ACO's repayment mechanism does not enable CMS to fully recoup the losses for a given performance year, CMS will not carry forward unpaid losses into subsequent performance years and agreement periods.

i. Timing of Repayment

We proposed that an ACO must make payment in full to CMS of any shared losses within 30 days of receipt of notification of the shared losses.

Comment: Commenters requested that we consider extending this deadline, for example to 60 or 90 or 120 days, stating this would be a more reasonable timeframe given capital restraints on some ACOs. Several commenters suggested offering ACOs the option of paying losses in installments.

Response: In developing the proposed rule, we considered repayment within 30 days to be a timeframe which would benefit ACOs because shared losses would be considered overpayments and under sections 1815(d) and 1833(j) of the Act would begin to accrue interest if not paid within 30 days of the ACO's notification of losses. We appreciate commenters' concerns about the burden that a 30 day requirement could pose to ACOs. We agree that ACOs, composed of many independent participants, may need additional time to gather the amount owed. Accordingly, to address these concerns, we will use our authority under section 1899(f) to waive the requirement under sections 1815(d) and 1833(j) that repayment be made within 30 days, and to extend the deadline for repayment and the date on which interest on shared losses owed by an ACO will start to accrue until 91 days after the ACO receives notification of shared losses. Thus, in order to avoid interest ACOs must make payment in full to CMS within 90 days of receipt of notification of shared losses. Given that commenters' suggestions for extending the repayment deadline ranged from 60 to 120 days, we consider 90 days an appropriate timeframe for ACOs to make the arrangements necessary to repay shared losses.

Final Decision: We are revising our proposed policies under § 425.606(h) concerning timing of repayment of losses. If an ACO incurs shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

j. Withholding Performance Payments

Over the course of its participation in the Shared Savings Program, an ACO may earn shared savings in some years and incur losses in other years. In the proposed rule, we considered the issue of whether the full amount of shared savings payments should be paid in the year in which they accrue, or whether some portion should be withheld to offset potential future losses. For example, under the PGP demonstration, a flat 25 percent withhold applied to annual earned performance payments to guard against losses in future years as well as to provide an incentive for PGPs to continue in the demonstration since the withhold was only released at the end of the demonstration period or when the PGPs were rebased. Under the two-sided model, we proposed that an ACO could use a withhold of its earned shared savings payment as one option for demonstrating an adequate repayment mechanism in the event it incurs shareable losses. We explained that the requirement that ACOs be willing to commit to completing a multiyear agreement to participate in the Shared Savings Program is necessary to ensure that the program achieves its long-term goal of redesigning health care processes, and our proposal to withhold performance payment was designed to reinforce that requirement. Since we wanted to encourage ACOs to participate for the entire term of their agreements, protect the Medicare program against losses, and ensure ACOs have an adequate repayment mechanism in the event they incur losses, we proposed that a flat 25 percent withholding rate would be applied annually to any earned performance payment. Under the two-sided model, we proposed that an ACO may withhold an additional portion of its earned performance payment as a way to demonstrate an adequate repayment mechanism in the event it should incur shareable losses. Furthermore, we proposed that at the end of each agreement period, positive balances would be returned to the ACO. However, if the ACO does not complete its agreement period, the ACO would forfeit any savings withheld.

Comment: Nearly all commenters opposed the proposed 25 percent withhold, suggesting that given the anticipated slow return on investment and potentially high startup and operating costs, it would adversely affect participation or pose financial hardship on ACOs by restricting necessary capital. As one commenter explained, the withhold may hinder ACO investment and reinvestment in infrastructure and program activities that may lead to further improvements in care and care delivery processes. Some commenters suggested the proposed withhold poses a barrier to participation by smaller, rural, safety net, and physician-only ACOs. One commenter considered the need for capital support to be potentially crucial to participation by safety net providers given the proposed withhold. Other commenters suggested that the withhold appears to penalize only the best-performing ACOs while having no impact on poor performing ACOs.

Other commenters questioned the ability of the proposed policy to achieve its aim of protecting CMS against losses and indicated that other proposed protections, such as a self executing repayment mechanism sufficient to cover 1 percent of total per capita expenditures, are more than adequate. Several commenters suggested the withhold is inappropriate for organizations accustomed to managing risk. Others questioned the need for the withhold under the one-sided model, and noted in particular, that the proposed 2 percent net sharing rate may be sufficient to cover CMS' risk of not recovering losses when ACOs transition to the two-sided model. One commenter suggested CMS consider requiring ACOs to have reserves similar to under an insurance model to participate, rather than holding back earned savings.

Several commenters addressed the use of the withhold as a means to encourage full-term participation. One commenter noted this proposal creates a sense that CMS does not trust its provider partners. One commenter stated forfeiture of the withhold for failure to complete the 3 year agreement unfairly punishes ACOs that must withdraw from the program, for example ACOs whose population falls below the required 5,000 beneficiaries.

Commenters typically suggested eliminating the withhold entirely, suggesting it is redundant or unnecessary in light of other proposed requirements (such that ACOs demonstrate an adequate repayment mechanism at the time of application). Several commenters suggested that, at a minimum, the amount of the withhold be reduced, recommending that it not exceed 10 percent of shared savings. In some cases, commenters recommended a temporary reduction in the amount withheld. Several recommended allowing ACOs a choice between a withhold and demonstrating adequate financial reserves to repay losses. Several commenters suggested CMS pay interest on the withheld amount, or clarify in the final rule its intent to pay interest on this amount. Another commenter urged CMS to ensure alignment between the withhold of payment under the Shared Savings Program and the mechanism for repayment under the Innovation Center's potential Advance Payment initiative.

Several commenters suggested alternative policies for linking the withhold to ACO performance. For example, one commenter favored an alternative to the proposed method for calculating shared savings whereby CMS would also use a multi-year metric of savings. This commenter suggested CMS would withhold a portion of annual savings (similar to the proposed 25 percent withhold) and award a net performance payment at the end of the agreement period based on the multi-year metric. This approach could address concerns expressed by several commenters that ACOs may have a financial disincentive to perform high cost procedures or order laboratory tests involving substantial upfront costs, which over time result in improved

health outcomes or savings (such as bariatric surgery or lab tests that lead to better treatment decisions).

Response: We are persuaded by comments recommending elimination of the 25 percent withhold. While we continue to believe that strong mechanisms for repayment of potential losses are necessary, we have concluded that the withhold may be an ineffective mechanism for ensuring repayment of potential losses. As commenters point out, an entity that generates savings in the first or second year is also likely to generate savings in the third year. Therefore, the withhold could serve as a penalty for successful ACOs while doing little to protect the Trust Fund against underperforming ACOs. Further, we agree with the commenters that suggested that other aspects of the program may be sufficient to ensure ACOs repay losses. In particular, we are finalizing the requirement for ACOs to establish a self-executing repayment mechanism, under which ACOs could elect an annual withhold on savings as part of their repayment mechanism. Commenters also noted the potential unintended consequences of using the withhold to encourage ACOs to complete their agreement periods. We are especially concerned that the forfeiture requirement could punish ACOs terminated from the program for circumstances beyond their control. Lastly, we are concerned that the withhold could pose a financial hardship for ACOs by forestalling payment of funds that could support operational costs, and thus, the policy could be a potential barrier to the formation of ACOs.

A smaller withhold, as suggested by some commenters, would not effectively address the aforementioned concerns. Even a smaller withhold could penalize high-performing ACOs or those terminated from the program for legitimate reasons beyond their control and pose a barrier to participation. Further, while we appreciate commenters' concerns about the need for a multi-year measure of savings, to be implemented through a withhold of savings, we decline to implement this approach. We believe that other program requirements offer ACOs sufficient incentive to provide high quality, cost-effective and patient-centered care, while the program's monitoring provisions will enable us to detect ACOs' avoidance of necessary services.

Final Decision: We are revising our proposal to eliminate the 25 percent withhold and the related proposed provision concerning forfeiture of the 25 percent withhold in the event of early termination from the program.

k. Determining First Year Performance for ACOs Beginning April 1 or July 1, 2012

As discussed in Section II.C. of this final rule, we will offer start dates on April 1, 2012 (agreement period of 3 years and 9 months), and July 1, 2012 (agreement period of 3 years and 6 months) for those ACOs that apply and are approved to participate in the Shared Savings Program during 2012. This section describes the methodology for determining shared savings and losses for the first performance year for April 1 and July 1 starters defined as 21 and 18 months respectively. This methodology will consist of an optional interim payment calculation based on the ACO's first 12 months of participation and a final reconciliation occurring at the end of the ACO's first performance year. Such first year reconciliation, taking into account the 12 months covered by the interim payment period as well as the remaining 6 or 9 months of 2013, will allow us to determine the overall savings or losses for the ACO's first performance year.

As we have previously discussed, commenters expressed support for policies allowing for a shorter turnaround period for feedback on quality metrics and shared savings reconciliation. In particular, commenters stressed the importance of shared savings for establishing return on investment, and supporting ongoing operations and likewise achievement of program goals. We agree with commenters about the importance of timely availability of funds.

In this final rule, we are adopting a policy that will enable ACOs with start dates of April 1 and July 1, 2012 to opt for an interim payment calculation as part of their application to participate in the Shared Savings Program. However, ACOs opting for interim payment under either the Track 1 one-sided or Track 2 two-sided model will need to assure CMS of their ability to repay monies determined to be owed upon final first year reconciliation. For ACOs under the two-sided model, their demonstration of an adequate repayment mechanism as part of their entrance into a shared loss arrangement will be sufficient also to assure return of an overpayment of shared savings under the interim payment calculation. ACOs under the one-sided model would, likewise, need to demonstrate an adequate repayment mechanism. We will, therefore, require ACOs entering Track 1 with start dates of April 1 or July 1, 2012, that opt to receive interim payment calculation to demonstrate an adequate repayment mechanism as under Track 2 to repay any overpayment of shared savings. This requirement will not apply to Track 1 ACOs with start dates of April 1 or July 1, 2012, that do not elect interim payment calculation.

(1) Interim Payment Calculation

In the interim payment calculation, we will determine shared savings and losses based on the ACO's first 12 months of program participation. Quality performance will be assessed as described in section II.F of this final rule. Quality performance for the interim payment calculation will be based on GPRO quality data reported for calendar year 2012. (Claims-based and CAHPS measures will be calculated for informational purposes for 2012.) We believe that quality data based on CY 2012 is an appropriate measure of ACO's quality performance for determining interim payment because ACOs beginning April 1 and July 1 will have submitted GPRO data for CY 2012 as part of demonstrating their eligibility for the 2012 PQRS incentive.

The same methodology for determining shared savings and losses, as specified in section II.G. of the final rule will apply to this interim payment period. More specifically, we will apply the methodology as stated elsewhere in section II.E. of this final rule for assigning beneficiaries and in section II.G. of this final rule for determining shared savings and losses (including calculating and risk adjusting expenditures, establishing the MSR and MLR, and determining shared savings or losses) based on the ACO's first 12 months of performance with the exception of calculating the update to the benchmark. For purposes of interim payment calculation, the historical benchmark will be updated (and adjusted for changes in beneficiary risk as described below) for the period which includes the ACO's first 12 months of participation.

Depending on the results of the interim payment calculation, the ACO may receive a shared savings payment or, in the case of ACOs under the two-sided model, be liable for shared losses. ACOs will be notified of shared savings or losses. Unless stated otherwise, program requirements which apply in the course of a performance year apply to the interim payment period.

(2) First Year Reconciliation

For ACOs beginning April 1 or July 1, 2012, the reconciliation for the first performance year will occur after the completion of the ACO's first performance year, defined as 21 months

for April 1 starters and 18 months for July 1 starters; that is at the conclusion of CY 2013. First year reconciliation will account for the entire 18 or 21 month period. Our assignment methodology and calculations of the updated benchmark and performance year expenditures will take into account the overlap between the ACO's first 12 months of performance and CY 2013. To simplify the summation of performance year expenditures and the updated benchmark for the two overlapping timeframes, we will state figures for first year reconciliation in the aggregate, rather than on a per capita basis. Quality performance for first year reconciliation will be based on complete and accurate reporting, for all required quality measures, for CY 2013.

The following steps outline the methodology for adjusting the ACO's interim payment determination to account only for the 6 or 9 months included in CY 2012 and summing it with the ACO's CY 2013 performance:

- *Assignment:* First performance year expenditures will be summed over beneficiaries assigned in two overlapping 12 month assignment windows. The first window will be the beneficiaries assigned for the first 12 months used for interim payment calculation. The second window will be beneficiaries assigned for CY 2013.
- *Aggregate expenditures for the first performance year:* We will sum aggregate interim payment expenditure dollars to account for the ACO's first 6 or 9 months during CY 2012 for beneficiaries assigned for the interim payment calculation with aggregate dollars calculated for CY 2013 for beneficiaries assigned for CY 2013.
- *Risk adjustment:* Risk adjustment for beneficiaries assigned in CY2013 will be performed as it would be for a normal calendar performance year, based on a comparison of risk scores for continuously assigned and newly assigned beneficiaries to BY3 risk scores. We will identify beneficiaries from the CY 2013 assignment window as either continuously assigned or newly assigned relative to the previous calendar year. We will base risk adjustment for the 6 or 9 months of performance year one (PY1) that lie within CY 2012 on the same adjustment factor identified for purposes of the interim payment calculation. Respective risk adjustment factors will be used to adjust updated benchmark dollars to the performance year risk level.
- *Updating the benchmark:* We will establish an updated benchmark for the first performance year stated in aggregate dollars. Based on the assigned beneficiary population for the ACO's first 12 months of performance we will calculate the ACO's interim updated benchmark for the average fraction of expenditures incurred in the latter 6 or 9 months of CY 2012, and restate it in terms of aggregate expenditures. We will add to that an updated aggregate benchmark representing CY 2013.
- *Determining shared savings/losses:* We will determine the savings percentage for the entire 18 or 21 month performance year by comparing summed expenditures to summed updated benchmark dollars. We will compare this percentage to the ACO's MSR or MLR as stated in terms of a percentage. For ACOs under the one-sided model, we will compare the PY1 savings percentage to an MSR obtained from Table 6 by counting all beneficiaries who have been assigned in at least one of the two assignment windows for PY1. For ACOs under the two-sided model, we will compare the PY1 savings percentage to a flat 2 percent MSR or MLR.

The reconciled amount of the shared savings or losses owed to or by the ACO for the performance year will be net of any interim payments of shared savings or losses. CMS may determine that it owes the ACO additional shared savings payments or received an overpayment of shared losses from the ACO. Conversely, following the first year reconciliation, CMS may determine the ACO has been overpaid for shared savings or owes additional shared losses. In either of these cases, the ACO would owe CMS the difference. ACOs will be notified of shared savings or losses, or other monies determined to be owed upon first year reconciliation. Unless stated otherwise, program requirements which apply in the course of a performance year apply to the ACO's first year reconciliation.

(3) Repayment Mechanism for ACOs Electing Interim Payment Calculation

An interim payment system therefore raises a concern about the ability of an ACO to repay CMS in the event that first year reconciliation results in a payment due to CMS. As described previously, ACOs under the program's two-sided model must demonstrate that they have a self-executing mechanism for repaying losses equal to at least 1 percent of the ACO's Medicare fee-for-service Parts A and B total per capita expenditures for its assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. However, as discussed in this section, the repayment mechanism would generally apply only to ACOs under the two-sided model.

We believe this same repayment mechanism is also sufficient to ensure that ACOs in the one- and two-sided models that opt for interim payments can repay CMS in the event that the ACO owes CMS money after first year reconciliation. ACOs must indicate in their application whether they are requesting an interim payment calculation. Therefore, similar to the requirements for two-sided model ACOs in this final rule, we will require those ACOs that choose to request an interim payment during their first performance year, regardless of Track, to demonstrate as part of their application that they have an adequate repayment mechanism in place.

Another issue raised by interim payments is the deadline for paying shared losses, as well as the deadline for refunding other monies determined to be owed by the ACO after first year reconciliation. As described previously in this final rule, ACOs under the program's two-sided model will be required to repay losses within 90 days of receipt of notification of losses. Therefore, to align the interim payment policy with our policy regarding payment of shared losses, we will require that any monies determined to be owed by the ACO after first year reconciliation must be repaid by the ACO, in full, within 90 days of receipt of notification.

Final Decision: We are adopting a policy under § 425.608 that will enable ACOs with start dates of April 1 and July 1, 2012 to opt for an interim payment calculation, to determine shared savings and losses, at the end of their first 12 months of program participation. Unless stated otherwise, the same methodology for determining shared savings and losses that applies under §§ 425.604 and 425.606 will apply to this interim payment calculation. For ACOs with start dates of April 1 or July 1, 2012, reconciliation for the first performance year will occur after the completion of the ACO's first performance year, defined as 21 months for April 1 starters and 18 months for July 1 starters. ACOs must indicate in their application whether they are requesting an interim payment calculation. ACOs that opt for interim payment during their first performance year must demonstrate as part of their application that they have an adequate repayment mechanism in place, consistent with the requirements for two-sided model ACOs in this final rule. ACOs that generate shared losses under the interim payment calculation must repay such losses within 90 days of notification of losses. Further, any monies determined to be owed by an

ACO after first year reconciliation, whether as a result of additional shared losses or an overpayment of shared savings, must be repaid to CMS, in full, within 90 days of receipt of notification.

3. Impact on States

In the proposed rule, we emphasized that, under our proposal for a two-sided model under the Shared Savings Program, the Medicare program would retain the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share risk against the benchmark would be solely between the Medicare program and the ACO. We did not intend that any of our proposals concerning the Shared Savings Program would render States responsible for bearing any costs resulting from the operation of this program. However, we noted that each State has its own insurance and risk oversight programs and that some States may regulate risk bearing entities, such as the ACOs participating in the two-sided model under the Shared Savings Program. Accordingly, we sought comment on whether any of our proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws, the adequacy of those provisions that we have set forth, and the ways that we can work with ACOs and States to minimize the burden of any additional regulation.

Comment: A few commenters expressed concern that the two-sided model could trigger some State insurance laws, or that States could decide to subject ACOs under the program's two-sided model to State licensure requirements (for example, requiring the ACO to obtain an HMO license). In particular, a few commenters expressed concern about potential overlap between State insurance requirements and the proposed requirements to demonstrate an adequate repayment mechanism (including establishing lines of credit, recoupment of losses from future FFS payments, and obtaining reinsurance sufficient to account for 1 percent of per capita expenditures for the assigned beneficiaries).

A few other commenters were concerned that State laws may serve as a barrier to ACO formation due to the added expense of compliance with State regulation of ACOs. Several commenters requested clarification on or recommended Federal protection from these State laws, for instance by Federal preemption of State insurance laws, a safe harbor or otherwise discouraging assertion of authority by State insurance agencies over ACOs that participate in the Shared Savings Program. One commenter suggested CMS promote a uniform national privacy requirement to preempt potentially conflicting State laws, particularly surrounding quality, data use, information sharing, and privacy protections.

One commenter wanted CMS to ensure that States will ''not require ACOs to obtain an HMO license * * * to meet financial and repayment requirements''. On the other hand, several commenters explained that State licensed organizations that accept insurance risk must comply with strict financial solvency criteria, and were supportive of State regulation of ACOs. Another commenter suggested that ACOs that assume risk for losses and/or perform other health plan functions that are regulated at the State level (for example, subject to State financial and consumer protection standards) should have to meet the same standards required of health plans. These standards include financial requirements (for example, capital, reserve and solvency requirements); network requirements (for example, ensuring access to adequate numbers and types of providers); filing, reporting and disclosure requirements; and quality improvement requirements, including accreditation standards and other consumer protection standards. The commenter expressed a concern that if ACOs are not subject to the same standards as heath plans, then consumers receiving care from an ACO may have less access to care, receive care of lesser quality, be faced with increased costs, and/or be more vulnerable to discontinuation of coverage if unforeseen events occur, such as a flu pandemic or similar disaster impacting the health care system. One commenter suggested that the proposed 25 percent withhold and repayment mechanism may not be necessary for ACOs complying with State financial solvency requirements, but should be required for ACOs that are not licensed to assume both professional and institutional risk by the State in which they operate.

Several commenters asked that CMS address whether Federal laws would preempt State laws that might conflict with the intent of the regulation. One commenter stated that without such preemption there could be barriers to clinical integration. One commenter suggested that CMS provide a list of States that either currently recognize or authorize ACOs under their State laws, or have pending legislation to recognize ACOs.

One commenter expressed concern that this regulation would override State and local protocols concerning ambulance transportation. The commenter was concerned that ambulances would be required to deliver patients to ACO participants instead of the closest or most appropriate facility.

Another commenter recommended that ACOs be exempt from State malpractice laws so that the burden of malpractice insurance and litigation costs are not added to the already significant cost of forming and maintaining an ACO. This commenter did not believe such protections for ACOs would preclude patients from pursuing claims for malpractice against ACO participants or from seeking discovery directly from such participants under existing State laws.

Another commenter urged medical liability protections for physicians complying with ACO guidelines, such as criteria for utilizing diagnostic imaging. The commenter recommended the following approaches:

- Deem an ACO and/or ACO-participating physician to be an employee of the Public Health Service for purposes of any civil action that may arise from ACO-related services. The commenter stated that this approach would require patients alleging malpractice to pursue their claim under the Federal Tort Claims Act.
- Allow physicians to introduce the relevant ACO guidelines into evidence as an affirmative defense to any medical liability claim.
- Establish a standard of proof of clear and convincing evidence for any medical liability lawsuit in which a physician utilized ACO guidelines.

Another commenter suggested that CMS structure the program to be flexible enough to facilitate State and local initiatives.

Finally, a commenter, reported that its State department of insurance indicated that the proposed rule does not implicate any State insurance laws.

Response: In the proposed rule we did not make a proposal regarding these State-level issues but instead, we sought comment on whether any of our proposals for the two-sided model in particular, or the Shared Savings Program in general, would trigger the application of any State insurance laws, the adequacy of those provisions that we have set forth, and the ways that we can work with ACOs and States to minimize the burden of any additional regulation.

We do not believe it would be appropriate to subject ACOs to the same standards as health plans as a way to

ensure that beneficiaries receiving care from an ACO do not have less access to care or receive care of lesser quality. ACOs that will be participating in the Shared Savings Program are very different from health plans. Further, these regulations, which are based on Federal law, would not preempt State insurance laws that govern providers within individual States, nor would they override State and local protocols concerning ambulance transportation. In addition, we are not adopting the comments related to the application of the malpractice laws, including the recommendation that ACOs be exempt from State malpractice laws.

At this time, we are not able to provide a list of States that currently recognize or authorize ACOs under their State laws, or have pending legislation to recognize ACOs. We believe it would be best for those interested in the Shared Savings Program to obtain such information directly from their individual State insurance agency.

Final Decision: We would emphasize that under the Shared Savings Program, the Medicare program retains the insurance risk and responsibility for paying claims for the services furnished to Medicare beneficiaries, and that the agreement to share potential losses against the benchmark would be solely between the Medicare program and the ACO. We will further consider these issues in future rulemaking should we become aware of any unexpected program issues that render States responsible for bearing any costs resulting from the operation of this program.

H. Additional Program Requirements and Beneficiary Protections

1. Background

Section 1899 of the Act (b)(2)(H) of the Act requires ACOs to demonstrate that they meet patient-centeredness criteria specified by the Secretary. We believe that one important aspect of patient centeredness is patient engagement and transparency. Therefore, we discuss in this section certain requirements for ACOs that we believe will protect beneficiaries by ensuring patient engagement and transparency, including requirements related to beneficiary notification and outreach, marketing, and public reporting.

Section 1899 of the Act sets forth a number of requirements for ACOs. In addition, section 1899(a)(1)(A) of the Act authorizes the Secretary to specify additional criteria that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. In this section, we discuss how ACOs will be monitored with respect to program requirements and what actions will be taken against ACOs that are not in compliance with the requirements of the Shared Savings Program.

Programs that include incentives to reduce costs for care may result in unintended consequences such as avoidance of at-risk patients, ''stinting'' on care, fraud and abuse, overutilization, deliberate delay in claims submission, and other such activities. We must ensure that beneficiaries continue to receive high quality and appropriate care, and that providers do not put beneficiaries or the Trust Fund at risk. In this section we also discuss our program integrity requirements, which we believe will help to deter inappropriate conduct by ACOs, while protecting the Trust Fund and the integrity of the Shared Savings Program and the Medicare program as a whole.

2. Beneficiary Protections

a. Beneficiary Notification

As we discussed in the proposed rule, the statute does not mandate that ACOs should provide information to beneficiaries about the Shared Savings Program. Such information could include whether the beneficiaries are receiving services from an ACO participant or ACO provider/supplier, or whether the beneficiaries' expenditure and quality data may be used to determine the ACO's eligibility to receive a shared savings payment. However, we believe the Shared Savings Program lays the foundation for a beneficiary-centered delivery system that should create a strong relationship between beneficiaries and care providers based, in large part, on patient engagement in the new care system. Such engagement would be more difficult if beneficiaries are not aware of the new delivery system available through ACOs, or the possibility of their being data used to assess the ACO's performance. In short, we believe transparency must be a central feature of the Shared Savings Program.

In the proposed rule, we stated that we intended to develop educational materials and other forms of outreach, to provide beneficiaries with timely, accurate, clear, and understandable information about the Shared Savings Program. Additionally, we indicated that we would update the annual Medicare & You Handbook to contain information about the Shared Savings Program and ACOs.

In the proposed rule, we proposed specifically to require ACO participants to post signs in their facilities indicating their ACO provider's/supplier's participation in the Shared Savings Program and to make available standardized written information developed by CMS to the Medicare FFS beneficiaries whom they serve. ACO participants would be required to provide standardized written notices of both their ACO provider's/supplier's participation in the Shared Savings Program and the potential for CMS to share beneficiary identifiable data with the ACO.

Likewise, we discussed whether beneficiaries should be made aware when an ACO participant does not renew its agreement at the end of the agreement period, or an ACO's participation agreement has been terminated. Thus, we proposed that ACOs be required to provide beneficiaries notice in a timely manner if the ACO participant or ACO provider/supplier will no longer be participating in the Shared Savings Program. We proposed the notice should include the effective date of the termination of the ACO agreement.

For a complete discussion of these notification proposals and rationale, please refer to the proposed rule published April 7, 2011 (76 FR 19567).

Comment: Many commenters supported our proposal to require ACO participants to notify FFS patients at the point of care that their ACO provider/supplier is participating in this Shared Savings Program. Some suggested CMS collaborate with stakeholders to educate beneficiaries about ACOs and the program and to seek stakeholder input on the materials CMS intends to provide, given the complexities of the program. Some suggested ensuring that language is culturally and linguistically appropriate and addresses low health literacy levels. Others suggested notices should include a detailed explanation of the expectations for patient engagement under the Medicare Shared Savings Program, and the ability of patients to receive care outside the ACO if they wish. Others suggested that ACOs be required to obtain the signature of the beneficiary in order to provide a mechanism for monitoring compliance with this requirement.

Commenters varied in their opinion of whether notification of the program should come from the ACO or CMS. One commenter suggested first contact should be from practitioners as trusted partners in the beneficiary's care, rather than from CMS. Other commenters suggested that CMS should ''bear the financial responsibility for such a

program'' and that ''since the Medicare program has created a strong relationship with its beneficiaries, it is more appropriate that the Medicare program take all responsibility for notifying beneficiaries of the benefits and opportunities of receiving care through an ACO.'' Some suggested that CMS send a letter to a participating PCP's active Medicare patients on an annual basis notifying them of the potential use of their data to assess ACO performance, and that all communications to beneficiaries should be written in ''plain English''.

Conversely, some commenters strongly objected to the proposed notification requirements for ACOs, suggesting that signs, even if developed by CMS, would not be able to convey the complexities of the program and would be ''confusing and annoying'' to beneficiaries as well as ''onerous and burdensome'' to ACOs. A health care public policy center criticized the sign proposal as ''costly, of unproven value, and duplicative given the requirement to provide written information, and therefore contributing to the problem of unnecessary administrative and financial burdens on ACOs.''

Response: We agree with those commenters who advocated that we retain a notification policy in this final rule. We believe that our proposal to inform beneficiaries at the point of care was tested and successfully employed in the PGP demonstration, and did not prove to be ''annoying'' or ''confusing'' to beneficiaries. Although we appreciate one commenter's concerns that the sign proposal might be costly, of unproven value, and duplicative, we believe that posting signs will serve the purpose of calling the attention of beneficiaries to the existence of the ACO and the choice of the ACO participant and its ACO providers/suppliers to participate in it, ultimately resulting in increased transparency and the opportunity for improving beneficiary engagement in this care delivery model. We believe that it is useful and important for every fee-for-service beneficiary to know they are receiving services from participants in such a program, even those beneficiaries whose data will not ultimately be used to assess the ACO's performance. This is because ACOs are intended to develop special methods for coordinating care and improving quality that should affect the care of every beneficiary and improve the engagement of the beneficiary as a consumer of health care, whether that beneficiary is ultimately ''assigned'' to the ACO or not. The presence of signs and written materials will provide a useful initial notification for every beneficiary and that could encourage beneficiaries to raise questions and engage in discussions with the physicians and other providers about the ACO and its potential effects on their care and to become a more active consumer and partner in the care delivered. Nor should posting signs be inappropriately burdensome, since CMS will develop appropriate language and there will be a limited number of locations in each ACO in which the signs will need to be posted. Finally, we believe that the notice should appropriately come from the ACO participant and its associated ACO providers/suppliers because this is the first and most immediate point of contact with the beneficiary. Therefore, we believe that it is appropriate to finalize the requirement that the ACO agree to post signs in the facilities of ACO participants indicating the ACO provider's/supplier's participation in the Shared Savings Program and make available standardized written notices to Medicare FFS beneficiaries whom they serve.

We agree with the recommendation from commenters suggesting we ensure the use of ''plain writing'', and we would note that President Obama signed the *Plain Writing Act of 2010* on October 13, 2010, which is intended to promote clear Government communication that the public can understand and use.'' We will incorporate the requirements of the Plain Writing Act in all CMS communications and standardized language regarding the Shared Savings Program. We will also clarify that beneficiary communications, such as notifications of provider participation in an ACO in the Shared Savings Program, must meet the applicable marketing guidelines described later in this section.

Final Decision: We are finalizing our proposal to require ACO participants to post signs in their facilities indicating their associated ACO provider's/supplier's participation in the Shared Savings Program and to make available standardized written notices developed by CMS to Medicare FFS beneficiaries whom they serve. All standardized written information provided by CMS will be in compliance with the Plain Writing Act of 2010. We are clarifying that the standardized written notices must be furnished in settings in which fee-for-service beneficiaries are receiving primary care services.

Additionally, as we noted in the proposed rule, under a retrospective assignment methodology it would not have been possible for ACOs to notify beneficiaries of the ACO's participation in advance of the period in which the beneficiary may seek services from an ACO participant or ACO provider/supplier. We believe the revised policy of preliminary prospective assignment with retrospective reconciliation that we are establishing in section II.E. of this final rule gives ACOs the information necessary to provide advance notice, if the ACO so chooses, to some beneficiaries who have previously received services from ACO providers/suppliers and who are likely to continue to do so. Specifically, we are revising our policy such that ACOs may choose to provide notification of their participation to the beneficiaries who appear on the preliminary prospective assignment list and quarterly assignment lists (described in section II.D. of this final rule).

Finally, to minimize beneficiary confusion and reduce burden on ACOs and its ACO providers/suppliers, we are modifying our rule such that in instances where either an ACO does not renew its agreement at the end of the agreement period, or an ACO's participation agreement is terminated, ACOs will not be required to provide beneficiaries notice that the ACO, its ACO participants and its ACO providers/suppliers will no longer be participating in the Shared Savings Program. Similarly, ACO participants and ACO providers/suppliers that terminate their participation in an ACO will not be required to provide such notice to beneficiaries. All beneficiary notification and signage are included in the definition of ''marketing materials and activities'' and must comply with applicable marketing requirements described later in this section.

b. ACO Marketing Guidelines

We realize that care coordination is an important component of the Shared Savings Program; however, the potential for shared savings may be an incentive for ACOs, ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO's activities to engage in marketing behavior that may confuse or mislead beneficiaries about the Shared Savings Program or their Medicare rights.

As an aspect of patient centeredness, we stated in the proposed rule we believe it is appropriate and consistent with the purpose and intent of the statute to limit and monitor the use of beneficiary communications specifically related to the ACO operations or functions as well as ACO marketing activities and materials to ensure that such communications and marketing by ACOs are used only for appropriate purposes, such as notification that a beneficiary's health care provider is

participating in the ACO, issuance of any CMS required notices, or notification of provider or ACO terminations. We therefore proposed a definition of ACO marketing materials and activities and proposed that CMS approve materials or activities, or any revisions to previously approved materials in advance of their use. We proposed that failure to comply with marketing requirements could result in a CAP or termination, at our discretion. For a complete discussion of these notification proposals and rationale, please refer to (76 FR 19642).

Comment: Several beneficiary advocacy organizations submitted comments strongly supporting our proposed marketing guidelines. They shared our concern that beneficiaries could be misled into thinking that an ACO is similar to a managed care organization and that they must receive services some or all services from the ACO participants and associated ACO providers/suppliers. These commenters also raised concerns that beneficiaries could be targeted by aggressive marketers seeking to take unfair advantage of them. Additionally, some commenters offered specific suggestions for strengthening our guidelines such as—

- Making approval of an ACO's application to the program dependent on approval of their marketing materials;
- Expanding the definition of marketing materials and activities to include marketing via social media.
- Providing beneficiary notification in ''plain'' English.

In contrast, providers and provider advocates questioned the necessity and feasibility of our proposed marketing guidelines. These commenters disagreed that there is any significant potential for beneficiaries to be misled and noted that to require approval of marketing materials in advance imposes a financial and operational burden on the ACO. Some commenters posited that ACOs should be allowed to communicate with beneficiaries as necessary without any prior approval because physicians have long-standing relationships with their patients, families and the communities they serve, and their honesty with their patients is critical to maintaining open, positive relationships. These commenters recommended reducing the burden imposed by our proposal by, for example:

- Placing a limitation on review and approval of materials to those used specifically to notify beneficiaries of a provider's participation in an ACO and to describe the Shared Savings Program in addition to the notification informing beneficiaries of their opportunity to decline data sharing.
- Providing templates or model language for ACOs to use.
- Implementing a ''file and use'' method similar to the one used in the MA program and requiring the ACO to certify compliance with marketing requirements;
- Permitting ACOs to use outreach materials if they have been approved by a Regional Health Improvement Collaborative (RHIC) or if they have been developed and issued jointly with an RHIC.

Response: The wide range of comments demonstrates the importance of this topic to stakeholders, and the importance of balancing beneficiary protection with the burden marketing requirements imposed on potential ACOs. We agree with commenters that our definition of marketing materials should be refined in order to offer additional beneficiary protections. We agree with commenters that social media can be used as a marketing tool and therefore will modify our definition of ''marketing materials and activities'' to include social media, such as Twitter or Facebook.

We are also sensitive to the operational burden imposed by our proposal that the ACO seek prior approval before the use of any marketing materials. We decline the commenter's suggestion to make an ACO's application approval dependent on approval of marketing materials because it would not address the use of new or revised marketing materials and activities after the approval of an ACO's application to participate in the Shared Savings Program. In light of the comments, this final rule provides that marketing materials and activities may be used or conducted 5 business days following their submission to CMS, provided that the ACO certifies compliance with applicable marketing requirements and CMS does not disapprove the marketing materials and activities. This final rule further provides that marketing materials and activities are deemed approved after expiration of the initial five day review period, but permits CMS to disapprove marketing materials and activities at any time, including after the expiration of the initial 5 day review period. The ACO, ACO participant, or ACO provider/supplier, as applicable, must discontinue use of any marketing materials or activities disapproved by CMS and may be sanctioned for using disapproved marketing materials and activities.

We disagree with the commenter who suggested that there is little potential for marketing materials and activities to mislead beneficiaries. To ensure the accuracy of marketing materials, this final rule imposes a requirement that marketing materials and activities must not be inaccurate or misleading. In addition, we will make template language available for certain marketing materials and require that such template language be used when available. We agree with commenters that it is desirable for marketing and notification materials to be provided in ''plain writing'' according to the definition of the term ''plain writing'' which means writing that is clear, concise, well-organized, and follows other best practices appropriate to the subject or field and intended audience. We note that the Plain Writing Act of 2010, signed by President Obama on October 13, 2010, applies only to Government communications. To the extent that CMS supplies templates or model language for ACOs to use in marketing materials, we will ensure it complies with the Plain Writing Act of 2010.

In response to commenters recommending limiting review of only certain marketing materials and activities, we clarify that our proposed definition of marketing materials and activities includes materials ''used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers *regarding the Shared Savings Program.*'' Additionally, our definition of marketing materials and activities excludes materials that do not include information about the ACO, its ACO participants or its ACO providers/suppliers.

Comment: Commenters recommended that CMS prohibit certain behaviors such as discriminatory marketing directed at certain types of beneficiaries or beneficiaries with certain health profiles, marketing that misleads or confuses beneficiaries about benefits and services, making claims that the ACO is recommended or endorsed by Medicare. Commenters recommended modifying the definition of ''marketing materials and activities'' to remove the exception for ''informational materials customized or limited to a subset of beneficiaries,'' stating it creates a significant loophole for ACOs to engage in discriminatory behaviors.

Response: We understand the commenters' concerns and agree that targeting certain types of beneficiaries including beneficiaries with certain health profiles or beneficiaries with certain racial or ethnic profiles or with language barriers could be used in some circumstances to mislead beneficiaries and should be prohibited as discriminatory marketing. However, we

also believe that some targeted materials are necessary for care coordination. For example, an ACO may send materials targeted to heart patients because they have a specialized heart facility that can coordinate the care of such individuals. Requiring such materials to be sent to all beneficiaries would be less effective and imposes an additional financial burden on the ACO. Thus, where targeted materials promote beneficiary access and care coordination, they likely do not constitute discriminatory marketing. Because we do not believe that all targeted materials are necessarily discriminatory, we are not revising the definition of ''marketing materials and activities'' as suggested by the commenters. We are instead modifying the marketing requirements to provide that marketing materials and activities must not be used in a discriminatory manner or for discriminatory purposes.

Final Decision: We are finalizing the definition of marketing materials and activities without substantive change at § 425.20 of this final rule. We note that the definition is revised to include language proposed in the preamble that was inadvertently omitted from the proposed regulation text. Accordingly, § 425.20 excludes from the definition of marketing materials or activities those materials and activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

Further, this final rule allows ACOs to use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all applicable marketing requirements. We have revised the regulation to specify that all marketing materials and activities must use template language when available, must comply with the prohibition set forth at § 425.304(a) regarding certain beneficiary inducements, must not be used in a discriminatory manner or for discriminatory purposes, and must not be inaccurate or misleading. Materials will be provided in ''plain'' language that is easily comprehensible, clear, concise, well organized, and complies with requirements of the Plain Writing Act of 2010.

Finally, if ACOs are found not in compliance with marketing guidelines, they will be subject to penalties as discussed later in this section of the final rule.

c. Public Reporting and Transparency

Increasingly, transparency of information in the health care sector is seen as a means to facilitate more informed patient choice, offer incentives, and feedback that help improve the quality and lower the cost of care, and improve oversight with respect to program integrity. While the Act did not include a specific requirement for public reporting and transparency related to the Shared Savings Program, improved transparency would support a number of program requirements. In particular, increased transparency would be consistent with and support the requirement under section 1899(b)(2)(A) of the Act for an ACO to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it.

Therefore, as stated in the proposed rule, we believe it is desirable and consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's operation and performance to be transparent to the public. We proposed that certain information regarding the operations of the ACO would be subject to public reporting to the extent administratively feasible and permitted by law. We proposed that each ACO must be responsible for making this information available to the public in a standardized format that we will make available through guidance. This requirement would be included in each ACO's agreement. For a more complete discussion of these proposals and rationale, please refer to (76 FR 19653).

Comments: Numerous commenters wrote in support of public reporting and transparency but varied in their recommendations about how the reporting should occur. A few commenters suggested expanding public reporting beyond what was proposed. Some commenters supported ACOs reporting the data rather than CMS. However, other commenters believed that the cost and administrative burden of asking ACOs to report measures seemed unnecessary and possibly less effective than making CMS responsible for public reporting. One commenter suggested CMS work with states to develop public reporting sites. One commenter stated that both CMS and the ACO should report the data. A few recommended that ACOs be allowed some flexibility in how the reporting occurs in order to best meet the needs of their patients. A few commenters suggested public reporting not occur until the second or third year to allow ACOs to develop the necessary infrastructure and expertise. We received few comments regarding whether additional information should be required to be publicly reported by ACOs with a two-sided model. A few commenters suggested that ACOs be allowed to review and verify CMS data before the information is released.

Response: We believe it is consistent with section 1899(b)(2)(A) of the Act for several aspects of an ACO's operation and performance to be transparent to the public. Public reporting also supports the mandate for ACOs to be willing to ''become accountable for the quality, cost, and overall care'' of the Medicare beneficiaries assigned to it. Reports on ACO quality and cost performance will hold ACOs accountable and contribute to the dialogue on how to drive improvement and innovation in health care. Public reporting of ACO cost and quality measure data would improve a beneficiary's ability to make informed health care choices, and facilitate an ACO's ability to improve the quality and efficiency of its care. We believe publicly reporting certain ACO quality data on the Physician Compare Web site is a good first step toward Shared Savings Program transparency, consistent with comments and other quality program efforts. The mechanism for public reporting of other quality measures, such as measures of patient experience and claims- and administrative-based measures, will be addressed in guidance.

Final Decision: We are finalizing our proposal for public reporting as outlined in § 425.308. Consistent with the proposed regulation text, the final public reporting provision requires ACOs to publicly report the identity of each member of the governing body, not just the ACO participants.

We expect that the reporting of quality performance standards will align with the proposed new public reporting requirements under the Physician Quality Reporting System (76 FR 42841). Specifically, because an ACO will be considered to be a group practice under the Physician Quality Reporting System GPRO under the Shared Savings Program, we intend to report ACO quality performance GPRO measures on Physician Compare along with the performance of all other PQRS group practices. However, we note that this modification is contingent upon the final policies regarding public reporting under the PQRS, which will be announced in the CY 2012 Physician Fee Schedule final rule that will be issued later this year. We will issue guidance to provide ACOs with guidelines regarding public reporting of the quality performance scores.

3. Program Monitoring

a. General Methods Used To Monitor ACOs

In implementing other Medicare programs, including MA and the Medicare Prescription Drug programs,

we have gained extensive experience in monitoring organizational, provider, and supplier behavior with respect to compliance with the Medicare program and program integrity requirements, quality measurement, avoidance of particular types of beneficiaries, overutilization, and claims submissions. General monitoring methods can be used, for example, to assess whether the ACO provider/suppliers have been stinting on care provided to beneficiaries assigned to the ACO in an effort to artificially create savings to obtain a shared savings payment, or over utilizing items and services furnished to beneficiaries who are not assigned to the ACO in order to make up revenues it may no longer be receiving due to other efficiencies or to assess if an ACO is steering beneficiaries through selective billing for the purpose of affecting shared savings and losses. A number of factors may trigger our heightened oversight of ACOs by us, including conduct that may form the basis for terminating the ACO agreement described in this section II.H.5 of this final rule. Given the goals of the Shared Savings Program, we anticipate particularly close examination of ACOs that incur large losses.

In the proposed rule, we proposed to employ many of the methods we have developed for purposes of the MA and Medicare prescription drug programs to monitor and assess ACOs, ACO participants, and ACO providers/suppliers for noncompliance with statutory and regulatory eligibility and other program requirements. We proposed that the methods we could use to monitor ACO performance may include, but are not limited to the following:

- Analysis of specific financial and quality data as well as aggregated annual and quarterly reports.
- Site visits.
- Collection, assessment and follow up investigation of beneficiary and provider complaints.
- Audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits).

If based upon the results of our monitoring activities we conclude that the ACO may be subject to termination, we proposed to use our discretion to take any or all of the following actions prior to termination of the ACO from the Shared Savings Program:

- Provide a warning notice to the ACO describing the issue of concern.
- Request a CAP from the ACO.
- Place the ACO on a special monitoring plan.

We sought comment on additional actions or sanctions that may be appropriate prior to termination.

Comment: Some commenters agreed that a number of beneficiary protection policies within the ACO program, including rules around contacting the beneficiaries directly, monitoring avoidance of at-risk beneficiaries, monitoring beneficiary and provider complaints, record retention, termination, payment structure within the ACO, and monitoring quality metrics were needed to help avert any unintended consequences to beneficiaries.

Some commenters suggested additional protections were necessary, stating that our proposed monitoring methods lacked appropriate safeguards and operational details necessary to create a comprehensive program that is quality driven. Specifically, commenters suggested that the ACO should have a provider network that is inclusive of all medically necessary services, that ACOs should be held to the same standards required for MA plans, or that ACOs be required to implement a comprehensive independent monitoring program for monitoring ACO performance that includes collecting data on race and ethnicity, validating beneficiary satisfaction surveys, and providing oversight for financial solvency in order to ensure consumer protections and market stability.

Other commenters suggested that CMS implement an evaluation or monitoring program to allow lessons learned from this program to be integrated in the larger Medicare program and to determine the following: Whether an ACO is achieving desired goals, such as less fragmented care and improvement of quality of care beyond the set of identified performance measures; whether or not elements of the ACO structure are contributing to any identified improvements or whether they are having a negative effect; whether there are positive characteristics of certain ACOs that can be transferred to other ACOs; and whether ACOs work better in certain environments (rural vs. urban) or with certain populations. Finally, some commenters suggested that CMS should have just cause to audit an ACO or its participants because audits are costly and burdensome to Medicare providers. They suggested that CMS narrow the types of organizations to which it applies this open-ended audit policy or reduce monitoring requirements after an ACO has successfully delivered a minimum of 5 percent savings for 3 years in a row.

Response: We believe that the beneficiary and program monitoring and protections we are finalizing contain appropriate safeguards and are necessary to ensure that unintended consequences are minimized. We reiterate that the Shared Savings Program is built on the FFS system, and beneficiaries retain all rights and benefits under traditional FFS Medicare. Therefore, we do not believe it is necessary to impose the same protections or network adequacy requirements as are present in the MA program because the Shared Savings Program does not lock-in beneficiaries or restrict beneficiary access to services or their choice of providers. However, we have and will use our experience with monitoring MA plans to inform our monitoring of ACOs.

In our monitoring, we intend to rely primarily on claims-based measures and other information provided by beneficiaries and providers. We will conduct a sufficient number of audits necessary to assess ACOs performance. We disagree with the comments suggesting that we should narrow the number or type of organizations that are subject to audits or that audits should be conducted only if there is a suspicion of wrong doing of some other ''good cause'' to audit. To protect the program, we need the flexibility to audit and monitor compliance under a variety of circumstances. This is particularly critical for the Shared Savings Program, not only because it is a new program, but also because it includes the waiver of certain fraud and abuse authorities. However, as a practical matter, we may choose to target our resources to audit or monitor certain organizations or compliance with certain program requirements.

We agree with commenters that evaluation of the Shared Savings Program and ACOs can help us determine the impact and effectiveness of the program. We intend to improve the Shared Savings Program over time by integrating lessons learned by modifying program requirements as necessary to reflect lessons that demonstrated positive and effective characteristics of ACOs, or to mitigate any negative results. We may also use lessons learned to improve upon existing Medicare programs.

Final Decision: We appreciate both the support for our monitoring proposals by providers and the beneficiary advocate community, as well as the concerns expressed regarding the need for increased monitoring and concerns regarding burden on providers and ACOs. We believe our proposals balance these

concerns. Therefore, we will finalize without substantive change the proposal to use the many methods at our disposal to monitor ACO performance and ensure program integrity, including but not limited to, undertaking an audit if we determine it is necessary.

b. Monitoring Avoidance of At-Risk Beneficiaries

(1) Definition of At-Risk Beneficiaries

Section 1899(d)(3) of the Act authorizes the Secretary to ''impose an appropriate sanction'' on an ACO, including ''termination from the program,'' if the Secretary determines an ACO ''has taken steps to avoid patients at-risk in order to reduce the likelihood of increasing costs to the ACO.'' While the statute does not define what constitutes ''patients at-risk,'' we proposed a definition which is detailed in the proposed rule at (76 FR 19625). We sought comment on this definition of ''at-risk beneficiary'' and whether other beneficiary characteristics should be considered in determining whether a beneficiary is ''at-risk.''

Comment: Several commenters expressed concern that our definition of at-risk beneficiaries did not include certain high-risk diseases and conditions for which patients may need specialized care or follow-up during recovery. They made many suggestions for additional conditions or diagnoses that would cause a beneficiary to be considered at-risk such as—

- Persons with disabilities;
- Beneficiaries with limited proficiency in English or low economic status;
- Non-compliant patients;
- Patients who choose to have elective surgeries;
- Patients with recent diagnoses or conditions that are expected to result in increased cost, such as amputation, major multiple trauma, fracture of femur, various neurological disorders (such as stroke, spinal cord injury, brain injury, multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease), burns, bilateral knee and hip joint replacements, specific types of rheumatoid and osteoarthritis, transplant patients and beneficiaries with end-stage renal disease, persons diagnosed with diabetes or pre-diabetes, cancer patients and survivors;
- Patients with mental health or substance use disorders (MH/SUD); or
- Patients seen in an emergency room 3 times within 12 months.

Response: We believe that our proposed definition is general enough to include most of the specific suggestions made by commenters. For example, the suggestion was made to include beneficiaries who have brain injuries or other chronic conditions. We believe beneficiaries who have brain injury or other chronic conditions suggested by commenters are included in our proposed definition which we proposed in preamble would include beneficiaries who have one or more chronic conditions. We also believe that many beneficiaries with low socioeconomic status are included in our definition which includes dually eligible beneficiaries. We disagree that beneficiaries with limited proficiency in English should be included in the definition of at-risk beneficiaries. We do not believe that limited English proficiency puts patients at risk for significant increases in health care costs. However, we note, that this final rule prohibits ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities from engaging in discriminatory marketing directed at certain types of beneficiaries, includes those with language barriers. We believe that patients seen in an emergency room to three times in a 12 month period are included in the proposed definition of at-risk which specifically mentions emergency room use. However, we agree with commenters that our proposed definition should be expanded to include patients who are entitled to Medicare because of disability and those who are diagnosed with mental health or substance use disorders. Such conditions could also be very high-cost conditions and thus make these beneficiaries targets for avoidance. We also agree that as we learn more about the ACOs and the Shared Savings Program, other types of beneficiaries may be considered at-risk for avoidance

Final Decision: Given our reasoning described previously, we are finalizing the definition of at-risk beneficiary as proposed in § 425.20, with the addition of patients who are entitled to Medicaid because of disability and who are diagnosed with a mental health or substance abuse disorder.

(2) Penalty for Avoidance of At-Risk Beneficiaries

To identify ACOs that could be avoiding at-risk beneficiaries, we proposed to use a variety of methods that would begin with an analysis of claims and examination of other beneficiary-level documentation to identify trends and patterns suggestive of avoidance of at-risk beneficiaries. The results of these analyses could lead to further investigation and follow-up with beneficiaries or the ACO (including ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO's activities) in order to determine whether avoidance of at-risk beneficiaries has occurred. For example, as a part of our monitoring for avoidance of at risk beneficiaries, we would be interested in assessing the changes in risk adjustment of the assigned population over time. Changes in risk adjustment of the beneficiaries assigned in the prior year who are not assigned in the current performance year could help determine whether there is a pattern of avoidance. In cases where it appears the ACO has developed a pattern of avoidance, we stated we may determine an audit is necessary. If as a result of our analysis we conclude that an ACO has been avoiding at-risk beneficiaries during a performance year, we proposed to notify the ACO of our determination and to require the ACO to submit a CAP for our approval as discussed in later in this section II.H.5 of this final rule. We proposed that the CAP must address actions the ACO would take to ensure that the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities cease avoidance of at-risk beneficiaries and that the CAP must be implemented as approved. In addition, we proposed that the ACO would be re-evaluated both during and at the end of the CAP. If we determine that the ACO has continued to avoid at-risk beneficiaries, the ACO would be terminated from the Shared Savings Program. We also proposed that an ACO operating under a CAP because it has avoided at-risk beneficiaries would not receive shared savings payments while under a CAP regardless of the performance period in question, and would not be eligible to earn any shared savings for the period during which it is under this CAP.

We solicited comments on whether lesser sanctions would be appropriate when an ACO avoids at-risk beneficiaries.

Comment: Commenters shared CMS' concern that ACOs may seek to avoid at-risk beneficiaries. While the commenters did not directly address our proposed methods for monitoring, they did suggest that CMS implement a robust monitoring strategy to ensure beneficiary protections such as: Requiring ACOs to have an effective grievance process in place to ensure beneficiaries have recourse against unfair practices; requiring ACOs to provide access to specialists trained in

the care of complex, high-need patient populations (for example oncology patients or patients needing palliative or hospice care) across diagnostic categories and that the penetration of palliative care and hospice care among high-need high-cost beneficiaries be assessed; requiring ACOs to monitor primary care physician's referral patterns to ensure that medically necessary services are not denied to Medicare patients with cancer; use of individualized care plans for patients at-risk and other potentially critical conditions, and strict enforcement of penalties for avoiding beneficiaries.

A few commenters expressed concerns that CMS' proposal was not robust enough. These commenters stated they believe that CMS would only enforce penalties for avoiding patients at-risk in extreme circumstances and urged CMS to strictly enforce penalties. A few commenters suggested lesser sanctions, including the cessation of or reduction in the assignment of new beneficiaries, a reduction in the amount of shared savings payments, or a fine for each instance of avoiding an at-risk beneficiary.

Response: We believe that the proposed policy is necessary for beneficiary and program protections and is in accordance with section 1899(d)(3) of the Act. We do not agree that we should use the lesser sanctions suggested by the commenters for avoidance of at-risk beneficiaries because of the serious implications that avoidance of high risk patients has on Medicare beneficiaries. Also, this is a new program and we do not have any experience to determine the true severity of this issue. However, we may consider lesser sanctions as we gain experience. It is our intention to create policies that ensure beneficiary and program protections while minimizing the burden on ACOs. Since Medicare FFS beneficiaries have many mechanisms at their disposal to lodge their grievances against practitioners involved in their care (including 1–800 Medicare, the Medicare ombudsman's office, quality improvement organizations and others), we do not believe an additional grievance mechanism needs to be developed that is specific to ACOs. Instead, we will monitor complaints by beneficiaries assigned to ACOs that come in through these established mechanisms. We believe the CAP process described previously provides ACOs the opportunity to explain and correct any deficiencies to potentially avoid termination or other penalties. Therefore, we are finalizing our proposal to place ACOs under a CAP to correct the deficiency before termination of its participation agreement and to require the ACO to forfeit any shared savings it was eligible for while under the CAP. However, in response to comments, we will modify our proposal to retain the discretion to impose immediate termination in appropriate cases.

Final Decision: We are finalizing our proposal to use various methods at our disposal, as discussed previously in this section to monitor ACOs for avoidance of at-risk beneficiaries, and the actions we will take if we conclude an ACO has been avoiding at-risk beneficiaries (under § 425.316). In response to commenter concerns, we are retaining in this final rule the right to terminate immediately in appropriate cases.

c. Compliance With Quality Performance Standards

Section 1899(d)(4) of the Act authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. In the proposed rule, we made proposals related to termination of an ACO for failure to meet the established quality performance standards. For a complete discussion and description of our proposals, please refer to (76 FR 19625).

Comments: A few commenters believed that our proposal for monitoring compliance with quality performance standards were limited and insufficient. Commenters suggested that the language be revised to remove the warning for the first incident and to add language that the ACO will be evaluated during the subsequent 3 to 6 months depending on the number of affected beneficiaries and the seriousness of the problem, and if the ACO is still out of compliance, CMS may terminate the ACO or take other actions such as a reduction in shared savings payments. Additionally, commenters stated that CMS should differentiate between the failure to meet quality performance standards because of lack of data infrastructure rather than the failure to satisfy quality performance standards due to provisions of poor quality care. It was suggested that ACOs that furnish poor quality care should be subject to closer monitoring than ACOs that fail because of faulty data processes.

Response: We have considered the comments and agree that we should have flexible methods for enforcing compliance with the quality performance standards. We proposed in § 425.216 that the issuance of a warning letter followed by re-evaluation in 1 year applied *in addition to* the actions prior to termination set forth at proposed § 425.218. Thus, depending on the nature and severity of the noncompliance, we may forgo the issuance of a warning letter and instead place the ACO on a special monitoring plan or immediately impose a CAP and additional monitoring. At this time, we do not believe it necessary to create penalties or procedures in addition to those we proposed, although we have modified the regulation to permit immediate termination when warranted. We will consider appropriate additional penalties in the future as necessary.

Comment: A commenter suggested that when an ACO makes a written request for payment of shared savings (or acknowledges shared losses), it should describe how it was able to ensure that quality was not negatively impacted as a result of the changes it made to generate savings.

Response: Because an ACO cannot share in savings without satisfying the quality standards, we do not believe it is necessary to require an ACO to describe how it ensured that quality did not suffer as a result of its activities. With respect to ACOs that incur losses, we will be monitoring their quality performance and will take appropriate action in response to such monitoring. In light of the eligibility and program requirements, monitoring procedures, and sanctions provisions, we do not believe it is necessary to require ACOs, including those that incur losses, to submit a written description of how they ensured that quality was not negatively affected by the ACO's activities. The policy regarding a written request for shared savings has been modified as described later in this section.

Final Decision: We are finalizing our rule as proposed regarding termination for poor quality performance under § 425.316(c), except that this final rule permits for immediate termination or a CAP in addition to a warning letter for ACOs who are underperforming on quality performance standards.

4. Program Integrity Requirements

Section 1899(a)(1)(A) of the Act authorizes the Secretary to specify criteria that groups of providers of services and suppliers must meet in order to work together to manage and coordinate care for Medicare FFS beneficiaries through an ACO. Using this authority, we proposed several program integrity criteria to protect the Shared Savings Program from fraud and abuse and to ensure that the Shared Savings Program does not become a vehicle for, or increase the potential for, fraud and abuse in other parts of the

Medicare program or in other Federal health care programs.

Comment: Commenters generally agreed with the need for the proposed program integrity requirements. A few commenters expressed concern that although the ACO participants and ACO providers/suppliers undergo stringent screening to participate in Medicare, the ACO entity itself is not required to enroll in Medicare, which may make this program vulnerable to fraud, waste, and abuse. Several commenters suggested that our proposed program integrity requirements impose operational and administrative burdens on ACOs which would increase costs and distract organizations from focusing on improving care coordination and quality of care. Other commenters suggested strengthening our proposed requirements.

Response: The goal of our program integrity proposals are to protect the rights of beneficiaries and minimize the risk of fraud and abuse in the Shared Savings Program. We are seeking to strike the right balance between helping providers provide high quality coordinated and efficient care to Medicare beneficiaries, while also protecting the Medicare Trust Funds. Striking this balance requires us to ensure that the ACO implements certain compliance requirements. As described later in this final rule, we are adopting our program integrity proposals with clarification in this final rule.

Comment: A commenter expressed concern that because of financial pressures to reduce utilization and costs, practitioners will be exposed to an increased likelihood of malpractice suits. The commenter suggested that CMS create a specialty health court to handle suits against ACOs and their providers by ACO patients.

Response: We do not have the statutory authority to create such a system. We expect ACO providers/suppliers to provide high quality, coordinated care, and are adopting a number of monitoring strategies to ensure that they are meeting these requirements. As a result, it is not clear that malpractice litigation will increase, and indeed may decrease if beneficiary outcomes improve as a result of the activities of the ACO.

a. Compliance Plans

We proposed that an ACO have a compliance plan. We recognize that the specific design and structure of an effective compliance plan may vary depending on the size and business structure of the ACO. However, we proposed requiring that the ACO demonstrate that it has a compliance plan that includes at least the following elements: A designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body; mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance; a method for employees or contractors of the ACO, the ACO participants, or the ACO providers/suppliers to report suspected problems related to the ACO; compliance training for the ACO, the ACO participants, the ACO providers/suppliers; and a requirement for the ACO, its ACO participants, and other individuals or entities performing functions or services related to ACO activities to report suspected violations of law to an appropriate law enforcement agency. We also noted that an ACO may want to coordinate its compliance efforts with the compliance functions of its ACO providers/suppliers.

Comment: Commenters generally agreed with the proposed compliance plan requirement. However, a few commenters pointed out that they believe a compliance plan does not stop fraud, waste, and abuse. These commenters believe that the program requirements should be strengthened. Some commenters recommended that CMS establish compliance plan requirements and intermediate sanctions for the Shared Saving Program, similar to those used for Medicare Advantage programs or that CMS explain why it does not believe that an ACO should adhere to the same or similar requirements that MA organization must meet.

Response: We agree that compliance plans on their own do not stop fraud and abuse; however, compliance programs increase the likelihood of identifying and preventing unlawful and unethical conduct; provide a centralized source for distributing information on health care statutes, regulations, and other program directives related to fraud and abuse; and create an environment that encourages employees and others to anonymously report potential problems, among other benefits. We believe the compliance plan helps guide the organization in the right direction and is necessary to ensure the ACO is taking action regarding suspected fraud and abuse. Therefore, we are finalizing our proposal on compliance plans to require a method for employees or contractors of the ACO, the ACO participants, or the ACO providers/suppliers to anonymously report suspected problems related to the ACO and to require that ACOs report suspected fraud and abuse to an appropriate law enforcement agency. In addition to finalizing the compliance plan requirements, this final rule strengthens other program requirements and remedies (for example, we may impose immediate termination in appropriate circumstances) to minimize the potential for fraud and abuse.

Comment: One commenter suggested that CMS consider limiting the compliance training to the compliance officer to reduce some of the burden on ACOs.

Response: We believe that requiring compliance training for the ACO and all of its ACO participants and ACO providers/suppliers help to ensure that every ACO participant, ACO providers/suppliers, and contractor understands their legal obligations with respect to the ACO's operations and performance, as well as the requirements of the compliance program and the manner in which their ACO is implementing such requirements. Without compliance training, ACO participants, ACO providers/suppliers, and contractors may not be aware of potential compliance risks and how to report compliance concerns. We do not believe that only training the compliance officer is sufficient to ensure that the entire ACO is aware of compliance risks.

Comment: A few commenters disagreed with our proposal that the compliance officer is not permitted to also be legal counsel to the organization. These commenters suggested if CMS will not allow an attorney to be both legal counsel and compliance officer, it would be important to have a clear statement from CMS that an attorney may not serve as the compliance officer.

Response: We believe it is important that the authorized, designated compliance officer not also be the legal counsel to the organization. However, many compliance officers are trained as attorneys, and we did not mean to suggest that an attorney would not be able to serve as a compliance officer. We clarify that the legal counsel to the ACO and the compliance officer must be different individuals, in order to ensure independent and objective legal reviews and financial analyses of the organization's compliance efforts and activities by the compliance officer. We are also clarifying that for existing organizations, ACOs can use their current compliance officer, who must report directly to the ACO's governing body, provided that the compliance officer is not legal counsel to the existing organization. We believe this decision allows the ACO to take full advantage of the compliance

requirements already in existence and reduces the burden on ACOs.

Comment: One commenter believed that attempting to meet legal requirements of two or more different entities in cases such as when providers may be participating in an ACO for some patients, but continue to function as an independent provider for others can create considerable complexity and confusion.

Response: In order to provide ACOs with the flexibility they need to define a compliance plan that meets the needs of the ACO, its ACO participants, its ACO providers/suppliers, and contractors, we decline to specify how various organizations should work together to develop their plan. We look forward to innovation from the industry in this area. We will monitor reports of any difficulty in this area and may address this issue further in future rulemaking.

Comment: A few commenters recommended that the requirement to report suspected violations of law to an appropriate law enforcement agency be removed because it deviates from accepted compliance practices. The commenters pointed out that the phrases ''suspected violations'' and ''suspected fraud, waste, and abuse'' are unclear and too general. Additionally, commenters are concerned that this reporting requirement suggests that there is no chance for the ACO to resolve the problem first, before reporting it.

Response: Health care providers have had compliance obligations for many years and have developed successful approaches to combating fraud and abuse in their organizations. The Office of the Inspector General has outlined industry best practices for compliance programs as well as a description of the risks of fraud and abuse that various providers may face. We suggest that providers without experience developing compliance programs review the various resources that are available from the OIG'S web site to help determine the risk of fraud and abuse in the ACO and when an activity may rise to the level of a violation that may need to be reported. The Office of the Inspector General has consolidated its compliance guidance at: *http://oig.hhs.gov/compliance/compliance-guidance/index.asp*. Resources are also available for ACOs and ACO participants to self disclose potential violations. For example, the Medicare self-referral disclosure protocol for potential violations of the physician self-referral statute is available at: *https://www.cms.gov/physicianselfreferral/65_self_referral_disclosure_protocol.asp* and the OIG's provider self-disclosure protocol is available at: *http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf.*

We believe ACOs should have a compliance program that allows for the prompt and thorough investigation of possible misconduct by ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities, corporate officers, managers, employees, and independent contractors, as well as, early detection and reporting of violations, thus minimizing the loss to the Federal government from false or improper claims and thereby reducing the ACO and ACO participants' and its ACO providers/suppliers' to applicable civil damages and penalties, criminal sanctions, or administrative remedies, such as program exclusion, as applicable. As such, ACOs should consider implementing a system for identifying and addressing possible violations when designing their compliance plan. We are modifying the final rule to provide that ''probable'' violations should be reported to law enforcement.

Final Decision: We are finalizing our proposed compliance plan requirements with minor modifications, as outlined in § 425.300. Like the proposal, the final rule allows an ACO to coordinate and streamline compliance efforts with those of its ACO participants and ACO providers/suppliers. We have added a provision requiring compliance plans to be updated periodically to reflect changes in law, including new regulations regarding mandatory compliance plan requirements of the Affordable Care Act. In addition, we provide that ''probable'' violations of law should be reported to law enforcement. Finally, we clarify that although both legal counsel to the ACO and the compliance officer may have a legal education, legal counsel to the ACO and the compliance officer must be different individuals. ACOs may use their current compliance officer, who must report directly to the ACO's governing body, provided that the compliance officer is not legal counsel to the existing organization and meets the requirements of § 425.300.

b. Compliance With Program Requirements

We proposed that, notwithstanding any relationships that the ACO may have with other entities regarding ACO related activities, the ACO maintains ultimate responsibility for compliance with all terms and conditions of its participation agreement with CMS. We proposed to require that all contracts or arrangements between or among the ACO, its ACO participants and ACO providers/suppliers, and other entities furnishing services related to ACO activities must require compliance with the ACO's obligations under its agreement with CMS, including the document retention and access requirements discussed in this section II.H.4.f of this final rule. Further, we proposed that an individual with the authority to legally bind the ACO (for example, the ACO's chief executive officer (CEO), chief financial officer (CFO)) must certify the accuracy, completeness, and truthfulness of information contained in its Shared Savings Program application, agreement with CMS, and submissions of quality data and other information. The certification must be made at the time the application, agreement, and information is submitted.

We proposed that, as a condition of receiving a shared savings payment, an individual with the authority to legally bind the ACO (for example the ACO's chief executive officer (CEO) or chief financial officer (CFO)), must make a written request to CMS for payment of the shared savings in a document that recertifies the ACO's compliance with program requirements as well as the accuracy, completeness, and truthfulness of any information submitted to CMS by the ACO, its ACO participants, or its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities to CMS, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of, a shared savings payment. To ensure the accuracy of information relied upon in calculating shared losses, we proposed to require submission of a similar recertification by an ACO that incurs losses under the two-sided model. We further proposed that, if any data or information on which we rely to determine shared savings or losses are generated by ACO participants or another entity, or a contractor, or subcontractor of the ACO, the ACO participants or the ACO provider/suppliers, must similarly certify the accuracy, completeness, and truthfulness of the data and provide the government with access to such data for audit, evaluation, and inspection.

Comment: A few commenters were concerned about the requirement that a single, authorized representative of the ACO must ''certify the accuracy, completeness and truthfulness of information contained in the Shared

Savings Program application.'' as well as quality data and other data, because the penalty for an individual's false certification, is not clear. The commenters were concerned that, given the amount of data being provided and the variety of individuals and entities other than the ACO that may generate the data (for example, ACO participants, ACO providers/suppliers, and contractors to such entities), it is possible that the ACO may unintentionally submit some incorrect information. The commenters recommended a ''to the best of my knowledge'' attestation or some other resolution that would apportion the responsibility to submit accurate information among the ACO, ACO participants, ACO providers/suppliers and their contractors.

Response: An individual or entity may be prosecuted under Federal law for the submission of false information, including a false certification, only if he or she knowingly submits false information (that is, with actual knowledge of its falsity or in reckless disregard or deliberate ignorance of the truth or falsity of the information). If the individual or entity later realizes that incorrect information has been submitted unintentionally, the individual or entity must timely submit corrected information. We expect that the submission and certification of forms, data, and other information will be completed by an appropriately authorized individual who knows or should know that the information submitted is true, accurate, and complete. Although we did expressly state in the preamble that the certification must be provided to the best of the certifying official's knowledge, information, and belief (76 FR 19544), we acknowledge that this language was not included in the text of the proposed regulation. As such, we wish to clarify that the certification language may include ''to the best of my knowledge or belief'' or similar language appearing in other Medicare certifications. We will provide the forms that require certification in guidance. We note that if it is discovered that the authorized designee knew or should have known that the information submitted was inaccurate, then he and/or the ACO, and/or the participants/providers/suppliers could be subject to liability for making false statements, termination, or other sanctions.

Comment: Some commenters thought that we proposed a cumbersome or burdensome process for requesting payment of shared savings and recertifying the accuracy of the information relied upon for calculating shared savings and losses.

Response: We agree a simpler process is warranted, although it is critical that ACOs certify the accuracy of information we rely upon in calculating shared savings and losses. We will require ACOs to certify after each performance period the accuracy of all information and data that we rely upon in determining eligibility for shared savings, the amount of any shared savings payments, and the amount of shared losses, if applicable. If the ACO or one of its ACO participants or ACO providers/suppliers has become aware that incorrect information was submitted during the performance year, corrected information must be submitted before the recertification.

Final Decision: We are finalizing, at § 425.302, our proposals with the clarification described previously and the modification that ACOs will be required to submit annual certifications by the timeframe CMS will establish through guidance.

c. Conflicts of Interest

We proposed that the ACO governing body have a conflicts of interest policy that applies to members of the governing body. For a full discussion of this proposal and the rationale for it, please refer to the proposed rule (76 FR 19643).

Comment: A commenter asked CMS to provide examples of conflicts of interest members of the governing body should disclose.

Response: The existence of a conflict of interest may vary depending on the composition and activities of an ACO, as well as other factors. In general, we believe that an ACO should adopt an appropriate conflict of interest policy consistent with relevant best practices in the industry and general principles of good corporate governance. An ACO should consider the variety of potential conflicts of interest that may exist among of members of the governing body, the term of applicable State and Federal laws, and other relevant concerns when adopting a policy that fits the scope of the ACO's operations.

As a starting point for organizations unfamiliar with conflict of interest policies, a sample conflict of interest policy for organizations exempt from Federal income tax is available from the Internal Revenue Service in the Instructions for Form 1023 Appendix A at *http://www.irs.gov/instructions/i1023/ar03.html.* ACOs should consider sample conflict of interest policies as a starting point only and should customize the policy for their operations.

Final Decision: We finalizing without change our proposal to require the ACO governing body have a conflict of interest proposal that applies to members of the governing body under § 425.106(d).

d. Screening of ACO Applicants

Although the Medicare program includes substantial screening procedures for enrolling providers and suppliers, ACOs may not be subject to those procedures if they are not providers that are eligible to enroll in Medicare. We proposed to screen ACOs during the Shared Savings Program application process with regard to their program integrity history, including any history of program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. We proposed that ACOs whose screening reveals a history of program integrity issues and/or affiliations with individuals or entities that have a history of program integrity issues may be subject to rejection of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks. We sought comment on the nature and extent of such screening and the screening results that would justify rejection of an application or increased scrutiny.

Comment: Several commenters supported the proposed screening process.

Response: We appreciate the commenters' support of the proposal. We believe it is important to set a level of screening that is appropriate to address the risk of fraud and abuse in the Shared Savings Program.

Comment: One commenter found our proposal confusing because it appeared to contain conflicting language about whether ACOs would be subject to screening. Other commenters were concerned that because an ACO does not go through the Medicare enrollment process, the potential for fraud and abuse would be increased. Commenters recommended that ACOs enroll in the Medicare program using the Provider Enrollment, Chain and Ownership System (PECOS). One commenter asked CMS to discuss the screening procedures for the Shared Saving Program and explain how the screening procedures will be any different for physician offices and hospitals than what were in place before the publication of the final rule with comment period entitled ''Medicare, Medicaid, and CHIP; Additional Screening Requirements, Applications Fees, Temporary Enrollment Moratoria,

Payment Suspensions, and Compliance Plans for Providers and Suppliers'' that appeared in the **Federal Register** on February 2, 2011 (76 FR 5862) (the ''provider screening rule'').

Response: Providers of services and suppliers that desire to participate in the Medicare program are subject to the screening procedures set forth in a provider screening rule. For example, an ACO that is a provider of services, such as a hospital employing ACO professionals, would be eligible to enroll in Medicare and would undergo the usual screens at enrollment. However, if the ACO entity is not a provider of services or a supplier that is eligible to enroll in Medicare, the ACO would not undergo the same screening procedures applicable to providers of services or suppliers, or be required to submit enrollment information through PECOS. For example, if some providers or suppliers that are not already integrated join together to form an ACO, they must create a new legal entity as described in section II.B.3 of this final rule. Such an ACO is not eligible to enroll in Medicare and would not undergo the usual screens.

Therefore, in addition to considering the program integrity history of ACOs and ACO participants that can enroll in Medicare, we proposed a separate screening process for ACOs that are not eligible to enroll in Medicare in order to ensure that the ACO undergoes appropriate screening prior to participating in the Shared Savings Program. Due to statutory limitations, we are unable to apply the provisions of the provider screening rule to ACOs that are not eligible to enroll in Medicare.

Comment: Commenters believed that the proposed screening requirements are too broad and should be narrowed based on the nature of the relationship between an ACO applicant and an entity with a history of program integrity issues. It was suggested that CMS consider parameters so that potential rejection or exclusion by CMS is not so broad as to prevent reasonable and appropriate participation by organizations that have only passing contact with potentially problematic providers.

Some commenters believed that a provider operating under a corporate integrity agreement is committed to correcting any error it may have made in the past and putting in place new procedures to prevent any future concerns and that these providers should not be excluded from participation in the Medicare Shared Savings Program.

A few commenters were concerned that increased attention to program integrity may also lead to increased reports of unfounded and inaccurate allegations being made by CMS and its contractors against Medicare providers; therefore, program integrity allegations should not be held against aspiring or approved ACOs until the claims have been fully adjudicated.

Response: We believe that the results of the screening will need to be considered in light of the relevant facts and circumstances. Therefore, we decline to draw a bright line regarding when an entity's history of program integrity issues justify denial of a Shared Savings Program participation agreement. We would likely consider the nature of the applicant's program integrity issues (including the program integrity history of affiliated individual and entities), the available evidence, the entity's diligence in identifying and correcting the problem, and other factors. We intend to ensure that ACOs, ACO participants, and ACO providers/suppliers would not pose a risk of fraud or abuse within the Shared Savings Program while recognizing that some program integrity allegations may not have been fully adjudicated.

Comment: Some commenters had concerns that the proposed rule is a violation of the Administrative Procedures Act and the commitment to government transparency by the current Administration. These commenters recommended that CMS solicit public comments through the proposed rulemaking process prior to establishing a screening process for ACOs.

Response: We included a proposal to screen ACOs that are not eligible to enroll in Medicare and solicited comments on our proposal in the proposed rule. We have considered public comments on the proposal to make our final decision, in accordance with the notice and comment rulemaking provisions of the Administrative Procedures Act.

Final Decision: We finalize our proposed screening requirements without change. ACOs and ACO participants that are providers of services or suppliers who are eligible to enroll in Medicare will be subject to screening in accordance with applicable regulations, and their program integrity experience will be considered when reviewing the ACO's application to participate in the Shared Savings Program. For ACOs that are not eligible to enroll in Medicare, we will consider the ACO's program integrity history, including any history of program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues, as a part of our application process. We clarify that our screening process will be based upon the information submitted with the ACO's application as further described in section II.B. of this final rule. An ACO whose screening reveals a history of program integrity issues and/or affiliations with individuals or entities (including ACO participants and ACO providers/suppliers) that have a history of program integrity issues may be subject to rejection of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

e. Prohibition on Certain Required Referrals and Cost Shifting

In the proposed rule, we stated that we are concerned that ACOs, their ACO participants, or their ACO providers/suppliers may offer or be offered inducements to over utilize services or to otherwise increase costs for Medicare or other Federal health care programs with respect to the care of individuals who are not assigned to the ACO. We noted that this risk might be heightened if the final rule provides for prospective assignment of beneficiaries. In other words, we are concerned that ACOs, ACO participants, or ACO providers/suppliers might shift Medicare or Federal health care program costs for other beneficiaries not assigned to the ACO.

To address the risk of this inappropriate cost shifting, we stated that we were considering prohibiting ACOs, and ACO participants from conditioning participation in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, and its ACO providers/suppliers know or should know is being provided to beneficiaries who are not assigned to the ACO.

Comment: One commenter stated that there is no perceived risk of abuse or inappropriate cost shifting with prospective assignment and that the Medicare program already causes cost shifting so the concern about new cost shifting is misplaced. A commenter expressed concerns that the rule did not address potential drug cost shifting from Part B to Part D and suggested that CMS develop mechanisms in the event that an ACO shifts drug utilization by not allowing patients to receive their appropriate medication and puts patients at-risk. Another commenter was concerned that ACOs, ACO participants, and ACO providers/suppliers who also participate in the 340B program (a program that allows physicians to purchase outpatient drugs at a discount rate and administer those drugs to their

patients) may purchase and administer drugs for patients of other ACO participants and providers/suppliers. This commenter suggested that CMS work with HRSA to gain a better understanding of the 340B program and establish protections against fraud, waste, and abuse.

Response: This final rule adopts a preliminary prospective assignment methodology with final retrospective reconciliation, as fully described in section II.E. of this final rule. We disagree with the commenter that there is no potential for inappropriate cost shifting in a prospective assignment model. We remain concerned that some ACOs, ACO participants, and ACO providers/suppliers, while working together to decrease costs for beneficiaries preliminarily assigned to the ACO, might inappropriately offer or be offered inducements to over utilize services or otherwise increase Federal health care program expenditures for beneficiaries not assigned to the ACO. To this end, our final regulations prohibit an ACO from conditioning participation in the ACO on referrals of non-ACO business.

We recognize the importance of appropriate beneficiary drug utilization and the concerns of the commenter regarding potential cost shifting of drug costs from Part B to Part D. As part of our ACO monitoring activities, described previously in this section, we intend to monitor the available claims data to detect patterns of cost shifting in the Federal health care programs by ACOs, including patterns of shifting drug costs. The ACO is not itself a 340B eligible entity. Health care providers in an ACO that participates in the 340B program must continue to meet all the requirements of the 340B statute, including ensuring they are not diverting drugs to non-patients or receiving duplicate discounts. A 340B provider is prohibited from purchasing or transferring drugs to non-340B entities and patients of non-340B providers, including those which are a part of an ACO. We will consult with HRSA regarding the risk of fraud and abuse in the 340B program to determine if there are additional monitoring needs for ACOs participating in the 340B program.

We intend to review specific circumstances of inappropriate cost shifting to determine if corrective action or other sanctions, is necessary

Comment: A commenter expressed the need for clarification as to how our proposal will successfully mitigate cost shifting in the Medicare program to patients outside of ACOs. Commenters also expressed concerns that ACOs will shift costs to other health plan types in the private sector by stinting on care. One commenter noted that the private market could also face cost shifting as an attempt to recover losses incurred by ACO participants and ACO providers/suppliers under the proposed two-sided model.

Another commenter recommended that CMS: (1) Require all participating ACOs to have a mechanism for assessing performance on private sector per capita costs by the second year of the program; gather data regarding current market shares, market entries and exits, and pricing trends for the ACOs; (2) set expectations for resource stewardship and waste reduction, including public reporting of quality and cost metrics (for example, cost to charge ratios, professional fee billing rates, prices for episodes for public and private payers, total costs for beneficiaries assigned to the ACO for public and private payers, etc.); (3) specify a standardized set of measures for costs, with input from consumers, purchasers, and other stakeholders; (4) hold ACOs in the Shared Savings Program to a maximum threshold of price increase with their commercial market clients; and (5) require ACOs take part in all-payer claims databases. Finally, one commenter suggested that we coordinate with the FTC and DOJ to thwart anti-competitive behavior.

Response: We expect ACOs to manage resources of all payers carefully and respectfully and ensure continual waste reduction so that every step in care adds value to the beneficiary. However, we share the commenters' concern that there is potential for ACOs to shift costs to other health plan types in the private sector and to engage in anti-competitive behavior.

In section II.C. of this final rule we discuss our concerns about issues related to market power and the interaction of the Shared Savings Program with the antitrust laws. As part of our ACO monitoring activities, described previously in this section, we intend to monitor the available data to detect patterns of cost shifting by ACOs. However, we recognize that we do not hold the private sector claims data that would be necessary for a complete analysis. We will work in consultation with the Federal Trade Commission (FTC), the Department of Justice (DOJ) Antitrust Division, and the HHS OIG, as appropriate, if patterns of inappropriate cost shifting in the Shared Savings Program are reported to identify any needed responses on our part or the part of other Federal agencies.

We are unable to implement the five suggestions raised in the last paragraph of the comment summary because they are outside the scope of the statutory authority of the Shared Savings Program, were not included in the proposed rule for public comment, or require analysis of data that is not currently available to CMS.

However, please see section II.F. of this final rule for a full discussion of our quality measurement requirements, which have undergone notice and comment rulemaking to obtain public input and which may be refined in the future to include additional measures regarding cost and efficiency. This section also describes the information we plan to report publicly regarding shared savings or losses data for each ACO.

Comment: Commenters stated that CMS should establish a strict prohibition against any behavior that seeks to limit the ability of an ACO provider/supplier to referral beneficiaries to professionals who are not participating in the ACO. One commenter expressed concern with his experience that network providers use coercive methods to keep patients ''within network,'' or to ensure that the patients receive care from a particular provider or supplier, which may be owned by the physician or his or her employer. The commenter asserted that such methods may include a physician's refusal to order services or to continue to serve as the patient's treating physician. The commenter asked CMS to make sure such methods will not be permitted and to describe how patient freedom of choice will be enforced. Another commenter asked whether an ACO would be deemed to be diminishing or restricting the rights of beneficiaries assigned to it if it—(1) required its ACO providers, consistent with its care coordination and management efforts under the Shared Savings Program, to refer the ACO's assigned beneficiaries to ACO participants and ACO providers/suppliers to the extent services are available from those parties, unless the beneficiary specifically requests referral to another provider or supplier; and (2) provided written notice of the foregoing to its assigned beneficiaries, to include notice that the beneficiary retains freedom of choice to select a provider of services or supplier, and that such freedom of choice, as communicated to the ACO provider making any such referral, will be respected.

Response: The Shared Savings Program maintains the beneficiary's freedom under Medicare FFS program to choose any participating Medicare provider for care. We anticipate that beneficiaries will prefer receiving care

from the ACO, the ACO participants, and the ACO providers/suppliers because the care will be patient-centered and coordinated among providers. We expect that the ACO, its ACO participants, and its ACO providers/suppliers will discuss the need for services with the beneficiary using shared decision-making. However, such discussions should not serve as roadblocks to beneficiaries who seek to obtain high quality care from the providers or suppliers of their choice. We understand commenters' concerns regarding behavior that seeks to limit or restrict referrals to professionals who are participating in the same ACO, but we also are concerned that a strict prohibition as advocated by some commenters would disrupt arrangements that are permitted under the physician self-referral law (see § 411.354(d)(4)), thereby requiring the restructuring of many legitimate arrangements. Therefore, we are modifying our final rule to prohibit limiting or restricting referrals of beneficiaries to ACO participants or ACO providers/suppliers within the same ACO, or to any other provider or supplier except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the judgment of the referring party. For example, an employer or contracting entity, such as a hospital, may require its employees and contractors to refer to the employer or contracting entity (for example, to the hospital's laboratory or imaging center), provided that the referring party is free to honor patient choice, insurer requirements, and medical best interests of the patients. As part of our ACO monitoring activities, described in this section, we intend to monitor the actions of ACOs, including the results of beneficiary experience of care surveys, to determine whether an ACO, its ACO participants, or its ACO providers/suppliers are interfering with the beneficiary's freedom of choice by improperly limiting or restricting referrals and care to ACO participants or ACO providers/suppliers in the same ACO.

Comment: One commenter advocated that we interpret the fraud and abuse laws liberally for purposes of the Shared Savings Program because Congress has recognized that such laws were written and interpreted for a health care delivery system designed for different payment incentives and not with ACOs in mind. However, other commenters stated that that the remedies do not provide enough protection from the compliance risks associated with the physician self-referral law, anti-kickback statute, antitrust laws, and other regulations. One commenter was troubled by the proposal to waive the physician self-referral law, anti-kickback statute, and civil monetary penalties law because ACOs create incentives similar to those that have historically concerned CMS and these laws are paramount to protecting Medicare beneficiaries. The commenter further expressed concern that Shared Savings Program necessarily involved incentives to stint on care. Therefore, the commenter asserted, it is critical that CMS incorporate into the final rule robust and explicit protections similar to those that Medicare has traditionally found necessary to ensure that no Medicare beneficiaries are harmed by the program.

Response: We disagree with the commenter's assertion that the Shared Savings Program ''necessarily involves incentives to stint on care.'' This final rule incorporates a variety of program protections, and we intend to monitor the program closely for fraud and abuse. Elsewhere in this issue of the **Federal Register,** HHS OIG and CMS have jointly issued an interim final rule with comment period regarding issues related to the physician self-referral law, anti-kickback statute, and certain civil monetary penalty law provisions. See that interim final rule with comment period for a consideration of comments related to the physician self-referral law, anti-kickback statute, and certain civil monetary penalty law provisions. We believe the waivers will balance effectively the need for innovation and flexibility in the Shared Savings Program with protections for beneficiaries and the Medicare program.

Final Decision: We are finalizing the requirement to prohibit ACOs, their ACO participants, their ACO providers/suppliers, from conditioning participation in the ACO on referrals of Federal health care program business to the ACO, its ACO participants, or its ACO providers/suppliers for services they know or should know are being provided to beneficiaries who are not assigned to the ACO. For the reasons discussed above, we are modifying our final rule to prohibit limiting or restricting referrals of patients to ACO participants or ACO providers/suppliers within the same ACO, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the judgment of the referring party.

f. Record Retention

In order to ensure that we have the information necessary to conduct appropriate monitoring and oversight of ACOs, we proposed that ACOs, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must retain records of their activities under the Shared Savings Program for a sufficient period of time to allow the government to conduct the appropriate audits, evaluations, investigations and inspections of their activities. For a complete discussion of these proposals, please refer to the proposed rule published April 7, 2011 (76 FR 19651).

Comment: Commenters agreed with the record retention and audit proposals but recommended that the six year record retention requirement be limited to disputes involving only the ACO, not its ACO participants, its ACO providers/suppliers, or other contracted entities. In addition, commenters expressed concern that the record retention requirements would continue to apply even after the ACO has dissolved. The commenter asked CMS to address the question of which party is liable for any issues that surface after the ACO no longer exists. Commenters suggested that the responsibility should be divided among the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

Response: We see no reason to limit the 6-year record retention provision as suggested by the commenter. We note that the proposed record retention and audit requirements are consistent with other Medicare programs, such as MA. In order to provide ACOs with flexibility, we decline to specify how ACOs, ACO participants, ACO providers/suppliers, or other

individuals or entities performing functions or services related to ACO activities will develop a records retention plan or apportion responsibility for record retention in the event the ACO dissolves prior to conclusion of the audit and record retention period. We anticipate that the ACO and the entities participating in the ACO will develop policies related to audit and record retention that address the needs of the ACO's operations while retaining records and permitting access to records for audit for the required time period.

Final Decision: We finalize our proposed audit and record retention requirements (§ 425.314) with the clarification that, as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination. We further clarify that, consistent with our authority, the record retention requirements in this rule do not limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the records of the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

g. Beneficiary Inducements

As noted in section II.B of this final rule, section 1899(b)(2)(G) of the Act requires an ACO to ''define processes to promote * * * patient engagement.'' We described in the proposed rule that the term ''patient engagement'' is the active participation of patients and their families in the process of making medical decisions. Patient engagement is an important part of motivating and encouraging more active participation by beneficiaries in their care delivery.

Comment: Some commenters noted that beneficiary engagement and coordination of care could be enhanced by providing additional incentives to beneficiaries to motivate and encourage them to be actively involved in their care. Some commenters suggested that one way to promote patient engagement would be to offer beneficiaries incentives to encourage health awareness. One commenter gave the example of supplying scales to beneficiaries with CHF to help them better manage this chronic disease.

On the other hand, one commenter recommended that CMS and the OIG closely monitor ACOs to ensure that exceptions to the physician self-referral laws are not abused; and prohibit ACOs from waiving co-pays, giving deep discounts, or offering other incentives to ACO patients in order to induce them to receive services within the ACO. One commenter expressed concern with his experience that network providers use coercive methods to keep patients ''within network,'' or to ensure that the patients receive care from a particular provider or supplier, which may be owned by the physician or his or her employer. The commenter asserted that such methods may include a physician refusal to order services, or to continue to serve as the patient's treating physician. The commenter asked CMS to make sure such methods will not be permitted and to describe how patient freedom of choice will be enforced.

Others recommended that CMS prohibit the ACO from providing gifts, cash, or other remuneration as inducements for receiving services or remaining assigned to an ACO or with a particular ACO participant or ACO provider/supplier. Commenters stated that CMS should prohibit ACOs from waiving co-pays, giving deep discounts, or offering other incentives to ACO beneficiaries in order to incentivize them to receive services within the ACO.

Response: We agree with commenters that providing gifts, cash, or other remuneration to beneficiaries as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO should be prohibited.

This final rule therefore provides at § 425.304 that an ACO, its ACO participants, its ACO providers/suppliers, and other individuals and entities performing functions or services related to ACO activities are prohibited from providing gifts, cash, or other remuneration as inducements for receiving services or remaining in an ACO or with a particular provider within the ACO.

However, we also believe that there are certain instances when an ACO, its ACO participants, and its ACO providers/suppliers may offer items or services to beneficiaries for free or below market value to encourage care coordination and encourage beneficiary health awareness. For this reason, and consistent with the joint CMS and OIG interim final rule with comment period published elsewhere in this issue of the **Federal Register** describing waivers of certain fraud and abuse authorities in connection with the Shared Savings Program, we are adding a provision at § 425.304 to provide that an ACO, its ACO participants, or its ACO providers/suppliers may provide to beneficiaries items or services for free or below fair-market-value if all the following conditions are met:

- The ACO remains in good standing under its participation agreement.
- There is a reasonable connection between the items or services and the medical care of the beneficiary.
- The items or services are in-kind and either are preventive care items or services or advance one or more of the following clinical goals: adherence to a treatment regime; adherence to a drug regime; adherence to a follow-up care plan; or management of a chronic disease or condition.

For example, an ACO provider may give blood pressure monitors to patients with hypertension in order to encourage regular blood pressure monitoring and thus educate and engage beneficiaries to be more proactive in their disease management. In this instance, such a gift would not be considered an improper inducement to encourage the beneficiary to remain with an ACO, ACO participant, or ACO provider/supplier. However, this final rule would prohibit an ACO, ACO participant, or ACO provider/supplier, or another individual or entity performing functions or services related to ACO activities from offering monetary or other gifts (for example: Baseball tickets, jewelry, household items, gift certificates for non-health care related retail items) that can be used for purposes other than direct health and care related purposes. We intend to interpret § 425.304 consistent with the joint OIG/CMS interim final rule referenced above, which contains additional discussion and information on the subject.

5. Terminating an ACO Agreement

a. Reasons for Termination of an ACO's Agreement

There are a number of important statutory requirements that ACOs must satisfy in order to be eligible to participate in the Shared Savings Program. In addition, using our authority under section 1899(a)(1)(A) of the Act, we proposed additional regulatory criteria that ACOs must satisfy to enter and remain in the Shared Savings Program. Although sections 1899(d)(3) and (d)(4) of the Act authorize termination for avoidance of at-risk beneficiaries and for failure to meet the quality standards, we do not believe that Congress intended the remainder of the regulatory scheme to be unenforceable. We believe that the Shared Savings Program participation agreement with an ACO should be contingent upon that ACO continuing to meet the requirements for eligibility and

other program requirements. Accordingly, we proposed that the participation agreement would require the ACO to comply with the requirements of the Shared Savings Program in order to participate in the program. In addition, we proposed that we would monitor compliance with eligibility requirements and that we could discretion terminate an agreement with an ACO before the end of the term of its agreement for a number of reasons which can be reviewed in detail at (76 FR 19649).

Furthermore, we proposed that an ACO may voluntarily terminate its agreement. We believe it is appropriate that an ACO should provide notice if it elects to terminate its participation in the Shared Savings Program. Accordingly, we proposed to require an ACO to provide us with a 60-day notice if it chooses to terminate its agreement. We also proposed that the ACO would be required to notify us of its decision to terminate its participation in the Shared Savings Program and would also be required to notify all of its ACO participants and ACO providers/suppliers, who would in turn be required to notify beneficiaries in a timely manner of the ACO's decision to withdraw from the Shared Savings Program. We also proposed that, as described in section II.F.13. of the proposed rule (76 FR 19615), the ACO would forfeit its mandatory proposed 25 percent withhold of shared savings.

Comment: Commenters stated that 60-day notices for an ACO to exercise its right to terminate its agreement is not appropriate in the commercial market and allowing an ACO to terminate the agreement with such limited notice, especially in the first and second year of a one-sided only risk agreement, will add costs to the system rather than reduce them. These commenters are concerned that allowing such short notice may permit increased potential for ''gaming'' in that ACOs easily terminate when they are experiencing losses.

Response: We appreciate all the commenters concerns, however, we believe there is a distinction between the MA and the Shared Savings Programs which does not require the same restrictions. Unlike managed care plans, ACOs do not need to transition beneficiaries to another plan. Moreover, as discussed previously in this section, and in response to comments, we are eliminating the requirement for the ACO to notify beneficiaries that the ACO, ACO participants or ACO providers/suppliers are no longer participating in the program. Thus, ACOs are only required to notify CMS and their ACO participants and ACO providers/suppliers that they are terminating their agreement.

Comment: Some commenters stated that the myriad reasons proposed for termination pose too much risk for providers to participate. Specifically, commenters disagreed with termination of an ACO's agreement for use of improper or unapproved marketing materials, underperforming on quality performance standard or failure to submit quality data, failure to submit payment of losses in a timely manner and changes in the ACO's leadership and management structure. A few commenters suggested that CMS does not have the authority to terminate an agreement for reasons other than avoidance of at-risk beneficiaries and failure to meet quality standards.

In contrast, several commenters believe CMS should expand the reasons for termination so that they are consistent with the MA program. Commenters suggested ACO should be terminated if the number of assigned beneficiaries to the ACO fall below 5,000 in any given month; felony, conviction or indictment of any owner of the parent of the ACO; OIG exclusion, or lack of meaningful beneficiary participation in the ACO.

Response: We believe it is necessary to be able to terminate ACOs for failure to comply with the regulations because that is an important protection for beneficiaries and against abuse. As discussed in this section, we intend to use a variety of sanctions such as warning letters and CAPs to address noncompliance, at CMS' sole discretion, in addition to termination. Termination is only one option and CAPs may be sufficient to certain correct types of noncompliance; situations where noncompliance is more serious may require immediate termination.

It is our intent to ensure beneficiary and program protections (especially in light of the fraud waivers) while minimizing burden for ACOs interested in participating in the program. Concurrently with our proposed rule, CMS and the Office of Inspector General published a Joint Notice on Waiver Designs in Connection with the Medicare Shared Savings Program that proposed certain waivers of the physician self-referral law, anti-kickback statute, and civil monetary penalties law. Elsewhere in this issue of the **Federal Register,** CMS and OIG have published final interim waivers of those laws. We are modifying this proposal to address how any continuing violations of those laws will affect the termination provisions. Specifically, we have clarified that ACOs may be terminated for violations of these three laws only to the extent that the laws are not waived. We have also clarified that ACOs may be terminated if their participants submit false certifications to CMS; we remind them that such false certifications may also trigger liability under the False Claims Act.

We decline to adopt commenters' suggestion that we expand the reasons for termination so they are consistent with the MA program. We believe there are important distinctions between the MA and the Shared Savings Program, as discussed throughout this final rule. It is our goal to create policies that ensure beneficiary and program protections while balancing burden imposed on ACOs.

We believe that meeting the 5,000 beneficiary threshold is an important eligibility requirement as discussed in section II.B. of this final rule and that ACO would no longer meet those requirements if it fall below 5,000 beneficiaries. An ACO assignment that falls below 5,000 would fail to meet the eligibility as outlined in this final rule, and therefore would be terminated under our proposal to terminate ACOs that fail to meet eligibility requirements. We would use various monitoring methods discussed in this section such as quarterly aggregated reports to determine if ACOs no longer meet the 5,000 beneficiary threshold. This comment and others raise a good point that despite the list proposed in the proposed rule, there are a number of reasons why it may be desirable to terminate an ACO for non-compliance with program requirements and for failure to meet eligibility. Therefore, we will generalize the reasons why an ACO may be terminated to include non-compliance with program requirements and for failure to meet requirements necessary for eligibility.

Comment: Some commenters suggested we give ACOs an opportunity to explain why they are not in compliance with program rules before terminating an ACO agreement.

Response: Where appropriate, we will work with the ACO to understand why the noncompliance occurred so that we can develop an effective CAP and monitoring technique. However, in instances where we believe the circumstances are more serious or pose risk of harm to beneficiaries or access to care, we reserve the right to terminate a participation agreement immediately without providing an ACO the opportunity for a CAP or warning notice.

Final Decision: We are therefore finalizing our proposal under § 425.218 for terminating an ACO and for taking

certain actions before termination under § 425.216. Specifically, CMS may terminate an ACO's agreement for non-compliance with the requirements of the Shared Savings Program, which includes maintaining eligibility. Examples include termination for avoidance of at-risk beneficiaries, failure to meet quality performance standards as previously described previously. We have modified this final rule to retain the right to terminate an ACO's agreement immediately for violations we determine are more serious.

Additionally, as discussed in this section, we are finalizing our proposal to use a variety of sanctions such as warning letters and CAPs to address non-compliance, as CMS' sole discretion, in addition to termination. We are clarifying that we will work with ACOs where appropriate to understand why the noncompliance occurred and work to develop an effective CAP. Also, we wish to clarify that certain personnel changes in leadership and management would not necessarily result in termination, for example, one qualified medical director replacing the initial qualified medical director, provided the ACO continued to meet the eligibility criteria and remained able to perform all of the required functions of an ACO participating in the Shared Savings Program. However, as proposed, changes in leadership and management structures such that the ACO no longer meets eligibility to participate in the program, for example, no longer having a formal legal structure, would be grounds for termination. Finally, we have modified our proposal to clarify that CMS will provide the ACO with notice of termination.

Further, we would like to clarify that consistent with our proposal to terminate an ACO in the event sanctions or other actions are taken against an ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, by an accrediting organization, or by a State, Federal, or local government agency, an ACO agreement may be terminated if its providers are excluded by the OIG or have their privileges to participate in Medicare revoked. We are also clarifying that demonstrating meaningful beneficiary participation is a requirement for eligibility and as such, failure to adequately notify beneficiaries of participation in the program would constitute grounds for terminating the ACO.

We are also clarifying that if an ACO has violated the antitrust laws or the fraud and abuse authorities (except to the extent these laws are waived by the Secretary under section 1899(f) of the Act), the ACO's eligibility to participate in the Shared Savings Program will have to be reassessed by CMS. For example, if an antitrust agency disbands the ACO for violation of antitrust laws, the ACO no longer exists as the applicant that was approved for a participation agreement and may therefore be terminated.

After taking all comments into consideration, we are finalizing our rule that ACOs may voluntarily terminate and will be required to provide CMS and all of its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities with a 60-day notice of its decision to terminate its participation in the Shared Savings Program. We are clarifying that ACOs that terminate their participation agreement early will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement because it failed to complete the entire performance year by which we calculate shared savings payments (§ 425.316(c)(5)). After taking into consideration commenters' concerns and to reduce burden on ACOs, this final rule provides that an ACO would not be required to notify beneficiaries of the ACO's decision to withdraw from the Shared Savings Program. We have also not finalized our proposal to require the ACO to forfeit its mandatory proposed 25 percent withholding of shared savings if its agreement is terminated before the term is completed.

b. Corrective Action Plans

In the proposed rule, we proposed that, at our sole discretion, CMS could require the ACO to produce a corrective action plan (CAP) prior to termination for minor violations that we do not believe pose no immediate risk of harm to beneficiaries or impact care. Additionally, we proposed that an ACO must submit a CAP for our approval by the deadline indicated on the notice of violation. Under our proposal, the CAP would address what actions the ACO will take to ensure that the ACO, ACO participants, and other individuals or entities performing functions or services related to ACO activities would correct any deficiencies to remain in compliance with Shared Savings Program requirements. We proposed that the CAP would be implemented as approved, and that the ACO's performance would be monitored during the CAP process. We further proposed that failure of the ACO to submit a CAP by the requested deadline, obtain approval for, or implement a CAP may result in termination of the agreement. Similarly, failure of the ACO to demonstrate improved performance upon completion of the CAP may result in termination. We also proposed that the ACO would not receive shared savings payments while it is under a CAP regardless of the performance period in question and that the ACO would not be eligible to earn any shared savings for the period during which it is under a CAP.

Comment: We received very few comments regarding the CAP process. There were no comments received that opposed the CAP process.

Final Decision: We are finalizing our proposal under which we may require an ACO to produce a corrective action plan (CAP) for violations that we consider minor in nature and pose no immediate risk of harm to beneficiaries or impact on care.

c. Future Participation of Previously Terminated Program Participants

In our proposed rule, we discussed how ACOs would be handled that terminate their agreement to participate in the Shared Savings Program, are terminated from the Program, or underperform and do not achieve savings during the first agreement period (section II.H.3. of the proposed (76 FR 19653)) but wish to participate in the Program for an additional performance period.

We proposed that potential ACOs disclose to CMS as part of its application whether the ACO, its ACO participants, or its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities have participated in the program under the same or a different name, and specify whether the entity or person was terminated or withdrew voluntarily from the program. If the entity or person was previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the prospective ACO to participate in the program and complete the term of the new agreement. We proposed that terminated ACOs may not begin another agreement period until the original agreement period had lapsed. (See (76 FR 19653), for discussion of our proposal to prohibit ACO's which demonstrate a net loss in their first agreement period from reapplying to participate in the Shared Savings Program.) In addition, consistent with our proposal that ACOs may only have one agreement under the one-sided model, we proposed that previously

terminated ACOs that wish to reenter the program must do so under the two-sided model.

Comment: Some commenters indicated ACOs may have difficulty achieving net gains during their first agreement period. Others projected that it will take several years for an ACO to become fully operational. Commenters suggested that the prospect of being disqualified from the program before recovering the start-up costs required to form an ACO will deter providers from participating. Several commenters were supportive of allowing well-intentioned ACOs, terminated from the program, to reapply. In particular, one commenter recommended a more flexible approach in the final rule that does not penalize well-meaning, otherwise acceptable ACO who might have had understandable difficulties.

Response: We must ensure our policy on subsequent participation in the Shared Savings Program does not provide a second chance for under-performing organizations or for providers or suppliers who have been terminated for failing to meet program integrity or other requirements. We believe that this is an important protection for beneficiaries and the program. We do believe the commenter's standard of allowing ''well intentioned'' ACOs to reapply is easily enforced.

We have considered public comments received on this policy, however, we believe that in order to ensure protection for beneficiaries and the program, ACOs should not be allowed to re-enter the Shared Savings Program before the conclusion of their initial agreement period. We are therefore finalizing our rule such that ACOs who were previously terminated through enforcement action or voluntarily that wish to re-enter the Shared Savings Program may do so at the end of their initial agreement period. We note that excluded individuals or entities would not be permitted to participate in the Shared Savings Program unless and until their reinstatement. An ACO that was previously terminated may reenter the program only under the two-sided model unless it was terminated less than half way through its agreement under the one-sided model in which case it will be allowed to re-enter the one-sided model. An ACO that was terminated more than half way through its agreement will only have the option of entering in Track 2. Such an ACO must describe the reason for termination of its initial agreement and what safeguards are now in place to enable the prospective ACO to participate in the program for the full term of their participation agreement. We believe it is important beneficiary and program protections to limit participation in the program to providers and suppliers who are dedicated to the goals of the program.

Final Decision: We will finalize our proposal that the ACO disclose to us whether the ACO, its ACO participants, or its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, have participated in the program under the same or a different name, and specify whether it was terminated or withdrew voluntarily from the program. If the ACO, its ACO participants or ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities were previously terminated from the program, the applicant must identify the cause of termination and what safeguards are now in place to enable the prospective ACO to participate in the program for the full period of the initial term of agreement. We will consider this information in determining whether an ACO should be approved to participate in the program.

ACOs that are terminated from the program will be afforded the opportunity to re-apply to participate in the shared savings again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated. An ACO that was terminated less than half way through its agreement under the one-sided model will be allowed to re-enter the one-sided model at the conclusion of the term of their original agreement. ACOs that were terminated more than half way through its agreement will only have the option of entering under Track 2 at the conclusion of the term of their original agreement.

6. Reconsideration Review Process

In the proposed rule, we outlined certain actions specified in section 1899(g) of the Act for which there shall be no administrative or judicial review. However, we stated that it is important to establish a fair administrative process by which ACOs may request review of other decisions, such as the denial of an application to participate in the program or the termination of an existing participation agreement for reasons other than those exempted by statute. For a full discussion of our proposals and rationale, see the proposed rule published April 7, 2011 (76 FR 19627).

Comment: Commenters expressed concern that the statutory exceptions to administrative review should be construed narrowly so that additional reasons for administrative review are allowed and that the proposed timeframe to request a review (15 days) is too short. Commenters also expressed concern with the fairness of the reconsideration review process since CMS is not an independent party. Commenters specifically recommended that CMS—

- Establish an appeals and grievance system for patients and providers when care is compromised;
- Review all cases in which an ACO requests reconsideration; and
- Establish a review process through an independent party.

Response: The decisions excluded from the reconsideration review process are consistent with section 1899(g) of the Act. Our reconsideration review process was built on our experience with established, effective, and well accepted procedures used in other Medicare programs. The reconsideration review allows for significant procedural due process for all parties, a clear and easily understood linear process, and reviews by independent CMS officials. The timeframe allowed to request review under the reconsideration review process is consistent with the MA (§ 422.622) and Part D (§ 423.651) programs which both provide 15 calendar days after receipt of the notice of determination to request review. We agree that the reconsideration review should be conducted by an independent reviewer. The process as proposed allows the ACO the opportunity to have a reconsideration review conducted by an independent reviewer who was not involved with any previous determination including both the initial and review stage of the reconsideration. We also believe that we have proposed several monitoring tools that will ensure beneficiary protections and as a result, we do not believe it is necessary to establish a separate grievance process for ACOs.

Final Decision: After consideration of the comments received and for the reasons discussed previously, we are finalizing the reconsideration review process as proposed, with the exception of our decision to eliminate the specific provision related to review of determinations made by a reviewing antitrust agency as no longer applicable in light of the revisions to our procedures for Antitrust review, which are discussed in section II.C. of this final rule. We are clarifying that when we stated ''if any of the parties disagree with the recommendation of the reconsideration, they may request an on the record review,'' we were referring to both CMS and the ACO.

III. Collection of Information Requirements

As stated in section 3022 of the ACA, Chapter 35 of title 44, United States Code, shall not apply to the MSSP. Consequently, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget.

IV. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

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 final rule has been designated an ''economically'' significant rule, under section 3(f)(1) of Executive Order 12866 and a major rule under the Congressional Review Act. Accordingly, the rule has been reviewed by the Office of Management and Budget.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This final rule does not include any mandate that would result in spending by State, local or tribal governments, in the aggregate, or by the private sector in the amount of $136 million in any one year. We acknowledge that there will be costs borne by the private sector, as discussed in this regulatory impact section, in order to participate in this program; however, participation is voluntary and is not mandated.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We do not believe that there is anything in this final rule that either explicitly or implicitly pre-empts any State law, and furthermore we do not believe that this final rule will have a substantial direct effect on State or local governments, preempt State law, or otherwise have Federalism implications.

B. Statement of Need

This final rule is necessary to implement section 3022 of the Affordable Care Act which amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding a new section 1899 to establish a Shared Savings Program that promotes accountability for a patient population, coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Section 1889(a)(1) of the Act requires the Secretary to establish this program not later than January 1, 2012. Also, section 1889(a)(1)(A) of the Act states that under this program, ''groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to * * * as an 'ACO')''; and section 1889(a)(1)(B) of the Act provides that ''ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings * * *.''

The Shared Savings Program is a new approach to the delivery of health care aimed at reducing fragmentation, improving population health, and lowering growth in overall health care costs.

The Shared Savings Program should provide an entry point for all willing organizations who wish to move in a direction of providing value-driven healthcare. Consequently, in accordance with the authority granted to the Secretary under sections 1899(d) and 1899(i) of the Act, we looked at creating both a shared savings model (one-sided) and a shared savings/losses model (two-sided). The sharing parameters under the two options are balanced so as to provide greater reward for organizations that accept risk while maintaining sufficient incentive to encourage providers to participate in the one-sided model, which provides an entry point to risk-oriented models.

C. Overall Impact

As detailed in Table 8, we estimate a total aggregate median impact of $470 million in net Federal savings for calendar years (CY) 2012 through 2015 from the implementation of the Shared Savings Program. The 10th and 90th percentiles of the estimate distribution, for the same time period, yields a net savings of $940 million and $0 million, respectively. These estimated impacts represent the effect on Federal transfers. Median estimated Federal savings are somewhat less than the estimate published for the proposed rule (estimated $510 million net savings through 2014) due in part to increased program generosity, led by first-dollar (below benchmark) sharing. This, combined with the easing of a number of program requirements and burdens, expands our expected range of participation, resulting in a somewhat greater median net savings amidst a wider stochastic projection range.

Furthermore, we estimate a total aggregate median impact of $1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for CYs 2012 through 2015. The 10th and 90th percentiles of the estimate distribution, for the same time period, yield a bonus payment to ACOs of $890 million and $1.9 billion, respectively.

We estimate the aggregate cost associated with the start-up investment of ACOs participating in the Shared Savings Program will range from $29 million to $157 million. The program's first agreement period has been expanded by up to 6 to 9 months, rewarding ACOs who enter the program early in 2012 with a longer agreement period under their initial benchmark, while also accommodating ACOs that might require an additional year (or partial year) of preparation. Furthermore, aggregate ongoing annual operating costs for the participating ACOs are estimated to range from $63 million to $342 million. Both start-up investment and ongoing annual operating cost ranges utilize an anticipated participation rate of 50 to 270 ACOs in the Shared Savings Program. Lastly, when utilizing the anticipated mean participation rate of ACOs in the Shared Savings Program, this yields an estimated aggregate average start-up investment and ongoing annual operating costs of $451 million for CYs 2012 through 2015. Therefore, as illustrated in Table 8, for CYs 2012 through 2015 the total median ACO bonus payments of $1.31 billion

coupled with the aggregate average start-up investment and ongoing annual operating cost of $451 million, incurred at the mean participation rate of ACOs in the Shared Savings Program, result in an estimated benefit-cost ratio of 2.9.

In addition to rewarding ACOs who enter the program early in 2012 with a longer effective agreement, while also accommodating ACOs that might require an additional year (or partial year) of preparation, the Shared Savings Program will also benefit beneficiaries since the program requires ACOs to be accountable for Medicare beneficiaries, improve the coordination of FFS items and services, and invest in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrate a dedication and focus toward patient-centered care. Accordingly, we have prepared a regulatory impact analysis (RIA) that to the best of our ability presents the costs and benefits of this final rule.

TABLE 8—ESTIMATED NET FEDERAL SAVINGS, COSTS AND BENEFITS, CYS 2012 THROUGH 2015

	CY 2012	CY 2013	CY 2014	CY 2015	CYs (2012–2015)
Net Federal Savings:					
10th Percentile	−$30 Million	−$20 Million	$10 Million	$0 Million	$0 Million.
Median	$20 Million	$90 Million	$160 Million	$190 Million	$470 Million.
90th Percentile	$70 Million	$210 Million	$320 Million	$370 Million	$940 Million.
ACO Bonus Payments:					
10th Percentile	$60 Million	$180 Million	$280 Million	$360 Million	$890 Million.
Median	$100 Million	$280 Million	$410 Million	$520 Million	$1,310 Million.
90th Percentile	$170 Million	$420 Million	$600 Million	$740 Million	$1,900 Million.
Costs	The estimated start-up investment costs for participating ACOs range from $29 million to $157 million, with annual ongoing costs ranging from $63 million to $342 million, for the anticipated range of 50 to 270 participating ACOs. With the mean participation of ACOs, the estimated aggregate average start-up investment and four year operating costs is $451 million.				
Benefits	Improved healthcare delivery and quality of care and better communication to beneficiaries through patient centered-care.				

* Note that the percentiles for each individual year do not necessarily sum to equal the percentiles estimated for the total four year impact, in the column labeled CYs 2012–2015, due to the annual and overall distributions being constructed independently.

Participating ACOs will have the opportunity to earn shared savings payments by reducing Medicare expenditure growth for their assigned beneficiaries below specified target thresholds or benchmarks while simultaneously meeting quality performance measures. An ACO could initially opt for one of two program tracks. The first option (one-sided model) offers eligibility for shared savings payments in all years without the risk of being responsible for repaying any losses if actual expenditures exceed the benchmark. Combined with rolling enrollments into the program in 2012, ACOs will have options to ease their transition toward responsibility for quality of care improvement and the total cost of care for the beneficiaries they serve. The second option (two-sided model) provides an opportunity for receiving a higher percentage of shared savings for all years of the agreement period, but with potential liability in each of the agreement years for annual expenditures that exceed the benchmark, thereby increasing associated risk.

There is substantial uncertainty as to the number of ACOs that will participate in the program, their characteristics, provider and supplier response to the financial incentives offered by the program, and the ultimate effectiveness of the changes in care delivery that may result as ACOs work to improve the quality and efficiency of patient care. These uncertainties complicate efforts to assess the financial impacts of the Shared Savings Program and result in a wide range of potential outcomes regarding the net impact on Medicare expenditures.

To best reflect these uncertainties, we designed a stochastic model that incorporates assumed probability distributions for each of the key variables that will affect the overall financial impact of the Shared Savings Program. Using a Monte Carlo simulation approach, the model randomly draws a set of specific values for each variable, reflecting the expected covariance among variables, and calculates the program's financial impact based on the specific set of assumptions. We repeated the process for a total of 5,000 random trials, tabulating the resulting individual cost or savings estimates to produce a distribution of potential outcomes that reflects the assumed probability distributions of the incorporated variables, as shown in Table 8. In this way, we can evaluate the full range of potential outcomes based on all combinations of the many factors that will affect the financial impact, and with an indication of the likelihood of these outcomes. It is important to note that these indications do not represent formal statistical probabilities in the usual sense, since the underlying assumptions for each of the factors in the model are based on reasonable judgments, using independent expert opinion when available.

The median result from the distribution of simulated outcomes represents the ''best estimate'' of the financial effect of the Shared Savings Program, recognizing the uncertainty inherent in a new program with uncertain responses. The full distribution illustrates the uncertainty surrounding the mean or median financial impact from the simulation.

As detailed in Table 9, the median estimate involves a combination of: (1) Reduced actual Medicare expenditures due to more efficient care; (2) shared savings payments to ACOs; and (3) payments to CMS for shared losses when actual expenditures exceed the benchmark, resulting in a projected total of $470 million in net savings over CYs 2012 through 2015. Greater participation is estimated due to the option for a longer 42 or 45 month agreement period, gentler transition period, and greater generosity provided. The extra year also amplifies our estimated savings and cost totals.

A net savings (costs) occurs when the payment of earned and unearned

shared-savings bonuses (less penalties collected) resulting from: (1) Reductions in spending; (2) program design; and (3) random group claim fluctuation, in total are less than (greater than) assumed savings from reductions in expenditures.

As the actual number of participating ACOs and their characteristics become known, the range of financial outcomes will narrow. Similarly, as data become available on the initial differences between actual expenditures and the target expenditures reflected in ACO benchmarks, it will be possible to evaluate the financial effects with greater certainty. The estimate distribution shown in Table 9 provides an objective and reasonable indication of the likely range of financial outcomes, given the chosen variables and their assumed distributions at this time in the program's implementation.

D. Anticipated Effects

1. Effects on the Medicare Program

As a voluntary program involving an innovative and complex mix of financial incentives for quality of care and efficiency gains within FFS Medicare, the Shared Savings Program could result in a wide range of possible outcomes. While examples exist across the healthcare marketplace for risk-sharing arrangements leading to efficiency gains, a one-sided model would presumably provide a weaker incentive to ACOs than other approaches. Track 2 introduces downside risk while offering a lower minimum savings rate and a greater sharing percentage, all of which enhance the incentive for efficiency while protecting the Trust Funds against losses for fluctuation or other exogenous factors. It is possible that participation in Track 1 might enable such ACOs to gain the experience necessary to take on risk in a subsequent two-sided arrangement, possibly enhancing the opportunity for greater program savings in years beyond the first agreement period. Conversely, if in that first agreement period ACOs come to reliably predict a bias that ensures an outcome—whether favorable or unfavorable—the program would be at risk for increasingly selective participation from favored ACOs and any real program savings could be overwhelmed by outsized shared-savings payments.

Even ACOs that opt for Track 2 could eventually terminate their agreement if they anticipate that efforts to improve efficiency are overshadowed by their particular market circumstances. (Under section 1899(d) of the Act, we update ACO benchmarks by the estimated annual increase in the absolute amount of national average Medicare Part A and Part B expenditures, expressed as a flat dollar amount for each year. As a result, the updates to ACO benchmarks in percentage terms will be higher in low-cost areas of the country and lower in high-cost areas.) This scenario could contribute to selective program participation by ACOs favored by the national flat-dollar growth target, or favored by other unforeseen biases affecting performance.

While shared FFS savings, even with optional liability for a portion of excess expenditures, offers less incentive to reduce costs than, say, full capitation, it still represents a new incentive for efficiency. Shared-savings (and potential liabilities) will have varying degrees of influence on hospitals, primary physicians, specialty physicians, and other providers. The expectation is for different ACOs to comprise a varying mix of these providers and suppliers. And while certain care improvements might be achieved relatively quickly (for example, prevention of hospital readmissions and emergency-room visits for certain populations with chronic conditions), many potential ACOs might need more than 3 years to achieve comprehensive efficiency gains. Challenges include identification of assigned beneficiaries, coordinating care furnished by providers and suppliers outside the ACO, lack of similar contracts with other payers, achieving buy-in from ACO providers/suppliers, and the extent to which possible future shared savings or losses will affect the perceived value of immediate FFS revenue for providers and suppliers participating in an ACO.

While there remains great uncertainty for the aggregate financial impact of the program, the impact on quality, as will be measured and reported, is likely to show gains for most participating ACOs over the course of their agreement.

Comment: One commenter recommended that we include further detail regarding the beneficiary population expected to be assigned to ACOs participating in the Shared Savings Program, including characteristics of ethnicity and gender, and further requested that we provide baseline per capita FFS expenditures. Another commenter requested that we analyze the average expenditures for beneficiaries in States with low, median, and high average expenditures, were they assigned to an ACO participating in the Shared Savings Program achieving maximum shared-savings, were they enrolled in a Medicare Advantage organization of various quality star ratings, or were they simply in traditional Medicare.

Response: Due to the great uncertainty regarding the quantity and composition of ACOs that will participate in the Shared Savings Program, such estimates of the demographic characteristics or per capita expenditures of affected beneficiaries are not currently feasible. Even were we confident of specific markets that were likely to generate ACOs, we would require the mix of TINs that would be aggregated to form the basis of assignment to such potential ACOs in order to estimate any potential differences in the demographic characteristics for all ACO-assigned patients relative to the greater FFS Medicare population, or to analyze differences in average expenditures relative to MA or traditional Medicare. Such expenditures could vary significantly based not only on geography but also an ACO's provider composition, which can mean ACOs in the same market may have widely varying baseline per capita expenditures for their assigned beneficiaries. Indeed, a stochastic model was chosen to illustrate such great uncertainty presented by voluntary participation in a new and complex program. However, we agree that such analysis would be beneficial within future evaluations based on actual program experience.

a. Assumptions and Uncertainties

We sought input from a wide range of external experts, including credentialed actuaries, consultants, and academic researchers, to identify the pertinent variables that could determine the efficacy of the program, and to identify the reasonable ranges for each variable. Also, subsequent to publication of the proposed rule, we studied rule comments, expert reactions, and letters of intent for the Innovation Center Pioneer ACO Model. The assumptions ultimately identified and stochastically modeled include the following:

- Number of participating ACO provider groups, including the sensitivity to burdens of participation and the generosity of the sharing arrangement.
- Size mix of participating ACOs.
- Type of ACO that would consider accepting risk under Track 2.
- Participating ACOs' current level of integration and preparedness for improving the quality and efficiency of care delivery.
- Baseline per-capita costs for prospective ACOs, relative to the national average.
- Number and profile of providers and suppliers available to participate in the Shared Savings Program as a result

of Innovation Center ACO model initiatives.

- Range of gross savings achieved by ACOs, and the time required for full phase-in.
- Local variation in expected claims cost growth relative to the national average.
- Quality reporting scores and resulting attained sharing (or loss) percentages.

Overall we assumed 1 to 5 million Medicare beneficiaries would align with between 50 and 270 ACOs during the first four years of the program. We assumed ACOs to be equally likely to participate from markets exhibiting baseline per-capita FFS expenditures above, at, or below the national average, as opposed to our assumption for the proposed rule that ACOs would be more likely to form in high-cost markets. In addition, we assumed the level of savings generated by an ACO to positively correlate to the achieved quality performance score and resulting sharing percentage.

We anticipate a minority of ACOs—a more capable subset of the total program participation—will opt for Track 2 in the first agreement period, enabled by experience accepting risk for other populations and motivated by a lower minimum savings rate and greater sharing percentage. However, most participating ACOs are expected to choose Track 1 in order to simultaneously—(1) avoid the potential for financial loss if expenditures experience a significant upward fluctuation or efficiency improvements are less effective than planned; and (2) build organizational experience to achieve a per-capita cost target as presented by the program's unique benchmark methodology.

A particularly important cause for uncertainty in our estimate is the high degree of variability observed for local per-capita cost growth rates relative to the national average ''flat dollar'' growth (used to update ACO benchmarks). The benchmark or expenditure target effectively serves as the only measure of efficiency for participating ACOs. Factors such as lower-than-average baseline per-capita expenditure and variation in local growth rates relative to the national average can trigger shared savings payments even in the absence of any efficiency gains. Similarly, some ACOs could find that factors, such as prevailing per-capita expenditure growth in their service area that is higher than the national average, limit efficiency gains and reduce or prevent shared savings.

b. Detailed Stochastic Modeling Results

Table 9 shows the distribution of the estimated net financial impact for the 5,000 stochastically generated trials. (The amounts shown are in millions, with negative net impacts representing Medicare savings). The net impact is defined as the total cost of shared savings less—(1) any amount of savings generated by reductions in actual expenditures; and (2) any losses collected for ACOs that accepted risk and have actual expenditures exceeding their benchmark.

The median estimate of the Shared Savings Program financial impact for calendar years 2012 through 2015 is a net Federal savings of $470 million. This amount represents the ''best estimate'' of the financial impact of the Shared Savings Program initiative during the agreement period. It is important to note, however, the relatively wide range of possible outcomes. Overall, 90 percent of the stochastic trials resulted in net program savings, and the remaining 10 percent represented cost increases. The 10th and 90th percentiles of the estimated distribution show net savings of $940 million and a net cost of $ zero million, respectively, suggesting a 10 percent likelihood that the actual impact would fall outside respective percentile amounts. In the extreme scenarios, the results were as large as $2.0 billion in savings or $1.1 billion in costs. Relative to the proposed rule, the final rule projections reflect greater generosity (and cost to Medicare) offset by greater participation over an extended agreement period, leading to a higher median net savings but also a wider stochastic range than we would now estimate for the proposed rule over the same period. (Market response to the proposed rule causes us to decrease the participation levels we would assume for the originally proposed program design.)

The stochastic model and resulting financial estimates were prepared by the CMS Office of the Actuary (OACT). The median result of $470 million in savings is a reasonable ''point estimate'' of the impact of the Shared Savings Program provision in current law, as it would be implemented through this final rule. However, we emphasize the possibility of outcomes differing substantially from the median estimate, as illustrated by the estimate distribution. With additional data on the actual number and characteristics of participating ACOs, we can estimate the financial impact with greater precision.

The projections assume the assignment of roughly 1 to 5 million beneficiaries to participating ACOs during the first program agreement period. To the extent that the Shared Savings Program will result in net savings or costs to Part B of Medicare, revenues from Part B beneficiary premiums would also be correspondingly lower or higher. In addition, because MA payment rates depend on the level of spending within traditional FFS Medicare, Shared Savings Program savings or costs would result in corresponding adjustments to MA payment rates. Neither of these secondary impacts has been included in the analysis shown.

TABLE 9—STOCHASTIC DISTRIBUTION FOR THE ESTIMATED NET SAVINGS (–) OR COSTS (+), CYs 2012 THROUGH 2015
($ millions)

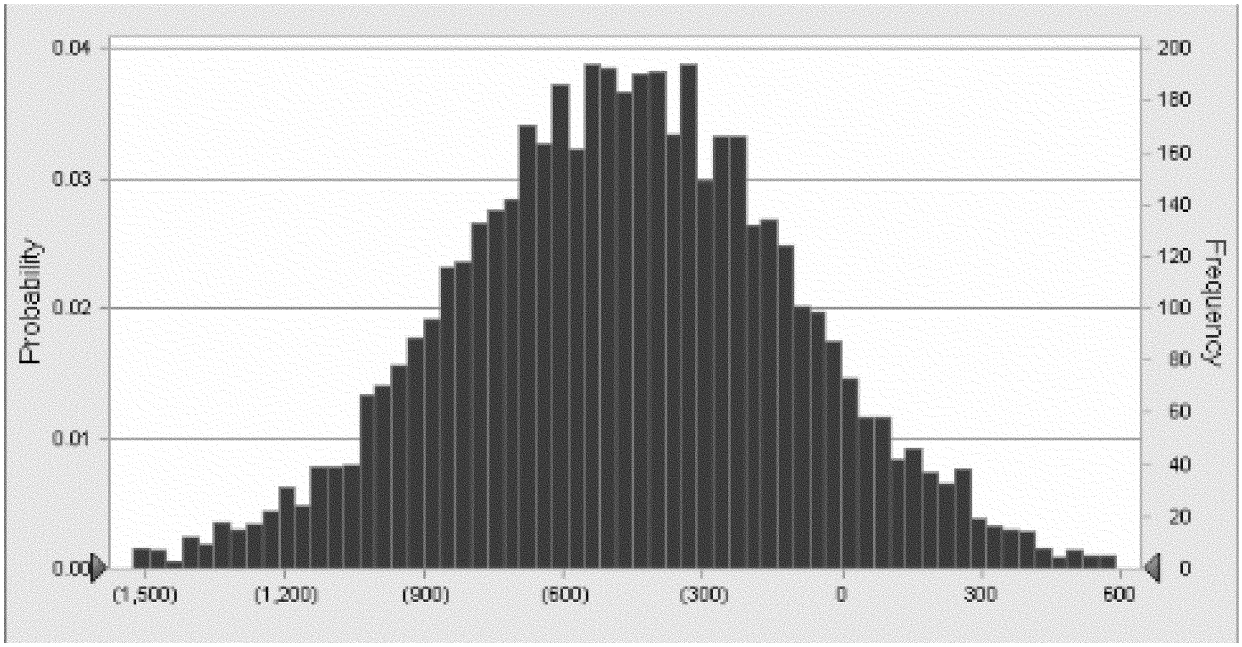
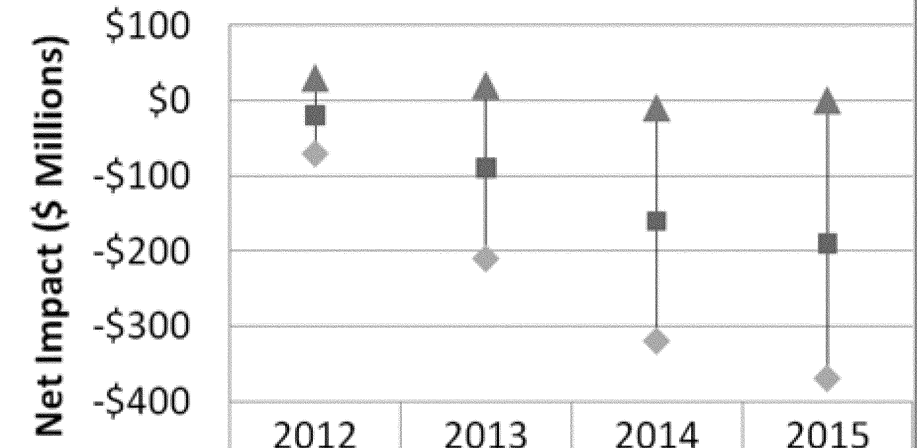


Table 10 shows the median estimated financial effects for the Shared Savings Program initiative, and the associated 10th and 90th percentile ranges, broken out during the first agreement period. Net savings (characterized by a negative net impact on Federal outlays) are expected to be marginal in 2012 ($20 million) due to gradual enrollment assumed over that first year as well as the assumption that cost-saving initiatives will require time for maturation. In calendar years 2013 through 2015 net savings are expected to grow as maturing cost-saving effectiveness is partially offset by increasing cost from growing variation in the accuracy of updated national targets compared to actual local growth. As a result, the projections for CYs 2013 through 2015 cover a wider range of possible outcomes, reflecting a growing dependence on uncertain assumptions for savings and expenditure growth variation relative to the national average. We note that the percentiles are tabulated for each year separately, and therefore the overall net impact distribution (Table 9) will not necessarily exactly match the sum of distributions for each distinct year.

TABLE 10—STOCHASTIC DISTRIBUTION FOR ESTIMATED FEDERAL NET SAVINGS (–) OR COSTS (+), CYs 2012 THROUGH 2015
($ MILLIONS)



	2012	2013	2014	2015
▲ 90th %-ile	$30	$20	-$10	$0
■ median	-$20	-$90	-$160	-$190
◆ 10th %-ile	-$70	-$210	-$320	-$370

c. Further Consideration

The impact analysis shown is only for the first agreement period. Beyond this initial period, there is additional uncertainty, in significant part because the rules governing subsequent Shared Savings Program agreement periods have not yet been developed. In addition, uncertainties exist in the short and long term regarding providers' responses to the program. For example, a voluntary program may eventually draw selective participation by ACOs that develop an ability to predict a favorable bias in the savings formula. However, ACOs that participate in the program during the first agreement period may foster significant improvements in the quality and cost-efficiency of health care delivery, leading to broader use of these techniques nationwide and accelerated adoption of risk-sharing arrangements (such as partial capitation, bundled payments, etc.). These changes could result in significant efficiency gains in FFS Medicare. The stochastic model for the first agreement period of the program does not incorporate either of these longer-run scenarios, but both remain possibilities. At this time, an impact estimate expanded to include performance beyond the initial agreement period would likely entail a significantly wider range of possible outcomes. The results of the first performance cycle, however, will help inform estimates of the ongoing financial effects of the Shared Savings Program.

2. Impact on Beneficiaries

We anticipate the Shared Savings Program will benefit beneficiaries because the intent of the program is to require ACOs to be accountable for Medicare beneficiaries, improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery that demonstrates a dedication and focus toward patient-centered care. This program does not affect the beneficiary's freedom of choice regarding providers or care since beneficiaries assigned to an ACO continue to be in the traditional Medicare program. Also, a requirement of ACO participation in the Shared Savings Program is reporting of, and successful performance related to, quality measures and patient-experience surveys. These aspects of the Shared Savings Program will encourage the provider and supplier community to focus on and deliver improved quality care. In addition to existing Medicare monitoring programs that are in place to protect beneficiaries, the Shared Savings Program will include monitoring and auditing processes to protect beneficiary choice as well as ensure that beneficiaries are receiving the appropriate care. As is discussed in more detail in the preamble, these processes include monitoring ACO avoidance of at-risk beneficiaries, assessing and providing follow up on beneficiary complaints, audits (including, for example, analysis of claims, chart review, beneficiary surveys, coding audits) and analysis of quality performance.

More specifically, we believe that advantages for beneficiaries would be maximized as the ACO meets the mission of the Shared Savings Program, as established by the Affordable Care Act and embraces the goals of better health and experience of care for individuals, better health for populations and lower expenditure growth. The ACO's impact will be demonstrated by how effectively it delivers care as measured under the financial methodology outlined in section II.G. of this final rule, how well it improves and delivers high quality care outlined in the quality measurement and reporting methodology in section II.F. of this final rule, and in meeting program requirements for patient-centered care

outlined in the discussion of eligibility in section II.B. of this final rule.

Because ACOs are accountable for both the quality and overall cost of care provided to their assigned beneficiary population and must meet the quality performance standards prior to sharing any savings, they have new incentives to improve the health and well being of the beneficiaries they treat. ACOs will report on conditions and areas that are high prevalence and high cost in the Medicare population, such as chronic disease, ambulatory care sensitive conditions, care transitions and readmissions, and patient experience. We have observed that measuring quality and providing incentives can result in redesigned care processes that provide clinicians with actionable information on their patients at the point of care which can lead to improved patient care processes and outcomes. For example, the Medicare Physician Group Practice Demonstration Fact Sheet (CMS, July 2011) showed that over the first 4 years of the PGP Demonstration, physician groups increased their quality scores an average of 10 percentage points on the ten diabetes measures, 13 percentage points on the ten congestive heart failure measures, 6 percentage points on the seven coronary artery disease measures, 9 percentage points on the two cancer screening measures, and 3 percentage points on the three hypertension measures. Further analysis is provided in the Physician Group Practice Demonstration Evaluation Report (Report to Congress, 2009; *http://www.cms.gov/DemoProjectsEvalRpts/downloads/PGP_RTC_Sept.pdf*).

In addition to the overall increases in quality scores, we can examine the impact of the PGP Demonstration on quality by comparing the values of the seven claims-based quality measures for each PGP site and its comparison group. Our analysis found that, on the claims-based measures, PGP performance exceeded that of the comparison groups (CGs) on all measures between the base year (BY) and performance year 2 (PY2). It also found that the PGP sites exhibited more improvement than their CGs on all but one measure between the BY and PY2. Even after adjusting for pre-demonstration trends in the claims-based quality indicators, the PGP sites improved their claims-based quality process indicators more than their comparison groups.

3. Impact on Providers and Suppliers

In order to participate in the program, we realize that there will be costs borne in building the organizational, financial and legal infrastructure that is required of an ACO as well as performing the tasks required (as discussed throughout the Preamble) of an eligible ACO, such as: Quality reporting, conducting patient surveys, and investment in infrastructure for effective care coordination. While provider and supplier participation in the Shared Savings Program will be voluntary, we have examined the potential costs of program participation.

In this final rule, we have revised many of the policies in the proposed rule, so as to allow for greater flexibility regarding the specific structure and requirements of an ACO, and we believe these changes will substantially reduce the burden associated with the infrastructure start-up and ongoing annual operating costs for participating ACOs in the Shared Savings Program. Significant modifications to reduce burden and cost for participating ACOs include offering flexibility in the: (1) Eligibility to participate in the Shared Savings Program; (2) program start date; (3) establishment of the agreement period; (4) governance and legal structure of an ACO; (5) quality performance standards and reporting on quality and cost measures; (6) adjustment to the benchmark and performance year expenditures; (7) shared savings determination and availability of first dollar savings; (8) transition to risk; (9) withholding 25 percent of shared savings; (10) timing for the evaluation of sharing savings (claims run-out); (11) antitrust review; and (12) timing for repayment of losses. Specific analyses regarding these significant final policy modifications are discussed in detail in section II. of this final rule.

Furthermore, beyond the statutory requirement that ACOs have at least 5,000 assigned Medicare beneficiaries, the size of ACOs will also vary in relation to beneficiary participation and associated costs. Due to the limited precedence for this program and uncertainty regarding the structure and strategies that the provider community will pursue in order to participate as an ACO, precise estimates of expected provider costs are difficult to create. An analysis produced by the Government Accountability Office (GAO) of first year total operating expenditures for participants of the Medicare PGP Demonstration varied greatly from $436,386 to $2,922,820, with the average for a physician group at $1,265,897 (Medicare Physician Payment: Care Coordination Programs Used in Demonstration Show Promise, but Wider Use of Payment Approach May Be Limited. GAO, February 2008). These costs (for groups which all had 200 or more physicians) include investments in infrastructure and information technology enhancements, management, quality reporting, and focused care coordination programs. The GAO also discovered that start-up investment expenditures in the PGP Demonstration varied between $82,573 and $917,398, with the average for a physician group at $489,354.

It is worth noting that the 10 participating physician groups in the demonstration were large compared with other physician practices in terms of annual medical revenues and non-physician staff. GAO claims that their larger relative size gave the 10 participating physician groups in the PGP Demonstration three size-related advantages over smaller physician practices. First, participants typically had institutional affiliations with an integrated delivery system, a general hospital, or a health insurance entity. Specifically 9 of the 10 participating physician groups were part of an integrated delivery system, 8 affiliated with a general hospital, and 5 affiliated with an entity that marketed a health insurance product. As a result of these affiliations, GAO claims that participating physician groups generally had greater access to relatively large amounts of financial capital needed to initiate or expand programs. The second advantage, GAO claims, the 10 large participating physician groups had over smaller physician practices is the increased probability of having or acquiring EHR systems, which was essential in participants' ability to gather data and track progress in meeting quality-of-care targets. For example, 8 of the 10 participating physician groups had an EHR in place before the demonstration began, and the 2 other participants, out of necessity, developed alternative methods for gathering patient data electronically. Lastly, GAO claims that the third size-related advantage that most of the 10 participating physician groups had over smaller physician practices was the larger groups' experience with other pay-for-performance systems prior to participating in the PGP Demonstration. That is, 8 of the 10 participants had previous experience with pay-for-performance programs initiated by private or public sector organizations. This experience, GAO concludes, may have eased their adjustment to the PGP Demonstration and allowed them greater initial and overall success. Therefore, we recognize that start-up and ongoing annual operating costs will vary greatly between ACOs for various reasons, including those related to the

experience, size and funding available to the participating ACO.

We use this analysis not to predict cost investment and operating expenditures, but to demonstrate that we expect the range of investment to vary greatly across ACOs and to provide potential scope for aspiring participants. We expect that due to the difference in program requirements between the Shared Savings Program and the PGP Demonstration Project, and the potential variation in ACO size and structure, the PGP related costs may be a subset of the investment required by entities seeking participation in this program. However, we also recognize that potential advantageous key drivers for participating physician groups would include institutional affiliations that allow greater access to financial capital, access to and experience using EHR and other IT systems and experience with pay-for-performance programs. As a result, we continue to believe that the structure, maturity, and thus associated costs represented by those participants in the Medicare PGP Demonstration are most likely to represent the majority of anticipated ACOs participating in the Shared Savings Program. Lastly, we recognize that participating ACOs may involve Medicare and the commercial side within their business scope, thereby stratifying start-up investment and ongoing annual operating costs across various business segments, and not solely attributable to the Medicare Shared Savings Program.

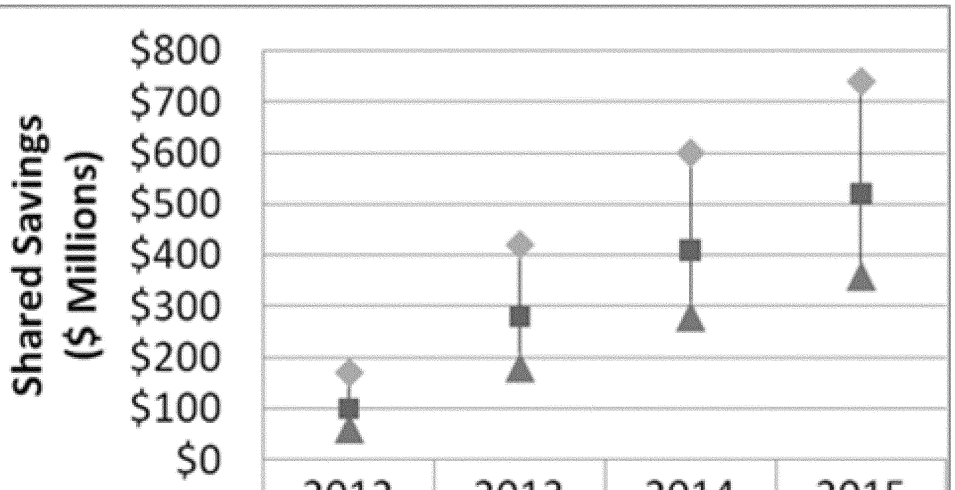
We contacted several experienced provider organizations, private health plan network executives and investors involved with integrated delivery systems to assess the infrastructure costs associated in establishing a new ACO. As a result, we have revised our cost estimates relative to the proposed rule to reflect new information we learned regarding the start-up investment cost for an ACO. The ongoing annual operating costs presented in the proposed rule were validated and thus remain within the same range in the final rule. Therefore, our cost estimates for purposes of this final rule reflect an average estimate of $0.58 million for the start-up investment costs and $1.27 million in ongoing annual operating costs for an ACO participant in the Shared Savings Program. Lastly, assuming an expected range of ACOs participating in the Shared Savings Program of 50 to 270 ACOs yields an estimated start-up investment cost ranging from $29 million to $157 million, with ongoing annual operating costs ranging from $63 million to $342 million for CYs 2012 through 2015. When utilizing the anticipated mean participation rate of ACOs in the Shared Savings Program coupled with the average start-up investment and ongoing annual operating costs, this yields an estimated aggregate average start-up investment and ongoing annual operating costs of $451 million for the CYs 2012 through 2015.

While there will be a financial cost placed on ACOs in order to participate, there will be benefits to the respective organizations in the form of increased operational and healthcare delivery efficiency. Furthermore, as discussed previously, and explained in more detail in the preamble of this final rule, there will be an opportunity for financial reward for success in the program in the form of shared savings. As shown in Table 11, the estimated bonuses paid are a median of $1.31 billion during CYs 2012 through 2015, with $890 million and $1.90 billion reflecting the 10th and 90th percentiles. (Similar to the previously presented stochastic distributions, the distribution represents uncertainty given the range of expert opinion, rather than a true statistical probability distribution.) Therefore, the total median ACO bonus payments of $1.31 billion during CYs 2012 through 2015 coupled with the aggregate average start-up investment and ongoing annual operating cost of $451 million, incurred by the mean participation rate of ACOs in the Shared Savings Program during the same time period, yields a benefit-cost ratio of 2.9.

We expected an increased amount of total bonuses relative to the proposed rule due to a more favorable sharing CYs 2012 through 2015 arrangement and simplified requirements of participation, highlighted by first-dollar sharing and removal of year-3 risk in Track 1. The increase in bonuses is also in part due to the added participation expected as a result of these changes. Participating Track 2 ACOs will be assuming a risk of a financial penalty for failing to achieve savings (that is, if actual expenditures exceed the benchmark). At the median, we do not anticipate the collection of penalties during the first agreement period, with our 90th percentile projecting only $20 million in collected penalties. Penalties decrease relative to the proposed rule despite the increased participation assumptions. This is primarily due to the enhanced attractiveness of Track 1 relative to Track 2, as well as the removal of required risk from year three of Track 1. Due to the voluntary nature of this program, we expect the formation of ACOs by entities that aspire to receive benefits that outweigh their costs. ACOs that opt for Track 2 are expected to achieve significant savings in a shorter time period. We anticipate that not all ACOs will achieve shared savings and some may incur a financial loss, due to the requirement to repay a share of actual expenditures in excess of their benchmark.

TABLE 11—STOCHASTIC DISTRIBUTION FOR ESTIMATED ACO BONUS PAYMENTS, CYs 2012 THROUGH 2015

($ millions)



	2012	2013	2014	2015
▲ 10th %-ile	$60	$180	$280	$360
■ median	$100	$280	$410	$520
◆ 90th %-ile	$170	$420	$600	$740

We invited comment on the provider and supplier cost impact assessment, including the start-up investment and ongoing annual operating costs considered.

Comment: Commenters expressed concern that the ACO infrastructure costs, including start-up and first year operating costs, presented in the proposed rule were low. Furthermore, the commenters referenced a study by the American Hospital Association (AHA) estimating start-up investment and ongoing annual operating costs as more accurately reflecting the associated costs of participating in the Medicare Shared Savings Program.

Response: The AHA study presented estimates much higher than those utilized in this RIA and the independent GAO study. Their estimates focused on two prototypes. The first prototype included a 200 bed, 1 hospital system, with 80 primary care providers and 150 specialists. The second prototype included a 1,200 bed, 5 hospital system, with 250 primary care providers and 500 specialists.

The overall estimates in the AHA study reflect an all inclusive cost structure well beyond the minimum requirements of the Medicare Shared Savings Program and the anticipated average participating ACO. As a result, the AHA study identifies three notes of caution relative to its findings. First, depending on the organization and circumstances of the ACO, some of the costs identified in the study may have already been incurred or attributable to purposes other than ACO-related development. Second, AHA acknowledges that the four case studies presented are not a large sample size from which to estimate costs. Third, their research work was conducted before the Medicare Shared Savings Program proposed rule was published and does not reflect the policies for the program put forth in either the proposed rule or this final rule. Furthermore, the study acknowledges that at the time of their research, the nature of ACOs and the process of developing them had not been standardized. In addition, the reporting requirements for ACOs had not yet been disclosed. Lastly, the study concludes that these estimates should be used as ''early indicators,'' and ''certainly not as definitive measures for ACOs in the Medicare Shared Savings Program.'' We agree with the limitations of the study and as a result, we continue to believe that the independent GAO analysis provided on the Medicare PGP Demonstration and the analysis to support the advanced payment model offer a more closely aligned benchmark for assessing the start-up investment and ongoing annual operating costs associated with participation in the Medicare Shared Savings Program under the policies established in this final rule.

4. Impact on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most physician practices, hospitals and other providers are small entities, either by nonprofit status or by qualifying as small businesses under the Small Business Administration's size standards (revenues of less than $7.0 to $34.5 million in any 1 year; NAIC Sector-62 series). States and individuals are not included in the definition of a small entity. For details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.*

For purposes of the RFA, approximately 95 percent of physicians

are considered to be small entities. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the Physician Fee Schedule (PFS).

Although the Shared Savings Program is a voluntary program and payments for individual items and services will continue to be made on a FFS basis, we acknowledge that the program can affect many small entities and have drafted the rules and regulations accordingly in order to minimize costs and burden on such entities as well as maximize their opportunity to participate. The Shared Savings Program is designed to encourage individual physicians and small physician practices to integrate with other such practices as well as larger entities to create ACOs. Small entities will both be allowed and encouraged to participate in the Shared Savings Program, provided they have a minimum of 5,000 assigned beneficiaries, thereby realizing economic benefits through the utilization of enhanced and efficient systems of care and care coordination. Examples of increased economic benefits as a result of participating in this program include shared savings from this program, as well as qualifying for financial incentives from other CMS programs, such as PQRS, EHR, and e-Rx incentive payments. Therefore, a solo, small physician practice or other small entity may realize these economic benefits as a function of participating in this program and the utilization of enhanced clinical systems integration, which otherwise may not have been possible.

Again, we note that the Shared Savings Program is a voluntary program and payments for individual items and services would continue to be made on a FFS basis. This final rule will have a significant impact on a substantial number of small entities and we present more detailed analysis on these impacts, including costs and benefits to small entities and alternative policy considerations throughout this RIA. However, as detailed in this RIA, the total median bonus payments will exceed the average costs borne by participating in the Shared Savings Program. As a result, this regulatory impact section, together with the remainder of the preamble, constitutes the Final Regulatory Flexibility Analysis.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis, if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Although the Shared Savings Program is a voluntary program, this final rule will have a significant impact on the operations of a substantial number of small rural hospitals. We have created the regulations such that rural hospitals will have the opportunity to participate and, where possible, be provided incentives to encourage participation, such as shared savings and the opportunity to qualify for financial incentives from other CMS programs, such as the EHR Incentive Program. As detailed in this RIA, the estimated aggregate median impact of bonus payments to participating ACOs more than exceeds the estimated average costs borne by voluntarily participating in the Shared Savings Program.

E. Alternatives Considered

This final rule contains a range of policies. Many tenets of the program are statutorily mandated and thus allow for little, if any, flexibility in the rulemaking process. Where there was flexibility, we made our policy decisions regarding alternatives based on a balance between creating the least possible negative impact on the stakeholders affected by the program and satisfactorily fitting the vision of the program within given operational constraints.

For example, while the Affordable Care Act mandates that an ACO be large enough to care for a minimum of 5,000 assigned beneficiaries, as is described in the preamble, we are adopting a sliding minimum percentage and confidence interval for the savings threshold based on the size of an ACO. This policy is a balance of protecting the program from paying out savings based on random variation, while allowing attainable thresholds for smaller ACOs and thus encouraging participation from various sized entities.

The preceding preamble provides descriptions of the various statutory provisions that are addressed in this final rule, identifies those policies when discretion has been allowed and exercised, presents the rationales for our final policies and, where relevant, alternatives that were considered. An important alternative involves making adjustments to an ACO's benchmark for changes in FFS price adjustments (such as the geographic practice cost index (GPCI) under the PFS and hospital wage index). Such price changes regularly occur and often impact counties or other localities in magnitudes that can significantly differ from the national average. If, for example, operating cost payments are reduced for section 508 of the MMA hospitals (as will occur under current law at the end of FY 2011) then ACO-attributed claims incurred in a section 508 of the MMA hospital would exhibit significant price decreases which could lead to shared savings payments unrelated to real improvements in ACO efficiency. Absent such adjustments, these statutory changes will impact the comparison of actual expenditures and the benchmark. As we have previously noted, the statute provides authority for adjustment to the benchmark for ''such other factors as the Secretary determines appropriate,'' and while there is no similar authority under section 1899(d) of the Act to adjust actual expenditures during a performance year for ''such other factors'' we considered using our authority under section 1899(i) of the Act to make such adjustments to the determination of actual expenditures. Although this potentially beneficial but operationally complex policy is not included in this final rule, we note that such adjustment may be explored by pilots designed within the Innovation Center and could potentially inform future rulemaking for this program. However, we do note, that we are using our authority under sections 1899(d) and (i) of the Act to make adjustments to remove IME and DSH payments from both benchmark and performance expenditures, constituting a partial step toward a bonus formula that responds to improvements in utilization rather than differences in price between performance and benchmark expenditures.

The proposed rule received numerous comments calling for a method for risk adjustment to take into account changes in the health status of the population between the benchmark period and performance year. Options were considered for the final rule that could reflect such changes in beneficiary characteristics without rewarding ACOs for more complete and accurate HCC coding of their assigned patient population than would occur for a comparable group of beneficiaries receiving care outside an ACO. Therefore a method was chosen for stratifying the benchmark by four distinct beneficiary eligibility categories that each share a unique expenditure profile: ESRD, disabled, aged dual-eligible beneficiaries and aged non-dual-eligible beneficiaries. The benchmark will be normalized to the mix of

beneficiaries aligned across the four strata in a given performance year, improving the fidelity of the updated benchmark to the beneficiary characteristics in such performance year. In addition, adjustments will be made to account for changes in severity and case mix for newly assigned beneficiaries utilizing CMS–HCC prospective scores. Demographic factors alone would be used to adjust for changes for continuously assigned beneficiaries in order to avoid rewarding ACOs for more complete and accurate diagnosis coding, unless this populations HCC risk score declines in which case it will be reset at the lower rate. Such combined method for accounting for shifts in the characteristics of the assigned population is expected to reduce variation in expenditure growth relative to the benchmark and also to mitigate the incentive for ACOs to reduce services to high-risk patients in order to compare favorably against a static benchmark.

Comments also frequently discussed the limited reward presented by the proposed rule relative to the costs that providers estimated they would incur for infrastructure and operation as an ACO under the program. Many elements of the final rule respond directly to this concern, including the removal of required risk in the third year under Track 1, the addition of first-dollar sharing in Track 1, the increased sharing caps for both tracks, the removal of the 25 percent withhold on shared-savings dollars, and the reduction in operational burdens such as the number of quality measures to be reported. All described changes likely improve the business-case for ACOs to join the program, whether in terms of reduced burden or enhanced benefit of participation. However, our modeling of these changes' impact on the Medicare program indicated that the removal of the 2 percent threshold is the most significant change that directly affects the more favorable program sharing arrangement. Raising the sharing caps is not likely to affect shared savings payments for even the highest-performing ACOs. The withholds were also expected to have minimal direct financial impact since an ACO incurring a withhold—and therefore generating measured savings in year 1 or 2—would be unlikely to incur a penalty in a following year of the agreement period (and would be even less likely to fail to repay the penalty in such rare case). Requiring risk in the third year was not anticipated to generate significant additional penalty dollars, since it would most likely cause ACOs experiencing difficulty meeting their benchmarks to terminate their agreements prior to that third year rather than face likely penalties. As a result, removing this requirement is expected to enhance program participation without negatively impacting the estimated net Federal savings.

Finally, a key design element with potential to significantly affect the impact of the program involves the method for establishing quality standards. We propose aggregating the quality domain scores into a single overall ACO score used to calculate the ACO's final sharing rate for purposes of determining shared savings or shared losses as described in section II.F. of this final rule. We would average all domain scores for an ACO together equally to calculate the overall quality score used to calculate the ACO's final sharing rate as previously described. We also considered a variety of scoring methodologies that would have differing incentives for improving clinical outcomes such as: Scoring measures individually under a method that would weigh all measures equally as well as weighing quality measures by their clinical importance. In addition to the performance score approach that rewards ACOs for better quality with larger percentages of shared savings as modeled in this analysis, we could use a threshold approach that allows any ACO that meets minimum standards for the quality measures to realize the full shared savings. However, our final policy encourages continuous quality improvement since ACOs that score higher on quality get to keep a higher percentage of the savings they generate compared to ACOs that perform lower on quality.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), in Table 12, we have prepared an accounting statement showing the classification of transfers, benefits and costs associated with the provisions of this final rule.

TABLE 12—ACCOUNTING STATEMENT: ESTIMATED TRANSFERS, BENEFITS AND COSTS

[CYs 2012–2015]

Category	Transfers			
Annualized monetized transfers	Year dollar	Units discount rate		Notes
	2011	7%	3%	
	Primary Estimate	−$110.08 million	−$112.85 million	These estimates represent the range of annualized impacts on the Medicare Program (net bonus payments) for CYs 2012–2015.
	90th Percentile Estimate	$11.02 million	$10.45 million.	
	10th Percentile Estimate	−$233.92 million	−$238.76 million.	
From/To	Federal Government to ACO Providers			
Category	COSTS			
Year Dollar: 2011: Primary Estimate	Primary Estimate	$112.2 million	$112.5 million	Estimated aggregate average start-up investment and ongoing annual operating costs based on the mean ACO participation rate for CYs 2012 through 2015.

TABLE 12—ACCOUNTING STATEMENT: ESTIMATED TRANSFERS, BENEFITS AND COSTS—Continued

[CYs 2012–2015]

Category	Transfers			
Annualized monetized transfers	Year dollar	Units discount rate		Notes
	2011	7%	3%	
Category	BENEFITS			
Qualitative Benefits	Improved healthcare delivery and communication to beneficiaries through patient centered-care.			

G. Conclusion

As a result of this final rule, the median estimate of the financial impact from implementation of the Shared Savings Program, for CYs 2012 through 2015, is a net savings (after bonus payments) of $470 million. Although this is the ''best estimate'' for the financial impact of the Shared Savings Program during CYs 2012 through 2015, a relatively wide range of possible outcomes exists. Overall, 90 percent of the stochastic trials resulted in net program savings, and the remaining 10 percent represented cost increases. The 90th and 10th percentiles of the estimate distribution show net savings of $940 million and $0 million, respectively, suggesting a 10 percent likelihood that the actual impact would exceed $940 million and a 10 percent likelihood that the actual impact would result in a negative net Federal savings (that is, a net Federal cost). In the extreme scenarios, the results were as large as $2.0 billion in savings or $1.1 billion in costs. In addition, at the anticipated mean participation rate of ACOs in the Shared Savings Program, participating ACOs may experience an estimated aggregate average start-up investment and ongoing annual operating cost of $451 million for CYs 2012 through 2015. Lastly, we estimate an aggregate median impact of $1.31 billion in bonus payments to participating ACOs in the Shared Savings Program for CYs 2012 through 2015. The 10th and 90th percentiles of the estimate distribution, for the same time period, yield bonus payments to ACOs of $890 million and $1.9 billion, respectively. Therefore, the total median ACO bonus payments of $1.31 billion during CYs 2012 through 2015 coupled with the aggregate average start-up investment and ongoing annual operating cost of $451 million, incurred by the mean participation rate of ACOs in the Shared Savings Program during the same time period, yields a benefit-cost ratio of 2.9.

Overall, we assumed greater participation by ACOs under the policies contained in this final rule due to the greater generosity and the longer agreement period, as well as the full agreement period with a one-sided option. The longer agreement period also amplified our saving and cost estimates from what they would have been in a 3-year program. This resulted in total bonuses increasing dramatically, while penalties decreased due to these changes.

List of Subjects in 42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV by adding part 425 to read as follows:

PART 425—MEDICARE SHARED SAVINGS PROGRAM

Sec.

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Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 425.10 Basis and scope.

(a) *Basis.* This part implements section 1899 of the Act by establishing a shared savings program that promotes accountability for a patient population, coordinates items and services under Medicare parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient services. The regulations under this part must not be construed to affect the payment, coverage, program integrity, and other requirements that apply to providers and suppliers under FFS Medicare.

(b) *Scope.* This part sets forth the following:

(1) The eligibility requirements for an ACO to participate in the Medicare Shared Savings Program (Shared Savings Program).

(2) Application procedures and provisions of the participation agreement.

(3) Program requirements and beneficiary protections.

(4) The method for assigning Medicare fee-for-service beneficiaries to ACOs.

(5) Quality performance standards, reporting requirements, and data sharing.

(6) Payment criteria and methodologies (one-sided model and two-sided model).

(7) Compliance monitoring and sanctions for noncompliance.

(8) Reconsideration review process.

§ 425.20 Definitions.

As used in this part, unless otherwise indicated—

Accountable care organization (ACO) means a legal entity that is recognized and authorized under applicable State, Federal, or Tribal law, is identified by a Taxpayer Identification Number (TIN), and is formed by one or more ACO participants(s) that is(are) defined at § 425.102(a) and may also include any other ACO participants described at § 425.102(b).

ACO participant means an individual or group of ACO provider(s)/supplier(s), that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants that is required under § 425.204(c)(5).

ACO professional means an ACO provider/supplier who is either of the following:

(1) A physician legally authorized to practice medicine and surgery by the State in which he performs such function or action.

(2) A practitioner who is one of the following:

(i) A physician assistant (as defined at § 410.74(a)(2) of this chapter).

(ii) A nurse practitioner (as defined at § 410.75(b) of this chapter).

(iii) A clinical nurse specialist (as defined at § 410.76(b) of this chapter).

ACO provider/supplier means an individual or entity that—

(1) Is a provider (as defined at § 400.202 of this chapter) or a supplier (as defined at § 400.202 of this chapter);

(2) Is enrolled in Medicare;

(3) Bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and

(4) Is included on the list of ACO providers/suppliers that is required under § 425.204(c)(5).

Agreement period means the term of the participation agreement which begins at the start of the first performance year and concludes at the end of the final performance year.

Antitrust Agency means the Department of Justice or Federal Trade Commission.

Assignment means the operational process by which CMS determines whether a beneficiary has chosen to receive a sufficient level of the requisite primary care services from a physician who is an ACO provider/supplier so that the ACO may be appropriately designated as exercising basic responsibility for that beneficiary's care.

At-risk beneficiary means, but is not limited to, a beneficiary who—

(1) Has a high risk score on the CMS–HCC risk adjustment model;

(2) Is considered high cost due to having two or more hospitalizations or emergency room visits each year;

(3) Is dually eligible for Medicare and Medicaid;

(4) Has a high utilization pattern;

(5) Has one or more chronic conditions.

(6) Has had a recent diagnosis that is expected to result in increased cost.

(7) Is entitled to Medicaid because of disability; or

(8) Is diagnosed with a mental health or substance abuse disorder.

Continuously assigned beneficiary means a beneficiary assigned to the ACO in the current performance year who was either assigned to or received a primary care service from any of the ACO's participant during the most recent prior calendar year.

Covered professional services has the same meaning given these terms under section 1848(k)(3)(A) of the Act.

Critical access hospital (CAH) has the same meaning given this term under § 400.202 of this chapter.

Eligible professional has the meanings given this term under section 1848(k)(3)(B) of the Act.

Federally qualified health center (FQHC) has the same meaning given to this term under § 405.2401(b) of this chapter.

Hospital means a hospital subject to the prospective payment system specified in § 412.1(a)(1) of this chapter.

Marketing materials and activities include, but are not limited to, general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, Web pages, data sharing opt out letters, mailings, social media, or other activities conducted by or on behalf of the ACO, or by ACO participants, or ACO providers/suppliers participating in the ACO, when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Savings Program. The following beneficiary communications are not marketing materials and activities: Certain informational materials customized or limited to a subset of beneficiaries; materials that do not include information about the ACO, its ACO participants, or its ACO providers/suppliers; materials that cover beneficiary-specific billing and claims issues or other specific individual health related issues; educational information on specific medical conditions (for example, flu shot reminders), written referrals for health care items and services, and materials or activities that do not constitute ''marketing'' under 45 CFR 164.501 and 164.508(a)(3)(i).

Medicare fee-for-service beneficiary means an individual who is—

(1) Enrolled in the original Medicare fee-for-service program under both parts A and B; and

(2) Not enrolled in any of the following:

(i) A MA plan under part C.

(ii) An eligible organization under section 1876 of the Act.

(iii) A PACE program under section 1894 of the Act.

Medicare Shared Savings Program (Shared Savings Program) means the program, established under section 1899 of the Act and implemented in this part.

Newly assigned beneficiary means a beneficiary that is assigned in the current performance year who was neither assigned to nor receives a primary care service from any of the ACO's participants during the most recent prior calendar year.

One-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, but is not liable for sharing any losses incurred under subpart G of this part.

Performance year means the 12-month period beginning on January 1 of each year during the agreement period, unless otherwise noted in the ACO's agreement. For an ACO with a start date of April 1, 2012 or July 1, 2012, the ACO's first performance year is defined as 21 months and 18 months, respectively.

Physician means a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Act).

Physician Quality Reporting System (PQRS) means the quality reporting system established under section 1848(k) of the Act.

Primary care physician means a physician who has a primary specialty designation of internal medicine, general practice, family practice, or geriatric medicine, or, for services furnished in an FQHC or RHC, a physician included in an attestation by the ACO as provided under § 425.404.

Primary care services mean the set of services identified by the following HCPCS codes:

(1) 99201 through 99215.

(2) 99304 through 99340, and 99341 through 99350, G0402 (the code for the Welcome to Medicare visit), G0438 and G0439 (codes for the annual wellness visits);

(3) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

Quality measures means the measures defined by the Secretary, under section 1899 of the Act, to assess the quality of care furnished by an ACO, such as measures of clinical processes and outcomes, patient and, where practicable, caregiver experience of care and utilization.

Reporting period, for purposes of subpart F of this part, means the calendar year from January 1 to December 31.

Rural health center (RHC) has the same meaning given to this term under § 405.2401(b).

Shared losses means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, above the applicable benchmark, it must repay to CMS. An ACO's eligibility for shared losses will be determined for each performance year. For an ACO requesting interim payment, shared losses may result from the interim payment calculation.

Shared savings means a portion of the ACO's performance year Medicare fee-for-service Parts A and B expenditures, below the applicable benchmark, it is eligible to receive payment for from CMS. An ACO's eligibility for shared savings will be determined for each performance year. For an ACO requesting interim payment, shared savings may result from the interim payment system calculation.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

Two-sided model means a model under which the ACO may share savings with the Medicare program, if it meets the requirements for doing so, and is also liable for sharing any losses incurred under subpart G of this part.

Subpart B—Shared Savings Program Eligibility Requirements

§ 425.100 General.

(a) Under the Shared Savings Program, ACO participants may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO that meets the criteria specified in this part. The ACO must become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) ACOs that meet or exceed a minimum savings rate established under § 425.604 or § 425.606, meet the minimum quality performance standards established under § 425.500, and otherwise maintain their eligibility to participate in the Shared Savings Program under this part are eligible to receive payments for shared savings under subpart G.

(c) ACOs that operate under the two-sided model and meet or exceed a minimum loss rate established under § 425.606 must share losses with the Medicare program under subpart G of the part.

§ 425.102 Eligible providers and suppliers.

(a) The following ACO participants or combinations of ACO participants are eligible to form an ACO that may apply to participate in the Shared Savings Program:

(1) ACO professionals in group practice arrangements.

(2) Networks of individual practices of ACO professionals.

(3) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(4) Hospitals employing ACO professionals.

(5) CAHs that bill under Method II (as described in § 413.70(b)(3) of this chapter).

(6) RHCs.

(7) FQHCs.

(b) Other ACO participants that are not identified in paragraph (a) of this section are eligible participate through an ACO formed by one or more of the ACO participants identified in paragraph (a) of this section.

§ 425.104 Legal entity.

(a) An ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates for purposes of the following:

(1) Receiving and distributing shared savings.

(2) Repaying shared losses or other monies determined to be owed to CMS.

(3) Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.

(4) Fulfilling other ACO functions identified in this part.

(b) An ACO formed by two or more otherwise independent ACO participants must be a legal entity separate from any of its ACO participants.

§ 425.106 Shared governance.

(a) *General rule.* An ACO must maintain an identifiable governing body with authority to execute the functions of an ACO as defined under this part, including but not limited to, the processes defined under § 425.112 to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care.

(b) *Responsibilities of the governing body and its members.* (1) The governing body must have responsibility for oversight and strategic direction of the ACO, holding ACO management accountable for the ACO's activities as described in this part.

(2) The governing body must have a transparent governing process.

(3) The governing body members must have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.

(4) The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple, otherwise independent ACO participants.

(5) If the ACO is an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies the other requirements of this section.

(c) *Composition and control of the governing body.* (1) The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.

(2) The ACO governing body must include a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(3) At least 75 percent control of the ACO's governing body must be held by ACO participants.

(4) The governing body members may serve in a similar or complementary manner for an ACO participant.

(5) In cases in which the composition of the ACO's governing body does not meet the requirements of paragraphs (c)(2) and (c)(3) of this section, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.

(d) *Conflict of interest.* The ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must—

(1) Require each member of the governing body to disclose relevant financial interests; and

(2) Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise.

(3) The conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy.

§ 425.108 Leadership and management.

(a) An ACO must have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the Shared Savings Program and the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(b) The ACO's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

(c) Clinical management and oversight must be managed by a senior-level medical director who is a physician and one of its ACO providers/suppliers, who is physically present on a regular basis at any clinic, office, or other location participating in the ACO, and who is a board-certified physician and licensed in a State in which the ACO operates.

(d) Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO's likely success.

(1) Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant and ACO provider/supplier to achieve the ACO's mission under the Shared Savings Program.

(2) A meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes required by § 425.112 and is held accountable for meeting the ACO's performance standards for each required process.

(e) CMS retains the right to give consideration to an innovative ACO with a management structure not meeting paragraphs (b) through (c) of this section.

§ 425.110 Number of ACO professionals and beneficiaries.

(a)(1) The ACO must include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subpart E of this part. The ACO must have at least 5,000 assigned beneficiaries.

(2) CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries specified in paragraph (a)(1) of this section if the number of beneficiaries historically assigned to the ACO participants in each of the three years before the start of the agreement period, using the assignment methodology in subpart E of this part, is 5,000 or more.

(b) If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO will be issued a warning and placed on a CAP.

(1) While under the CAP, the ACO remains eligible for shared savings and losses during that performance year and its MSR will be set at a level consistent with the number of assigned beneficiaries.

(2) If the ACO's assigned population is not returned to at least 5,000 or more by the end of next performance year, the ACO's agreement will be terminated and the ACO will not be eligible to share in savings for that performance year.

§ 425.112 Required processes and patient-centeredness criteria.

(a) *General.* (1) An ACO must—

(i) Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;

(ii) Adopt a focus on patient centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams; and

(iii) Have defined processes to fulfill these requirements.

(2) An ACO must have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, which must include the defined processes included in paragraphs (b)(1) through (4) of this section.

(3) For each process specified in paragraphs (b)(1) through (4) of this section, the ACO must—

(i) Explain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process (and subelement thereof), including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process; and

(ii) Explain how it will employ its internal assessments of cost and quality of care to improve continuously the ACO's care practices.

(b) *Required processes.* The ACO must define, establish, implement, evaluate, and periodically update processes to accomplish the following:

(1) Promote evidence-based medicine. These processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.

(2) Promote patient engagement. These processes must address the following areas:

(i) Compliance with patient experience of care survey requirements in § 425.500.

(ii) Compliance with beneficiary representative requirements in § 425.106.

(iii) A process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.

(A) In its plan to address the needs of its population, the ACO must describe how it intends to partner with community stakeholders to improve the health of its population.

(B) An ACO that has a stakeholder organization serving on its governing body will be deemed to have satisfied the requirement to partner with community stakeholders.

(iv) Communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.

(v) Beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities;

(vi) Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.

(3) Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.

(4) Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. The ACO must—

(i) Define its methods and processes established to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO); and

(ii) As part of its application, the ACO must:

(A) Submit a description of its individualized care program, along with a sample individual care plan, and explain how this program is used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients.

(B) Describe additional target populations that would benefit from individualized care plans. Individual care plans must take into account the community resources available to the individual.

§ 425.114 Participation in other shared savings initiatives.

(a) ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program under section 1866E of the Act, a model tested or expanded under section 1115A of the Act that involves shared savings, or any other Medicare initiative that involves shared savings.

(b) CMS will review and deny an ACO's application if any ACO participants are participating in another Medicare initiative that involves shared savings payments.

(c) CMS will determine an appropriate method to ensure no duplication in payments for beneficiaries assigned to other shared savings programs or initiatives, including initiatives involving dually eligible beneficiaries, when such other shared savings programs have an assignment methodology that is different from the Shared Savings Program.

Subpart C—Application Procedures and Participation Agreement

§ 425.200 Agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than three years.

(b) *Term of agreement.* (1) *For 2012.* For applications that are approved to participate in the Shared Savings Program for 2012, the start date for the agreement will be one of the following:

(i) April 1, 2012 (term of the agreement is 3 years and 9 months).

(ii) July 1, 2012 (term of the agreement is 3 years and 6 months).

(2) For 2013 and all subsequent years—

(i) The start date is January 1 of that year; and

(ii) The term of the agreement is 3 years.

(c) *Performance year.* (1) Except as specified in paragraphs (b)(1)(i) and (ii) of this section, the ACO's performance year under the agreement is the 12 month period beginning on January 1 of each year during the term of the agreement unless otherwise noted in its agreement.

(2) For an ACO with a start date of April 1, 2012 or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(d) During each calendar year of the agreement period, including the partial year associated with start dates specified in paragraph (b)(1)(i) and (ii) of this section, ACOs must submit measures in the form and manner required by CMS.

§ 425.202 Application procedures.

(a) *General rules.* (1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by CMS by the deadline established by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowledge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to participate in the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of their application with the Antitrust Agencies.

(b) *Condensed application form.* PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(c) *Application review.* (1) CMS determines whether an applicant satisfies the requirements of this part and is qualified to participate in the Shared Savings Program.

(2) CMS approves or denies applications accordingly.

§ 425.204 Content of the application.

(a) *Accountability for beneficiaries.* As part of its application and participation agreement, the ACO must certify that the ACO, its ACO participants, and its ACO providers/suppliers have agreed to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) *Disclosure of prior participation.* (1) The ACO must disclose to CMS whether the ACO, its ACO participants, or its ACO providers/suppliers have participated in the Medicare Shared Savings Program under the same or a different name, or is related to or has an affiliation with another Shared Savings Program ACO.

(2) The ACO must specify whether the related ACO agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary.

(3) If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the

cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must submit to CMS the following supporting materials to demonstrate that the ACO satisfies the eligibility requirements set forth in subpart B of this part:

(i) Documents (for example, participation agreements, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, including how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidenced-based clinical guidelines.

(ii) A description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under § 425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes.

(iii) Materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions for senior administrative and clinical leaders including administrative and clinical leaders specifically noted in § 425.108.

(iv) Evidence that the governing body is an identifiable body, that the governing body is comprised of representatives of the ACO's participants, and that the ACO participants have at least 75 percent control of the ACO's governing body.

(v) Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(vi) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the ACO's agreement with CMS becomes effective.

(2) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(i) Charters.

(ii) By-laws.

(iii) Articles of incorporation.

(iv) Partnership agreement.

(v) Joint venture agreement.

(vi) Management or asset purchase agreements.

(vii) Financial statements and records.

(viii) Resumes and other documentation required for leaders of the ACO.

(3) If an ACO requests an exception to the—

(i) Governing body requirements in § 425.106, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries or both; or

(ii) Leadership and management requirements in § 425.108, the ACO must describe how its alternative leadership and management structure will be capable of accomplishing the ACO's mission.

(4)(i) An ACO must certify that it is recognized as a legal entity in the State, Federal or Tribal area in which it was established and that it is authorized to conduct business in each State or Tribal area in which it operates.

(ii) An ACO formed among multiple, independent ACO participants must provide evidence in its application that it is a legal entity separate from any of the ACO participants.

(5) The ACO must provide CMS with such information regarding its ACO participants and its ACO providers/suppliers participating in the program as is necessary to implement the program.

(i) The ACO must submit a list of all ACO participants and their Medicare-enrolled TINs.

(A) For each ACO participant, the ACO must submit a list of the ACO providers/suppliers and their provider identifier (for example, NPI) and indicate whether the ACO provider/supplier is a primary care physician as defined in § 425.20.

(B) The list specified in paragraph (c)(5)(i)(A) of this section must be updated in accordance with § 425.302(d).

(ii) ACOs must also submit any other specific identifying information as required by CMS in the application process.

(iii) If the ACO includes an FQHC or RHC as an ACO participant, it must also do the following:

(A) Indicate the TINs, organizational NPIs, and other identifying information for its participant FQHCs or RHCs or both, as well as NPIs and other identifying information for the physicians that directly provide primary care services in the participant FQHCs or RHCs or both.

(B) Submit any other specific identifying information for its participant FQHCs or RHCs or both as required by CMS in the application process.

(iv) The ACO must certify the accuracy of this information.

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must describe the following:

(1) How it plans to use shared savings payments, including the criteria it plans to employ for distributing shared savings among its ACO participants and ACO providers/suppliers.

(2) How the proposed plan will achieve the specific goals of the Shared Savings Program.

(3) How the proposed plan will achieve the general aims of better care for individuals, better health for populations, and lower growth in expenditures.

(e) *Selection of track and option for interim payment calculation.*

(1) As part of its application, an ACO must specify whether it is applying to participate in Track 1 or Track 2 (as described in § 425.600).

(2)(i) An ACO applying to participate in the program with a start date of April 1, 2012 or July 1, 2012, has the option of requesting an interim payment calculation based on the financial performance for its first 12 months of program participation and quality performance for CY 2012.

(ii) An ACO must request interim payment calculation as part of its application to participate in the Shared Savings Program.

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay losses for which it may be liable, and any other monies determined to be owed upon first performance year reconciliation.

(i) As part of its application, an ACO that is applying to participate under the two-sided model of the Shared Savings Program or requesting an interim payment calculation under the one-sided model must submit for CMS approval documentation that it is capable of repaying losses or other monies determined to be owed upon first year reconciliation.

(ii) The documentation specified in paragraph (f)(1)(i) of this section must include details supporting the adequacy of the mechanism for repaying losses, or other monies determined to be owed

upon first year reconciliation, equal to at least 1 percent of the ACO's total per capita Medicare Parts A and B fee-for-service expenditures for its assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark.

(2) An ACO may demonstrate its ability to repay losses, or other monies determined to be owed upon first year reconciliation, by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, establishing a line of credit (as evidenced by a letter of credit that the Medicare program can draw upon), or establishing another appropriate repayment mechanism that will ensure its ability to repay the Medicare program.

(3) An ACO participating under the two-sided model must demonstrate the adequacy of this repayment mechanism annually, prior to the start of each performance year in which it takes risk.

§ 425.206 Evaluation procedures for applications.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an ACO's application on the basis of the information contained in and submitted with the application.

(2) CMS notifies applicant ACOs when the application is incomplete and provide an opportunity to submit information to complete the application. Applications remaining incomplete by the application due date will be denied.

(b) *Notice of determination.* (1) CMS notifies in writing each applicant ACO of its determination to approve or deny the ACO's application to participate in the Shared Savings Program.

(2) If CMS denies the application, the notice will indicate that the ACO is not qualified to participate in the Shared Savings Program, specify the reasons why the ACO is not so qualified, and inform the ACO of its right to request reconsideration review in accordance with the procedures specified in subpart I of this part.

§ 425.208 Provisions of participation agreement.

(a) *General rules.* (1) Upon being notified by CMS of its approval to participate in the Shared Savings Program, an executive of that ACO who has the ability to legally bind the ACO must sign and submit to CMS a participation agreement.

(2) Under the participation agreement the ACO must agree to comply with the provisions of this part in order to participate in the Shared Savings Program.

(b) *Compliance with laws.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to agree, or to comply with all applicable laws including, but not limited to, the following:

(1) Federal criminal law.

(2) The False Claims Act (31 U.S.C. 3729 *et seq.*).

(3) The anti-kickback statute (42 U.S.C. 1320a–7b(b)).

(4) The civil monetary penalties law (42 U.S.C. 1320a–7a).

(5) The physician self-referral law (42 U.S.C. 1395nn).

(c) *Certifications.* (1) The ACO must agree, as a condition of participating in the program and receiving any shared savings payment, that an individual with the authority to legally bind the ACO will certify the accuracy, completeness, and truthfulness of any data or information requested by or submitted to CMS, including, but not limited to, the application form, participation agreement, and any quality data or other information on which CMS bases its calculation of shared savings payments and shared losses.

(2) Certifications must meet the requirements at § 425.302.

§ 425.210 Application of agreement to ACO participants, ACO providers/suppliers, and others.

(a) The ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance.

(b) All contracts or arrangements between or among the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of this part, including, but not limited to, those specified in the participation agreement with CMS.

§ 425.212 Changes to program requirements during the agreement term.

(a)(1) ACOs are subject to all statutory changes that become effective during the term of their participation agreement.

(2) ACOs are subject to all regulatory changes with the exception of the following program areas:

(i) Eligibility requirements concerning the structure and governance of ACOs.

(ii) Calculation of sharing rate.

(iii) Beneficiary assignment.

(b) In those instances where there are changes in law or regulations, the ACO will be required to submit to CMS for review and approval, as a supplement to its original application, an explanation detailing how it will modify its processes to address these changes in law or regulations.

(c) If an ACO does not modify its processes to address a change in law or regulations, it will be placed on a CAP. If the ACO fails to effectuate the necessary modifications while under the CAP, the ACO will be terminated from the Shared Savings Program using the procedures in § 425.218.

(d) An ACO will be permitted to terminate its agreement, in those instances where Shared Savings Program statutory and regulatory standards are established during the agreement period which the ACO believes will impact its ability to continue to participate in the Shared Savings Program.

§ 425.214 Managing changes to the ACO during the agreement.

(a)(1) During the term of the participation agreement, an ACO may add or remove ACO participants or ACO providers/suppliers (identified by TINs and NPIs).

(2) An ACO must notify CMS within 30 days of such an addition or removal.

(3) The ACO's benchmark, risk scores, and preliminary prospective assignment may be adjusted for this change at CMS' discretion.

(b) ACOs must notify CMS within 30 days of any significant change. A ''significant change'' occurs when an ACO is no longer able to meet the eligibility or program requirements of this Part.

(c) Upon receiving an ACO's notice of a significant change described in paragraph (b) of this section, CMS reevaluates the ACO's eligibility to continue to participate in the Shared Savings Program and may request additional documentation. CMS may make a determination that includes one of the following:

(1) The ACO may continue to operate under the new structure.

(2) The ACO structure is so different from the initially approved ACO that it must terminate its agreement and submit a new application for participation.

(3) The ACO no longer meets the eligibility criteria for the program and its participation agreement must be terminated.

(4) CMS and the ACO may mutually decide to terminate the agreement.

§ 425.216 Actions prior to termination.

(a) *Pre-termination actions.* (1) If CMS concludes that termination of an ACO from the Shared Savings Program is warranted, CMS may take one or more

of the following actions prior to termination of the ACO from the Shared Savings Program.

(i) Provide a warning notice to the ACO regarding noncompliance with one or more program requirements.

(ii) Request a CAP from the ACO.

(iii) Place the ACO on a special monitoring plan.

(2) Nothing in this part, including the actions set forth in paragraph (a)(1) of this section, negates, diminishes, or otherwise alters the applicability of other laws, rules, or regulations, including, but not limited to, the Sherman Act (15 U.S.C. 1 *et seq.*), the Clayton Act (15 U.S.C. 12), and the Federal Trade Commission Act (15 U.S.C. 45 *et seq.*).

(b) *Corrective action plans.* (1) The ACO must submit a CAP for CMS approval by the deadline indicated on the notice of violation.

(i) The CAP must address what actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to the ACO's activities or both correct any deficiencies and comply with all applicable Shared Savings Program requirements.

(ii) The ACO's performance will be monitored and evaluated during and after the CAP process.

(2) CMS may terminate the ACO's agreement if the ACO fails to submit, obtain approval for, or implement a CAP, or fails to demonstrate improved performance upon completion of the CAP.

§ 425.218 Termination of the agreement by CMS.

(a) *General.* CMS may terminate the participation agreement with an ACO when an ACO, the ACO participants, ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the Shared Savings Program under this part.

(b) *Grounds for termination by CMS.* CMS may terminate the participation agreement for reasons including, but not limited to the following:

(1) Non-compliance with eligibility and other requirements described in this part.

(2) The imposition of sanctions or other actions taken against the ACO by an accrediting organization, State, Federal or local government agency leading to inability of the ACO to comply with the requirements under this part.

(3) Violations of the physician self-referral prohibition, civil monetary penalties (CMP) law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.

(c) CMS may immediately terminate a participation agreement without taking any of the pre-termination actions set forth in § 425.216.

(d) *Notice of termination by CMS.* CMS notifies an ACO in writing of its decision to terminate the participation agreement.

§ 425.220 Termination of an agreement by the ACO.

(a) *Notice of termination.* An ACO must provide at least 60 days advance written notice to CMS and its ACO participants of its decision to terminate the participation agreement and the effective date of its termination.

(b) *Payment consequences of early termination.* The ACO will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement.

§ 425.222 Re-application after termination.

(a) An ACO that has been terminated from the Shared Savings Program under § 425.218 or§ 425.220 may participate in the Shared Savings Program again only after the date on which the term of the original participation agreement would have expired if the ACO had not been terminated.

(b) To be eligible to participate in the Shared Savings Program after a previous termination, the ACO must demonstrate in its application that it has corrected the deficiencies that caused it to be terminated from the Shared Savings Program and has processes in place to ensure that it will remain in compliance with the terms of the new participation agreement.

(c) An ACO under the one-sided model whose agreement was previously terminated may reenter the program only under the two-sided model unless it was terminated less than half way through its agreement under the one-sided model in which case it will be allowed to re-enter the one-sided model. An ACO under the two-sided model whose agreement was terminated may only re-apply for participation in the two-sided model.

Subpart D—Program Requirements and Beneficiary Protections

§ 425.300 Compliance plan.

(a) The ACO must have a compliance plan that includes at least the following elements:

(1) A designated compliance official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body.

(2) Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.

(3) A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.

(4) Compliance training for the ACO, the ACO participants, and the ACO providers/suppliers.

(5) A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

(b)(1) ACOs that are existing entities may use the current compliance officer if the compliance officer meets the requirements set forth in paragraph (a)(1) of this section.

(2) An ACO's compliance plan must be in compliance with and be updated periodically to reflect changes in law and regulations.

§ 425.302 Program requirements for data submission and certifications.

(a) *Requirements for data submission and certification.*

(1) The ACO, its ACO participants, its ACO providers/suppliers or individuals or other entities performing functions or services related to ACO activities must submit all data and information, including data on measures designated by CMS under § 425.500, in a form and manner specified by CMS.

(2) *Certification of data upon submission.* With respect to data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, an individual with the authority to legally bind the individual or entity submitting such data or information must certify the accuracy, completeness, and truthfulness of the data and information to the best of his or her knowledge information and belief.

(3) *Annual certification.* At the end of each performance year, an individual with the legal authority to bind the ACO must certify to the best of his or her knowledge, information, and belief—

(i) That the ACO, its ACO participants, its ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are in compliance with program requirements; and

(ii) The accuracy, completeness, and truthfulness of all data and information that are generated or submitted by the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, including any quality data or other information or data relied upon by CMS in determining the ACO's eligibility for, and the amount of a shared savings payment or the amount of shared losses or other monies owed to CMS.

(b) [Reserved]

§ 425.304 Other program requirements.

(a) *Beneficiary inducements.* (1) ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are prohibited from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from or remaining in, an ACO or with ACO providers/suppliers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers.

(2) Consistent with the provisions of paragraph (a)(1) of this section and subject to compliance with all other applicable laws and regulations, ACO, ACO participants and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities may provide in-kind items or services to beneficiaries if there is a reasonable connection between the items and services and the medical care of the beneficiary and the items or services are preventive care items or services or advance a clinical goal for the beneficiary, including adherence to a treatment regime, adherence to a drug regime, adherence to a follow-up care plan, or management of a chronic disease or condition.

(b) *Screening of ACO applicants.* (1) ACOs, ACO participants, and ACO providers/suppliers will be reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.

(2) ACOs, ACO participants, or ACO providers/suppliers whose screening reveals a history of program integrity issues or affiliations with individuals or entities that have a history of program integrity issues may be subject to denial of their Shared Savings Program applications or the imposition of additional safeguards or assurances against program integrity risks.

(c) *Prohibition on certain required referrals and cost shifting.* ACOs, ACO participants, and ACO providers/suppliers are prohibited from:

(1) Conditioning the participation of ACO participants, ACO providers/suppliers, other individuals or entities performing functions or services related to ACO activities in the ACO on referrals of Federal health care program business that the ACO, its ACO participants, or ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities know or should know is being (or would be) provided to beneficiaries who are not assigned to the ACO.

(2) Requiring that beneficiaries be referred only to ACO participants or ACO providers/suppliers within the ACO or to any other provider or supplier, except that the prohibition does not apply to referrals made by employees or contractors who are operating within the scope of their employment or contractual arrangement to the employer or contracting entity, provided that the employees and contractors remain free to make referrals without restriction or limitation if the beneficiary expresses a preference for a different provider, practitioner, or supplier; the beneficiary's insurer determines the provider, practitioner, or supplier; or the referral is not in the beneficiary's best medical interests in the judgment of the referring party.

(d) *Required reporting of NPIs and TINs.* (1) The ACO must maintain, update, and annually furnish to CMS at the beginning of each performance year and at other such times as specified by CMS the list of each ACO participant's TIN and ACO providers/supplier's NPI that is required to be submitted under § 425.204(c)(5)(i).

(2) The ACO must notify CMS within 30 days of any changes to the list of NPIs and TINs.

§ 425.306 Participation agreement and exclusivity of ACO participant TINs.

(a) For purposes of the Shared Savings Program, each ACO participant TIN is required to commit to a participation agreement with CMS.

(b) Each ACO participant TIN upon which beneficiary assignment is dependent must be exclusive to one Medicare Shared Savings Program ACO for purposes of Medicare beneficiary assignment. ACO participant TINs upon which beneficiary assignment is not dependent are not required to be exclusive to one Medicare Shared Savings Program ACO.

§ 425.308 Public reporting and transparency.

For purposes of the Shared Savings Program, each ACO must publicly report the following information regarding the ACO in a standardized format as specified by CMS:

(a) Name and location.

(b) Primary contact.

(c) Organizational information including all of the following:

(1) Identification of ACO participants.

(2) Identification of participants in joint ventures between ACO professionals and hospitals.

(3) Identification of the members of its governing body.

(4) Identification of associated committees and committee leadership.

(d) Shared savings and losses information, including:

(1) Amount of any shared savings performance payment received by the ACO or shared losses owed to CMS.

(2) Total proportion of shared savings invested in infrastructure, redesigned care processes and other resources required to support the three-part aim goals of better health for populations, better care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants.

(e) Results of patient experience of care survey and claims based measures. Quality measures reported using the GPRO web interface will be reported on Physician Compare in the same way as for the group practices that report under the Physician Quality Reporting System.

§ 425.310 Marketing requirements.

(a) *File and use.* Marketing materials and activities, as defined in § 425.20, may be used or conducted five business days following their submission to CMS if—

(1) The ACO certifies compliance with all the marketing requirements under this section; and

(2) CMS does not disapprove the marketing materials or activities.

(b) *Deemed approval.* (1) Marketing materials and activities are deemed approved after expiration of the initial 5 day review period specified in paragraph (a) of this section.

(2)(i) CMS may issue written notice of disapproval of marketing materials and activities at any time, including after the expiration of the initial 5 day review period.

(ii) The ACO, ACO participant, ACO provider/supplier, or another individual or entity performing functions or services related to ACO activities as applicable, must discontinue use of any marketing materials or activities disapproved by CMS.

(c) *Marketing requirements.* Marketing materials and activities must meet all of the following:

(1) Use template language developed by CMS, if available.

(2) Not be used in a discriminatory manner or for discriminatory purposes.

(3) Comply with § 425.304(a) regarding beneficiary inducements.

(4) Not be materially inaccurate or misleading.

(d) *Sanctions.* Failure to comply with this section will subject the ACO to the penalties set forth in § 425.216, termination under § 425.218, or both.

§ 425.312 Notification to beneficiaries of participation in shared savings program.

(a) ACO participants must do all of the following:

(1) Notify beneficiaries at the point of care that their ACO providers/suppliers are participating in the Shared Savings Program.

(2) Post signs in their facilities to notify beneficiaries that their ACO providers/suppliers are participating in the Shared Savings Program.

(3) Make available standardized written notices regarding participation in an ACO and, if applicable, data opt-out. Such written notices must be provided by the ACO participants in settings in which beneficiaries receive primary care services.

(b)(1) ACOs have the option of notifying beneficiaries on the preliminary prospective assignment list and quarterly assignment list provided to the ACO under § 425.704(d).

(2) ACOs choosing this option must use the standardized written notice developed by CMS.

(c) The beneficiary notifications under this section meet the definition of marketing materials and activities under § 425.20 and therefore must meet all applicable marketing requirements described in § 425.310.

§ 425.314 Audits and record retention.

(a) *Right to audit.* The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree, that the CMS, DHHS, the Comptroller General, the Federal Government or their designees have the right to audit, inspect, investigate, and evaluate any books, contracts, records, documents and other evidence of the ACO, ACO participants, and ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities that pertain to all of the following:

(1) The ACO's compliance with Shared Savings Program.

(2) The quality of services performed and determination of amount due to or from CMS under the participation agreement.

(3) The ability of the ACO to bear the risk of potential losses and to repay any losses to CMS.

(4) If as a result of any inspection, evaluation, or audit, it is determined that the amount of shared savings due to the ACO or the amount of shared losses owed by the ACO has been calculated in error, CMS reserves the right to reopen the initial determination and issue a revised initial determination.

(b) *Maintenance of records.* An ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to agree to the following:

(1) To maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to all books, contracts, records, documents, and other evidence (including data related to Medicare utilization and costs, quality performance measures, shared savings distributions, and other financial arrangements related to ACO activities) sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements, quality of services performed, right to any shared savings payment, or obligation to repay losses, ability to bear the risk of potential losses, and ability to repay any losses to CMS.

(2) To maintain such books, contracts, records, documents, and other evidence for a period of 10 years from the final date of the agreement period or from the date of completion of any audit, evaluation, or inspection, whichever is later, unless—

(i) CMS determines there is a special need to retain a particular record or group of records for a longer period and notifies the ACO at least 30 days before the normal disposition date; or

(ii) There has been a termination, dispute, or allegation of fraud or similar fault against the ACO, its ACO participants, its ACO providers/suppliers, or other individuals or entities performing functions or services related to ACO activities, in which case ACOs must retain records for an additional 6 years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault.

(c) *Responsibility of the ACO.* Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS, including the requirements set forth in this section.

(d) *OIG authority.* None of the provisions of this part limit or restrict OIG's authority to audit, evaluate, investigate, or inspect the ACO, its ACO participants, its ACO providers/suppliers and other individuals or entities performing functions or services related to ACO activities.

§ 425.316 Monitoring of ACOs.

(a) *General rule.* (1) In order to ensure that the ACO continues to satisfy the eligibility and program requirements under this part, CMS monitors and assesses the performance of ACOs, their ACO participants, and ACO providers/suppliers.

(2) CMS employs a range of methods to monitor and assess the performance of ACOs, ACO participants, and ACO providers/suppliers, including but not limited to any of the following, as appropriate:

(i) Analysis of specific financial and quality measurement data reported by the ACO as well as aggregate annual and quarterly reports.

(ii) Analysis of beneficiary and provider complaints.

(iii) Audits (including, for example, analysis of claims, chart review (medical record), beneficiary survey reviews, coding audits, on-site compliance reviews).

(b) *Monitoring ACO avoidance of at-risk beneficiaries.* (1) CMS may use one or more of the methods described in paragraph (a)(2) of this section (as appropriate) to identify trends and patterns suggesting that an ACO has avoided at-risk beneficiaries. The results of these analyses may subsequently require further investigation and follow-up with beneficiaries or the ACO and its ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities, in order to substantiate cases of beneficiary avoidance.

(2)(i) CMS, at its sole discretion, may take any of the pre-termination actions set forth in § 425.216(a)(1) or immediately terminate, if it determines that an ACO, its ACO participants, any ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities avoids at-risk beneficiaries.

(ii) If CMS requires the ACO to submit a CAP, the ACO will—

(A) Submit a CAP that addresses actions the ACO will take to ensure that the ACO, ACO participants, ACO providers/suppliers, or other individuals or entities performing functions or services related to the ACO's activities cease avoidance of at-risk beneficiaries.

(B) Not receive any shared savings payments during the time it is under the CAP.

(C) Not be eligible to receive shared savings for the performance year attributable to the time that necessitated the CAP (the time period during which the ACO avoided at risk beneficiaries).

(iii) CMS will re-evaluate the ACO during and after the CAP implementation period to determine if the ACO has continued to avoid at-risk beneficiaries. The ACO will be terminated if CMS determines that the ACO has continued to avoid at-risk beneficiaries during or after the CAP implementation period.

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at § 425.216 and § 425.218, CMS will take the following actions:

(1) The ACO may be given a warning for the first time it fails to meet the minimum attainment level in one or more domains as determined under § 425.502 and may be subject to a CAP. CMS, may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(2) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet quality performance standards in the following year, the agreement will be terminated.

(3)(i) If an ACO fails to report one or more quality measures or fails to report completely and accurately on all measures in a domain, CMS will request that the ACO submit—

(A) The required measure data;

(B) Correct the data;

(C) Provide a written explanation for why it did not report the data completely and accurately; or

(D) A combination of the submission requirements in paragraphs (c)(3)(i)(A) through (c)(3)(i)(C) of this section.

(ii) If ACO still fails to report, fails to report by the requested deadline, or does not provide a reasonable explanation for not reporting, the ACO will be terminated immediately.

(4) An ACO that exhibits a pattern of inaccurate or incomplete reporting of the quality performance measures, or fails to make timely corrections following notice to resubmit, may be terminated.

(5) An ACO will not qualify to share in savings in any year it fails to report fully and completely on the quality performance measures.

Subpart E—Assignment of Beneficiaries

§ 425.400 General.

(a)(1)(i) A Medicare fee-for-service beneficiary is assigned to an ACO when the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402.

(ii) CMS applies a step-wise process based on the beneficiary's utilization of primary care services provided under Title XVIII by a physician who is an ACO provider/supplier during the performance year for which shared savings are to be determined.

(2)(i) Medicare assigns beneficiaries in a preliminary manner at the beginning of a performance year based on most recent data available.

(ii) Assignment will be updated quarterly based on the most recent 12 months of data.

(iii) Final assignment is determined after the end of each performance year, based on data from the performance year.

(b) Beneficiary assignment to an ACO is for purposes of determining the population of Medicare fee-for-service beneficiaries for whose care the ACO is accountable under subpart F of this part, and for determining whether an ACO has achieved savings under subpart G of this part, and in no way diminishes or restricts the rights of beneficiaries assigned to an ACO to exercise free choice in determining where to receive health care services.

(c) Primary care services for purposes of assigning beneficiaries are identified by selected HCPCS codes, G codes, or revenue center codes as indicated in the definition of primary care services under § 425.20.

§ 425.402 Basic assignment methodology.

(a) CMS employs the following step-wise methodology to assign Medicare beneficiaries to an ACO after identifying all patients that had at least one primary care service with a physician who is an ACO provider/supplier of that ACO:

(1)(i) Identify all primary care services rendered by primary care physicians during one of the following:

(A) The most recent 12 months (for purposes of preliminary prospective assignment and quarterly updates to the preliminary prospective assignment).

(B) The performance year (for purposes of final assignment).

(ii) The beneficiary is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all the primary care physicians who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians who are—

(A) ACO providers/suppliers in any other ACO; and

(B) Not affiliated with any ACO and identified by a Medicare-enrolled TIN.

(2) The second step considers the remainder of the beneficiaries who have received at least one primary care service from an ACO physician, but who have not had a primary care service rendered by any primary care physician, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by all ACO professionals who are ACO providers/suppliers in the ACO are greater than the allowed charges for primary care services furnished by—

(i) All ACO professionals who are ACO providers/suppliers in any other ACO; and

(ii) Other physicians, nurse practitioners, physician assistants, clinical nurse specialists who are unaffiliated with an ACO and are identified by a Medicare-enrolled TIN.

(b) [Reserved]

§ 425.404 Special assignment conditions for ACOs including FQHCs and RHCs.

CMS assigns beneficiaries to ACOs based on services furnished in FQHCs or RHCs or both consistent with the general assignment methodology in § 425.402, with two special conditions:

(a) Such ACOs are required to identify, through an attestation, physicians who directly provide primary care services in each FQHC or RHC that is an ACO participant and/or ACO provider/supplier in the ACO.

(b) Under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service if the—

(1) NPI of a physician included in the attestation is reported on the claim as the attending provider; and

(2) Claim includes a HCPCS or revenue center code that meets the definition of primary care services under § 425.20.

Subpart F—Quality Performance Standards and Reporting

§ 425.500 Measures to assess the quality of care furnished by an ACO.

(a) *General.* CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible for shared savings.

(b) *Selecting measures.* (1) CMS selects the measures designated to determine an ACO's success in promoting the aims of better care for individuals, better health for populations, and lower growth in expenditures.

(2) CMS designates the measures for use in the calculation of the quality performance standard.

(3) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(c) ACOs must submit data on the measures determined under paragraph (b) of this section according to the method of submission established by CMS.

(d) *Patient experience of care survey.* For performance years beginning in 2014 and for subsequent performance years, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(e) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO.

(1) In an audit, the ACO will provide beneficiary medical records data if requested by CMS.

(2) The audit will consist of three phases of medical record review.

(3) If, at the conclusion of the third audit process there is a discrepancy greater than 10 percent between the quality data reported and the medical records provided, the ACO will not be given credit for meeting the quality target for any measures for which this mismatch rate exists.

(f) Failure to report quality measure data accurately, completely, and timely (or to timely correct such data) may subject the ACO to termination or other sanctions, as described in § 425.216 and § 425.218.

§ 425.502 Calculating the ACO quality performance score.

(a) *Establishing a quality performance standard.* CMS designates the quality performance standard in each performance year.

(1) For the first performance year of an ACO's agreement, CMS defines the quality performance standard at the level of complete and accurate reporting for all quality measures.

(2) During subsequent performance years, the quality performance standard will be phased in such that the ACO must continue to report all measures but the ACO will be assessed on performance based on the minimum attainment level of certain measures.

(b) *Establishing a performance benchmark and minimum attainment level for measures.* (1) CMS designates a performance benchmark and minimum attainment level for each measure, and establishes a point scale for the measures.

(2) Contingent upon data availability, performance benchmarks are defined by CMS based on national Medicare fee-for-service rates, national MA quality measure rates, or a national flat percentage.

(3) The minimum attainment level is set at 30 percent or the 30th percentile of the performance benchmark.

(c) *Methodology for calculating a performance score for each measure.* (1) Performance below the minimum attainment level for a measure will receive zero points for that measure.

(2) Performance equal to or greater than the minimum attainment level for a measure will receive points on a sliding scale based on the level of performance.

(3) Those measures designated as all or nothing measures will receive the maximum available points if all criteria are met and zero points if one or more of the criteria are not met.

(4) Performance at or above 90 percent or the 90th percentile of the performance benchmark earns the maximum points available for the measure.

(d) *Establishing quality performance requirements for domains.* (1) CMS groups individual quality performance standard measures into four domains:

(i) Patient/care giver experience.

(ii) Care coordination/Patient safety.

(iii) Preventative health.

(iv) At-risk population.

(2) To satisfy quality performance requirements for a domain:

(i) The ACO must report all measures within a domain.

(ii) ACOs must score above the minimum attainment level determined by CMS on 70 percent of the measures in each domain. If an ACO fails to achieve the minimum attainment level on at least 70 percent of the measures in a domain, CMS will take the actions describe in § 425.216(c).

(iii)(A) If the ACO achieves the minimum attainment level for at least one measure in each of the four domains, and also satisfies the requirements for realizing shared savings under subpart G of this part, the ACO may receive the proportion of those shared savings for which it qualifies.

(B) If an ACO fails to achieve the minimum attainment level on all measures in a domain, it will not be eligible to share in any savings generated.

(e) *Methodology for calculating the ACO's overall performance score.* (1) CMS scores individual measures and determines the corresponding number of points that may be earned based on the ACO's performance.

(2) CMS adds the points earned for the individual measures within the domain and divides by the total points available for the domain to determine the domain score.

(3) Domains are weighted equally and scores averaged to determine the ACO's overall performance score and sharing rate.

§ 425.504 Incorporating reporting requirements related to the Physician Quality Reporting System.

(a) *Physician quality reporting system.* (1) ACOs, on behalf of their ACO provider/suppliers who are eligible professionals, must submit the measures determined under § 425.500 using the GPRO web interface established by CMS, to qualify on behalf of their eligible professionals for the Physician Quality Reporting System incentive under the Shared Savings Program.

(2)(i) ACO providers/suppliers that are eligible professionals within an ACO may only participate under their ACO participant TIN as a group practice under the Physician Quality Reporting System Group Practice Reporting Option of the Shared Savings Program for purposes of receiving an incentive payment under the Physician Quality Reporting System.

(ii) Under the Shared Savings Program, an ACO, on behalf of its ACO providers/suppliers who are eligible professionals, must satisfactorily report the measures determined under Subpart F of this part during the reporting period according to the method of submission established by CMS under the Shared Savings Program in order to receive a Physician Quality Reporting

System incentive under the Shared Savings Program.

(3) If ACO providers/suppliers who are eligible professionals within an ACO qualify for a Physician Quality Reporting System incentive payment, each ACO participant TIN, on behalf of its ACO supplier/provider participants who are eligible professionals, will receive an incentive, for those years an incentive is available, based on the allowed charges under the Physician Fee Schedule for that TIN.

(4) ACO participant TINs and individual ACO providers/suppliers who are eligible professionals cannot earn a Physician Quality Reporting System incentive outside of the Medicare Shared Savings Program.

(5) The Physician Quality Reporting System incentive under the Medicare Shared Savings Program is equal to 0.5 percent of the Secretary's estimate of the ACO's eligible professionals' total Medicare Part B Physician Fee Schedule allowed charges for covered professional services furnished during the calendar year reporting period from January 1 through December 31, for years 2012 through 2014.

(b) [Reserved]

§ 425.506 Electronic health records technology.

(a) ACOs, ACO participants, and ACO providers/suppliers are encouraged to develop a robust EHR infrastructure.

(b) As part of the quality performance score, the quality measure regarding EHR adoption will be measured based on a sliding scale.

(c) Performance on this measure will be weighted twice that of any other measure for scoring purposes and for determining compliance with quality performance requirements for domains.

Subpart G—Shared Savings and Losses

§ 425.600 Selection of risk model.

(a) For its initial agreement period, an ACO may elect to operate under one of the following tracks:

(1) *Track 1.* Under Track 1, the ACO operates under the one-sided model (as described under § 425.604 of this part) for the agreement period.

(2) *Track 2.* Under Track 2, the ACO operates under the two-sided model (as described under § 425.606), sharing both savings and losses with the Medicare program for the agreement period.

(b) For subsequent agreement periods, an ACO may not operate under the one-sided model.

(c) An ACO experiencing a net loss during the initial agreement period may reapply to participate under the conditions in § 425.202(a), except the ACO must also identify in its application the cause(s) for the net loss and specify what safeguards are in place to enable the ACO to potentially achieve savings in its next agreement period.

§ 425.602 Establishing the benchmark.

(a) *Computing per capita Medicare Part A and Part B benchmark expenditures.* In computing an ACO's fixed historical benchmark that is adjusted for historical growth and beneficiary characteristics, including health status, CMS determines the per capita Parts A and B fee-for-service expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the agreement period using the ACO participants' TINs identified at the start of the agreement period. CMS does all of the following:

(1) Calculates the payment amounts included in Parts A and B fee-for-service claims using a 3-month claims run out with a completion factor.

(i) This calculation excludes indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) This calculation considers individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(2) Makes separate expenditure calculations for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(3) Adjusts expenditures for changes in severity and case mix using prospective HCC risk scores.

(4) Truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each benchmark year in order to minimize variation from catastrophically large claims.

(5)(i) Using CMS Office of the Actuary national Medicare expenditure data for each of the years making up the historical benchmark, determines national growth rates and trends expenditures for each benchmark year (BY1 and BY2) to the third benchmark year (BY3) dollars.

(ii) To trend forward the benchmark, CMS makes separate calculations for expenditure categories for each of the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(6) Restates BY1 and BY2 trended and risk adjusted expenditures in BY3 proportions of ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(7) Weights each year of the benchmark using the following percentages:

(i) BY3 at 60 percent.

(ii) BY2 at 30 percent.

(iii) BY1 at 10 percent.

(8) The ACO's benchmark may be adjusted for the addition and removal of ACO participants or ACO providers/suppliers during the term of the agreement period.

(b) *Updating the benchmark.* CMS updates the historical benchmark annually for each year of the agreement period based on the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program.

(1) CMS updates this fixed benchmark by the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program using data from CMS' Office of the Actuary.

(2) To update the benchmark, CMS makes expenditure calculations for separate categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(c) *Resetting the benchmark.* An ACO's benchmark will be reset at the start of each agreement period.

§ 425.604 Calculation of savings under the one-sided model.

(a) *Savings determination.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are below the applicable updated benchmark determined under § 425.602.

(1) *Newly assigned beneficiaries.* CMS uses an ACO's HCC prospective risk score to adjust for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust for changes in the continuously assigned population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust for changes in severity and case mix in this

population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a). In adjusting for health status and demographic changes CMS makes adjustments for separate categories for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(5) CMS uses a 3 month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings rate (MSR).* CMS uses a sliding scale, based on the number of beneficiaries assigned to the ACO under subpart E of this part, to establish the MSR for an ACO participating under the one-sided model. The MSR under the one-sided model for an ACO based on the number of assigned beneficiaries is as follows:

Number of beneficiaries	MSR (low end of assigned beneficiaries) (percent)	MSR (high end of assigned beneficiaries) (percent)
5,000–5,999	3.9	3.6
6,000–6,999	3.6	3.4
7,000–7,999	3.4	3.2
8,000–8,999	3.2	3.1
9,000–9,999	3.1	3.0
10,000–14,999	3.0	2.7
15,000–19,999	2.7	2.5
20,000–49,999	2.5	2.2
50,000–59,999	2.2	2.0
60,000 +	2.0	

(c) *Qualification for shared savings payment.* In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 of this part (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under the one-sided model may not exceed 10 percent of its updated benchmark.

(f) *Notification of savings.* CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

§ 425.606 Calculation of shared savings and losses under the two-sided model.

(a) *General rule.* For each performance year, CMS determines whether the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services are above or below the updated benchmark determined under § 425.602. In order to qualify for a shared savings payment under the two-sided model, or to be responsible for sharing losses with CMS, an ACO's average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services for the performance year must be below or above the updated benchmark, respectively, by at least the minimum savings or loss rate under paragraph (b) of this section.

(1) *Newly assigned beneficiaries.* CMS uses an ACO's HCC prospective risk score to adjust for changes in severity and case mix in this population.

(2) *Continuously assigned beneficiaries.* (i) CMS uses demographic factors to adjust for changes in the continuously assigned beneficiary population.

(ii) If the prospective HCC risk score is lower in the performance year for this population, CMS will adjust for changes in severity and case mix for this population using this lower prospective HCC risk score.

(3) Assigned beneficiary changes in demographics and health status are used to adjust benchmark expenditures as described in § 425.602(a). In adjusting for health status and demographic changes CMS makes separate adjustments for each of the following populations of beneficiaries:

(i) ESRD.

(ii) Disabled.

(iii) Aged/dual eligible Medicare and Medicaid beneficiaries.

(iv) Aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) To minimize variation from catastrophically large claims, CMS truncates an assigned beneficiary's total annual Parts A and B fee-for-service per

capita expenditures at the 99th percentile of national Medicare fee-for-service expenditures as determined for each performance year.

(5) CMS uses a 3 month claims run out with a completion factor to calculate an ACO's per capita expenditures for each performance year.

(6) Calculations of the ACO's expenditures will include the payment amounts included in Part A and B fee-for-service claims.

(i) These calculations will exclude indirect medical education (IME) and disproportionate share hospital (DSH) payments.

(ii) These calculations will take into consideration individually beneficiary identifiable payments made under a demonstration, pilot or time limited program.

(7) In order to qualify for a shared savings payment, the ACO's average per capita Medicare expenditures for the performance year must be below the applicable updated benchmark by at least the minimum savings rate established for the ACO under paragraph (b) of this section.

(b) *Minimum savings or loss rate.* (1) To qualify for shared savings under the two-sided model, an ACO's average per capita Medicare expenditures for the performance year must be below its updated benchmark costs for the year by at least 2 percent.

(2) To be responsible for sharing losses with the Medicare program, an ACO's average per capita Medicare expenditures for the performance year must be at least 2 percent above its updated benchmark costs for the year.

(c) *Qualification for shared savings payment.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502 of this part, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate.* An ACO that meets all the requirements for receiving shared savings payments under the two-sided model will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 of this part (up to the performance payment limit described in paragraph (e)(2) of this section).

(e) *Performance payment.* (1) If an ACO qualifies for savings by meeting or exceeding the MSR, the final sharing rate will apply to an ACO's savings on a first dollar basis.

(2) The amount of shared savings an eligible ACO receives under the two-sided model may not exceed 15 percent of its updated benchmark.

(f) *Shared loss rate.* The shared loss rate—

(1) For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in § 425.606(d) (that is, 1 minus the final shared savings rate determined under § 425.606(d) of this part); and

(2) May not exceed 60 percent.

(g) *Loss recoupment limit.* The amount of shared losses for which an eligible ACO is liable may not exceed the following percentages of its updated benchmark as determined under § 425.602:

(1) 5 percent in the first performance year of participation in a two-sided model under the Shared Savings Program.

(2) 7.5 percent in the second performance year.

(3) 10 percent in the third and any subsequent performance year.

(h) *Notification of savings and losses.* (1) CMS notifies an ACO in writing regarding whether the ACO qualifies for a shared savings payment, and if so, the amount of the payment due.

(2) CMS provides written notification to an ACO of the amount of shared losses, if any, that it must repay to the program.

(3) If an ACO has shared losses, the ACO must make payment in full to CMS within 90 days of receipt of notification.

§ 425.608 Determining first year performance for ACOs beginning April 1 or July 1, 2012.

(a) For April 1 and July 1, 2012 starters, first year (defined as 21 and 18 months respectively) performance will be based on an optional interim payment calculation (based on the ACO's first 12 months of participation) and a final reconciliation at the end of the ACO's first performance year. Unless stated otherwise, for purposes of the interim payment calculation and first year reconciliation, the methodology under subpart E of this part for assigning beneficiaries and the methodology described in § 425.602 through § 425.606 for calculating shared savings and losses will apply, and quality performance will be assessed as described in subpart F of this part.

(b) In the interim payment calculation, based on the ACO's first 12 months of performance—

(1) CMS compares the first 12 months of per capita beneficiary expenditures to a historical benchmark updated for the period which includes the ACO's first 12 months of participation, taking into account changes in health status and demographics; and

(2) Quality performance is based on GPRO quality data reported for CY 2012.

(c)(1) The interim payment calculation is reconciled with the ACO's performance for its complete first performance year, defined as 21 months for April 1, 2012 starters and 18 months for July 1, 2012 starters.

(2) The first year reconciliation takes into account expenditures spanning the entire 21 or 18 months of the first performance year.

(3) First performance year expenditures are summed over beneficiaries assigned in two overlapping 12 month assignment windows.

(i) The first window will be the first 12 months used for interim payment calculation.

(ii) The second window will be CY2013.

(4) Expenditures for the first performance year are the sum of aggregate expenditure dollars accounting for the ACO's first 6 or 9 months of performance within CY 2012 for beneficiaries assigned for the interim payment calculation and aggregate dollars calculated for CY2013 for beneficiaries assigned for CY 2013.

(5) Adjustments for health status and demographic changes are performed as described in § 425.604 through § 425.606 with the following exceptions:

(i) Beneficiaries from the CY2013 assignment window are identified as continuously assigned or newly assigned relative to the previous calendar year.

(ii) The adjustment factor identified for purposes of the interim payment calculation is applied to the 6 months or 9 months of the ACO's first performance year that lie within CY2012.

(6) The updated benchmark, stated in aggregate dollars, is the sum of the interim updated benchmark for the average fraction of expenditures incurred in the latter 6 or 9 months of CY 2012 and an updated aggregate benchmark representing CY 2013.

(7) A savings percentage (based on a comparison of summed expenditures to summed updated benchmark dollars) for the ACO's 18 or 21 month performance year is compared to the ACO's MSR or MLR. The reconciled amount of the shared savings or losses owed to or by the ACO for the performance year is net of any interim payments of shared savings or losses.

(8) Quality performance for the first year reconciliation is based on complete and accurate reporting, of all required quality measures, for CYs 2012 and 2013.

(d) An ACO with a start date of April 1, 2012 or July 1, 2012 has the option to request an interim payment calculation based on quality and financial performance for its first 12 months of program participation. As required under § 425.204(f), the ACO requesting an interim payment calculation must have a mechanism in place to pay back the interim payment if final reconciliation determines an overpayment.

(e) Unless otherwise stated, program requirements which apply in the course of a performance year apply to the interim payment calculation and first year reconciliation.

Subpart H—Data Sharing With ACOs

§ 425.700 General rules.

(a) CMS shares aggregate reports with the ACO.

(b) CMS shares beneficiary identifiable data with ACOs on the condition that the ACO, its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities observe all relevant statutory and regulatory provisions regarding the appropriate use of data and the confidentiality and privacy of individually identifiable health information and comply with the terms of the data use agreement described in this subpart.

(c) The ACO must not limit or restrict appropriate sharing of medical record data with providers and suppliers both within and outside the ACO in accordance with applicable law.

§ 425.702 Aggregate reports.

CMS shares aggregate reports with ACOs as follows:

(a) Aggregate reports are shared at the start of the agreement period based on beneficiary claims data used to calculate the benchmark, and each quarter thereafter during the agreement period.

(b) These aggregate reports include, when available, the following information, deidentified in accordance with 45 CFR 164.514(b):

(1) Aggregated metrics on the assigned beneficiary population.

(2) Utilization and expenditure data at the start of the agreement period based on historical beneficiaries used to calculate the benchmark.

(c)(1) At the beginning of the agreement period, during each quarter (and in conjunction with the annual reconciliation), and at the beginning of each performance year, CMS, upon the ACO's request for the data for purposes of population-based activities relating to improving health or reducing growth in health care costs, process development, case management, and care coordination, will provide the ACO with information regarding preliminarily prospectively assigned beneficiaries whose data was used to generate the aggregate data reports under paragraphs (a) and (b) of this section. The information includes the following:

(i) Beneficiary name.

(ii) Date of birth.

(iii) HICN.

(iv) Sex.

(2) In its request for these data, the ACO must certify that it is seeking the following information:

(i) As a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(ii) As the business associate of its ACO participants and ACO providers/suppliers, who are HIPAA-covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

§ 425.704 Beneficiary-identifiable data.

Subject to providing the beneficiary with the opportunity to decline data sharing as described in this § 425.708, and subject to having a valid DUA in place, CMS, upon the ACO's request for the data for purposes of evaluating the performance of its ACO participants or its ACO providers/suppliers, conducting quality assessment and improvement activities, and conducting population-based activities relating to improved health, will provide the ACO with beneficiary identifiable claims data for preliminary prospective assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant upon whom assignment is based during the agreement period.

(a) If an ACO wishes to receive beneficiary identifiable claims data, it must sign a DUA and it must submit a formal request for data. ACOs may request data as often as once per month.

(b) The ACO must certify that it is requesting claims data about either of the following:

(1) Its own patients, as a HIPAA-covered entity, and the request reflects the minimum data necessary for the ACO to conduct its own health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501.

(2) The patients of its HIPAA-covered entity ACO participants or its ACO providers/suppliers as the business associate of these HIPAA covered entities, and the request reflects the minimum data necessary for the ACO to conduct health care operations work that falls within the first or second paragraph of the definition of health care operations at 45 CFR 164.501 on behalf of those participants.

(c) The use of identifiers and claims data will be limited to developing processes and engaging in appropriate activities related to coordinating care and improving the quality and efficiency of care that are applied uniformly to all Medicare beneficiaries with primary care services at the ACO, and that these data will not be used to reduce, limit or restrict care for specific beneficiaries.

(d) To ensure that beneficiaries have a meaningful opportunity to decline having their claims data shared with the ACO, the ACO may only request claims data about a beneficiary if—

(1) The beneficiary name appears on the preliminary prospective assignment list found on the initial or quarterly aggregate report, or has received primary care services from an ACO participant upon whom assignment is based (under Subpart E of this part), during the agreement period.

(2) The beneficiary has been notified in writing how the ACO intends to use beneficiary identifiable claims data in order to improve the quality of care that is furnished to the beneficiary and, where applicable, coordinate care offered to the beneficiary; and

(3) The beneficiary did not exercise the opportunity to decline having his/her claims data shared with the ACO as provided in § 425.708.

(e) At the ACO's request, CMS continues to provide ACOs with updates to the requested beneficiary identifiable claims data, subject to beneficiary's opportunity to decline data sharing under § 425.708.

(f) If an ACO requests beneficiary identifiable information, compliance with the terms of the data use agreement described in § 425.710 is a condition of an ACO's participation in the Shared Savings Program.

§ 425.706 Minimum necessary data.

(a) ACOs must limit their identifiable data requests to the minimum necessary to accomplish a permitted use of the data. The minimum necessary Parts A and B data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Procedure code.
(3) Gender.
(4) Diagnosis code.
(5) Claim ID.
(6) The from and through dates of service.
(7) The provider or supplier ID.
(8) The claim payment type.
(9) Date of birth and death, if applicable.
(10) TIN.
(11) NPI.

(b) The minimum necessary Part D data elements may include but are not limited to the following data elements:

(1) Beneficiary ID.
(2) Prescriber ID.
(3) Drug service date.
(4) Drug product service ID.
(5) Quantity dispensed.
(6) Days supplied.
(7) Brand name.
(8) Generic name.
(9) Drug strength.
(10) TIN.
(11) NPI.
(12) Indication if on formulary.
(13) Gross drug cost.

§ 425.708 Beneficiaries may decline data sharing.

(a) Before requesting claims data about a particular beneficiary, the ACO must inform the beneficiary that it may request personal health information about the beneficiary for purposes of its care coordination and quality improvement work, and give the beneficiary meaningful opportunity to decline having his/her claims information shared with the ACO.

(b) ACOs may contact preliminarily prospective assigned beneficiaries. in writing to request data sharing.

(1) If these beneficiaries do not decline within 30 days after the letter is sent, the ACO may request identifiable claims data from CMS.

(2) These beneficiaries must also be provided a form explaining the beneficiary's opportunity to decline data sharing as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(c) For beneficiaries that have a primary care service office visit with an ACO participant who provides primary care services, the ACO must supply the beneficiaries with a written notification explaining their opportunity to decline data sharing. The form must be provided to each beneficiary as part of their first primary care service visit with an ACO participant upon whom assignment is based (under Subpart E of this part) during the agreement period.

(d) The requirements specified in paragraphs (a) through (c) of this section do not apply to the initial identifiable data points that CMS provides to ACOs under § 425.702(d).

(e) CMS does not share beneficiary identifiable claims data relating to treatment for alcohol and substance abuse in accordance with 42 CFR 290dd–2 and the implementing regulations at 42 CFR part 2.

(f) The provisions of this section relate only to the sharing of Medicare claims data between the Medicare program and the ACO under the Shared Savings Program and are in no way intended to impede existing or future data sharing under other authorities.

§ 425.710 Data use agreement.

(a)(1) Before receiving any beneficiary identifiable data, ACOs must enter into a DUA with CMS. Under the DUA, the ACO must comply with the limitations on use and disclosure that are imposed by HIPAA, the applicable DUA, and the statutory and regulatory requirements of the Shared Savings Program.

(2) If the ACO misuses or discloses data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the DUA, it will no longer be eligible to receive data under subpart H of this part, may be terminated from the Shared Savings Program under § 425.218, and may be subject to additional sanctions and penalties available under the law.

(b) [Reserved]

Subpart I—Reconsideration Review Process

§ 425.800 Preclusion of administrative and judicial review.

(a) There is no reconsideration, appeal, or other administrative or judicial review of the following determinations under this part:

(1) The specification of quality and performance standards under § 425.500 and § 425.502.

(2) The assessment of the quality of care furnished by an ACO under the performance standards established in § 425.502.

(3) The assignment of Medicare fee-for-service beneficiaries under Subpart E of this part.

(4) The determination of whether an ACO is eligible for shared savings, and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO under § 425.602, § 425.604, and § 425.606.

(5) The percent of shared savings specified by the Secretary and the limit on the total amount of shared savings established under § 425.604 and 425.606.

(6) The termination of an ACO for failure to meet the quality performance standards established under § 425.502.

(b) [Reserved]

§ 425.802 Request for review.

(a) An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under § 425.800 by requesting a reconsideration review by a CMS reconsideration official.

(1) An ACO that wants to request reconsideration review by a CMS reconsideration official must submit a written request by an authorized official for receipt by CMS within 15 days of the notice of the initial determination.

(i) If the 15th day is a weekend or a Federal holiday, then the timeframe is extended until the end of the next business day.

(ii) Failure to submit a request for reconsideration within 15 days will result in denial of the request for reconsideration.

(2) The reconsideration review may be held orally (that is, in person, by telephone or other electronic means) or on the record (review of submitted documentation) at the discretion of the reconsideration official.

(b) An ACO that requests a reconsideration review for termination will remain operational throughout the review process.

§ 425.804 Reconsideration review process.

(a) *Acknowledgement of reconsideration review request.* The reconsideration official sends an acknowledgement of the reconsideration review request to the ACO and CMS that includes the following:

(1) Review procedures.

(2) Procedures for submission of evidence including format and timelines.

(3) Date, time, and location of the review.

(b) *Burden of proof, standard of proof, and standards of review.* The burden of proof is on the ACO to demonstrate to the reconsideration official with convincing evidence that the initial determination is not consistent with the

requirements of this part or applicable statutory authority.

(c) *Reconsideration official.* The reconsideration official is an independent CMS official who did not participate in the initial determination that is being reviewed.

(d) *Time and place of hearing.* The reconsideration official may, on his or her own motion, or at the request of CMS or the ACO, change the time and place for the reconsideration review, but must give CMS and the ACO notice of the change.

(e) *Evidence.* (1) The reconsideration official's review will be based only on evidence submitted by the reconsideration official's requested deadline, unless otherwise requested by the reconsideration official.

(2) Documentation submitted for the record as evidence cannot be documentation that was not previously submitted to CMS by the applicable deadline and in the requested format.

(3) All evidence submitted by the ACO and CMS, in preparation for the reconsideration review will be shared with the other party to the hearing.

(f) The reconsideration official will notify CMS and the ACO of his or her recommendation.

§ 425.806 On-the-record review of reconsideration official's recommendation by independent CMS official.

(a)(1) If CMS or the ACO disagrees with the recommendation of the reconsideration official, it may request an on the record review of the initial determination and recommendation by an independent CMS official who was not involved in the initial determination or the reconsideration review process.

(2) In order to request an on-the-record review, CMS or the ACO must submit an explanation of why it disagrees with the recommendation by the timeframe and in the format indicated in the reconsideration official's recommendation letter.

(b) The on-the-record review process is based only on evidence presented during the reconsideration review.

(c) The independent CMS official considers the recommendation of the reconsideration official and makes a final agency determination.

§ 425.808 Effect of independent CMS official's decision.

(a) The decision of the independent CMS official is final and binding.

(b) The reconsideration review process under this subpart must not be construed to negate, diminish, or otherwise alter the applicability of existing laws, rules, and regulations or determinations made by other government agencies.

§ 425.810 Effective date of decision.

(a) If the initial determination denying an ACO's application to participate in the Shared Savings Program is upheld, the application will remain denied based on the effective date of the original notice of denial.

(b) If the initial determination to terminate an agreement with an ACO is upheld, the decision to terminate the agreement is effective as of the date indicated in the initial notice of termination.

(c) If the initial determination to terminate an ACO is reversed, the ACO is reinstated into the Shared Savings Program, retroactively back to the original date of termination.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 6, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 19, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–27461 Filed 10–20–11; 11:15 am]

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

Office of the Inspector General

42 CFR Chapter V

Medicare Program; Final Waivers in Connection With the Shared Savings Program; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Chapter IV

Office of Inspector General

42 CFR Chapter V

[CMS–1439–IFC]

RIN 0938–AR30

Medicare Program; Final Waivers in Connection With the Shared Savings Program

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period establishes waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties (CMP) law provisions to specified arrangements involving accountable care organizations (ACOs) under section 1899 of the Social Security Act (the Act) (the Shared Savings Program), including ACOs participating in the Advance Payment Initiative. Section 1899(f) of the Act, as added by the Affordable Care Act, authorizes the Secretary to waive certain fraud and abuse laws as necessary to carry out the provisions of section 1899 of the Act.

DATES: *Effective date:* These regulations are effective on November 2, 2011.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 3, 2012. Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified here, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

ADDRESSES: In commenting, please refer to file code CMS–1439–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1439–IFC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1439–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1813.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–1066 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Neal Shah (410) 786–1167 or Kristin Bohl (410) 786–8680, for general issues and issues related to the Physician Self-Referral Law.

James A. Cannatti III (202) 619–0335, for general issues and issues related to the Federal anti-kickback statute or civil monetary penalties.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Introduction and Overview

Section I. of this interim final rule with comment period (IFC) provides an introduction and overview of this rule. Section II. of this IFC provides background on the Shared Savings Program. Section III. of this IFC summarizes public comments received in response to the Waiver Designs Notice and Shared Savings Program proposed rule (as those terms are defined below). Section IV. of this IFC sets out the waivers and applicable requirements. Section V. of this IFC explains the waivers and solicits comments on specific ways we might modify the waivers to address fraud and abuse or other problems that may arise.

A. Connection Between Shared Savings Program and Fraud and Abuse Waivers

Elsewhere in this issue of the **Federal Register**, the Centers for Medicare & Medicaid Services (CMS) published a final rulemaking setting forth the requirements for ACOs under the Shared Savings Program (hereinafter referred to as the ''Shared Savings Program final rule''). Section 1899 of the Act (as added by section 3022 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the ''Affordable Care Act'') describes the Shared Savings Program as a Medicare program to promote accountability for a Medicare patient population, coordinate items

and services under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. As described in the Shared Savings Program final rule, the Shared Savings Program is designed to achieve three goals: Better health for populations, better care for individuals, and lower growth in expenditures. CMS's expectation is that Shared Savings Program accountable care organizations (ACO) [1] will help foster a new approach to delivering care that reduces fragmented or unnecessary care and excessive costs for Medicare fee-for-service beneficiaries and other patients.

The Physician Self-Referral Law, the Federal anti-kickback statute, and the civil monetary penalties (CMP) law provisions addressing inducements to beneficiaries and hospital payments to physicians to reduce or limit services, described in greater detail elsewhere in this IFC, are some of the important tools used to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other harms. However, stakeholders have expressed concern that the restrictions these laws place on certain arrangements between physicians, hospitals, and other individuals and entities may impede development of some of the innovative integrated-care models envisioned by the Shared Savings Program. Section 1899(f) of the Act authorizes the Secretary to waive these and certain other laws as necessary to carry out the Shared Savings Program. Based on stakeholder input and other factors, the Secretary has found that it is necessary to waive these fraud and abuse laws in order to carry out the Shared Savings Program.

Accordingly, this IFC sets forth waivers of certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the CMP law prohibiting hospital payments to physicians to reduce or limit services (the Gainsharing CMP), and the CMP law prohibiting inducements to beneficiaries (the Beneficiary Inducements CMP) as necessary to carry out the provisions of section 1899 of the Act. We seek to waive application of these fraud and abuse laws to ACOs formed in connection with the Shared Savings Program so that the laws do not unduly impede development of beneficial ACOs, while also ensuring that ACO arrangements are not misused for fraudulent or abusive purposes that harm patients or Federal health care programs.

The waivers set forth in this IFC are promulgated pursuant to the specific authority at section 1899(f) of the Act. This authority applies only to the Shared Savings Program and to all ACOs participating in the Shared Savings Program. This includes those Shared Savings Program ACOs that are also participating in the Advance Payment Initiative to be administered by the Center for Medicare & Medicaid Innovation (Innovation Center). The Affordable Care Act includes separate authority for the Secretary to waive fraud and abuse laws for certain other demonstrations and pilot programs. Guidance regarding such waivers will be issued separately.

B. Overview of Final Waivers

On April 7, 2011, CMS and OIG jointly published a notice with comment period seeking public comment on certain proposed waivers and other waiver design considerations (Waiver Designs in Connection with the Shared Savings Program and the Innovation Center (76 FR 19655)) (hereinafter referred to as the ''Waiver Designs Notice''). In that same issue of the **Federal Register**, CMS published a proposed rulemaking setting forth proposed requirements for ACOs under the Shared Savings Program (Shared Savings Program: Accountable Care Organizations (76 FR 19528)) (hereinafter referred to as the ''Shared Savings Program proposed rule'') and soliciting public comments.

CMS and OIG are jointly establishing waivers under this IFC to provide stakeholders with a coordinated approach to the waivers of fraud and abuse laws in connection with the Shared Savings Program. Administration of the Physician Self-Referral Law is the responsibility of CMS; the OIG is responsible for enforcement of the CMP provisions under the Physician Self-Referral Law. OIG shares responsibility for the Federal anti-kickback statute with the Department of Justice. The Gainsharing CMP and Beneficiary Inducements CMP are administered by the OIG.

For reasons elaborated in more detail elsewhere in this IFC, the Secretary has determined, based on consideration of public input and the Department's own analysis, that it is necessary to waive certain provisions of the Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing CMP, and the Beneficiary Inducements CMP in some circumstances to carry out the Shared Savings Program.

Section IV. of this IFC sets out the specific waivers and the conditions pertaining to them. Section V. of this IFC provides commentary explaining the waivers and solicits comments on possible modifications. There are five waivers addressing different circumstances—

- An ''ACO pre-participation'' waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies to ACO-related start-up arrangements in anticipation of participating in the Shared Savings Program, subject to certain limitations, including limits on the duration of the waiver and the types of parties covered;
- An ''ACO participation'' waiver of the Physician Self-Referral Law, the Federal anti-kickback statute, and the Gainsharing CMP that applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the Shared Savings Program and for a specified time thereafter;
- A ''shared savings distributions'' waiver of the Physician Self-Referral Law, Federal anti-kickback statute, and Gainsharing CMP that applies to distributions and uses of shared savings payments earned under the Shared Savings Program;
- A ''compliance with the Physician Self-Referral Law'' waiver of the Gainsharing CMP and the Federal anti-kickback statute for ACO arrangements that implicate the Physician Self-Referral Law and meet an existing exception; and
- A ''patient incentive'' waiver of the Beneficiary Inducements CMP and the Federal anti-kickback statute for medically related incentives offered by ACOs under the Shared Savings Program to beneficiaries to encourage preventive care and compliance with treatment regimes.

These waivers include the two waivers proposed in the Waiver Designs Notice (the shared savings distributions waiver and the compliance with the Physician Self-Referral Law waiver), as well as three new waivers developed in response to public comments seeking additional pathways to address a broader array of ACO activities needed to achieve the purposes of the Shared Savings Program. These five waivers provide flexibility for ACOs and their constituent parts to pursue a wide array of activities, including start-up and operating activities that further the purposes of the Shared Savings Program. These waivers incorporate conditions that, in combination with

[1] For purposes of this IFC, the terms ''ACO,'' ''ACO participants,'' and ''ACO providers/suppliers'' have the meanings ascribed to them in 42 CFR 425.20.

additional safeguards in the Shared Savings Program final rule, are intended to protect Medicare beneficiaries and the Medicare program from fraud and abuse while furthering the quality, economy, and efficiency goals of the Shared Savings Program.

An arrangement need only fit in one waiver to be protected; parties seeking to ensure that an arrangement is covered by a waiver for a particular law may look to any waiver that applies to that law. In some cases, an arrangement may meet the criteria of more than one waiver.

II. Shared Savings Program: Background

A. Section 1899 of the Social Security Act

Section 1899 of the Act establishes the Shared Savings Program to encourage the development of ACOs in Medicare. The Shared Savings Program is one of the first initiatives implemented under the Affordable Care Act aimed specifically at improving ''value'' in the Medicare program—that is, both higher quality and lower total expenditures for individual Medicare beneficiaries and the Medicare program. Section 1899 of the Act encourages ACOs to promote accountability for individual Medicare beneficiaries and population health management, improve the coordination of patient care under Parts A and B, and encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Redesigned care processes may improve care, increase efficiency, and lower costs for Medicare and other patients served by the ACO.

In accordance with the Shared Savings Program final rule, ACOs will enter into a participation agreement with the Secretary to participate in the Shared Savings Program for no less than a 3-year period under one of two tracks. Under the first track, an ACO will have the opportunity to share in savings generated during the agreement. Under the second track, ACOs will operate under a ''two-sided risk'' model in which they will be eligible to receive a higher share of savings, but will also be required to repay a portion of the losses sustained by the Medicare program if costs for the ACO's assigned beneficiaries exceed certain thresholds. Under either model, in order to share a percentage of achieved savings with the Medicare program, ACOs must successfully meet quality and savings requirements and certain other conditions under the Shared Savings Program. ACO participants and ACO providers/suppliers will continue to receive fee-for-service payments, and, under the Shared Savings Program, the ACO legal entity may choose how it distributes shared savings or allocates risk among its ACO participants and its ACO providers/suppliers. ACOs in the Shared Savings Program must also comply with requirements addressing governance, management, and leadership of the ACO, as well as program integrity, transparency, compliance plan, and certification requirements, among others.

B. Waiver Authority Under Section 1899(f) of the Act

Section 1899(f) of the Act provides that ''[t]he Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of [the] Act as may be necessary to carry out the provisions of [section 1899 of the Act].'' This waiver authority is specific to the Shared Savings Program, and does not apply to other similar integrated-care delivery models. We may consider waivers (where authorized under the Affordable Care Act), exceptions, or safe harbors, as applicable, for other types of accountable care organizations, integrated-care delivery models, or arrangements at a later date. As explained in section V. of this IFC, any waivers for Innovation Center demonstration programs, apart from the Advance Payment Initiative, will be issued separately under the relevant authority.

We note that a waiver of a specific fraud and abuse law is not needed for an arrangement to the extent that the arrangement: (1) Does not implicate the specific fraud and abuse law; or (2) implicates the law, but either fits within an existing exception or safe harbor, as applicable, or does not otherwise violate the law. Arrangements that do not fit in a waiver have no special protection and must be evaluated on a case-by-case basis for compliance with the Physician Self-Referral Law, the Federal anti-kickback statute, and the CMP laws. Failure to fit in a waiver is not, in and of itself, a violation of the laws. Existing exceptions and safe harbors might apply to ACO arrangements, depending on the circumstances.[2] These include, among others, Physician Self-Referral Law exceptions for employment, personal services arrangements, in-office ancillary services, electronic health records (EHR) arrangements, risk-sharing, and indirect compensation arrangements (to the extent an ACO arrangement is an indirect financial relationship). Potential Federal anti-kickback statute safe harbors include, among others, those for employment, personal services and management contracts, EHR arrangements, and managed care arrangements.

The waiver authority under section 1899(f) is limited to sections 1128A and 1128B and title XVIII of the Act, and does not extend to any other laws or regulations, including, without limitation, the Internal Revenue Code (IRC) or State laws and regulations. Accordingly, nothing in this IFC affects the obligations of individuals or entities, including tax-exempt organizations, to comply with the IRC or other Federal or State laws and regulations. Moreover, nothing in this IFC changes any Medicare program reimbursement or coverage rule or alters any obligations parties may have under the Shared Savings Program. Although the waivers described in this IFC are necessary to ensure that the fraud and abuse laws do not unduly impede development of ACOs in connection with the Shared Savings Program, the waivers are not intended to suggest that any particular arrangement between particular parties is necessary to implementing the Shared Savings Program.

C. Fraud and Abuse Laws—Background

1. Physician Self-Referral Law (Section 1877 of the Act)

Section 1877 of the Act (42 U.S.C. 1395nn, the ''Physician Self-Referral Law'') is a civil statute that prohibits physicians from making referrals for Medicare ''designated health services,'' including hospital services, to entities with which they or their immediate family members have a financial relationship, unless an exception applies. These entities may not bill Medicare for services rendered as a result of a prohibited referral, and section 1877(g)(1) of the Act states that no payment may be made for a designated health service that is furnished pursuant to a prohibited referral. CMPs also apply to any person who presents (or causes to be presented) a bill for services for which he or she knows or should know payment may not be made under section 1877(g)(1) of the Act. For additional details, see section 1877(g)(3) of the Act. Violations of the Physician Self-Referral Law may also result in liability under the False Claims Act (31 U.S.C. 3729–33).

2. The Federal Anti-Kickback Statute (Section 1128B(b) of the Act)

Section 1128B(b) of the Act (42 U.S.C. 1320a–7b(b), the ''Federal anti-kickback statute'') provides criminal penalties for

[2] 42 CFR 411.355 through 411.357; 42 CFR 1001.952; 42 CFR 1003.110.

individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to 5 years. Violations of the Federal anti-kickback statute may also result in the imposition of CMPs under section 1128A(a)(7) of the Act (42 U.S.C. 1320a–7a(a)(7)), program exclusion under section 1128(b)(7) of the Act (42 U.S.C. 1320a–7(b)(7)), and liability under the False Claims Act (31 U.S.C. 3729–33). Certain practices that meet all of the conditions of a safe harbor at 42 CFR 1001.952 are not subject to prosecution or sanctions under the Federal anti-kickback statute.

3. Prohibition on Inducements to Beneficiaries (Section 1128A(a)(5) of the Act)

Section 1128A(a)(5) of the Act (42 U.S.C. 1320a–7a(a)(5)), the ''Beneficiary Inducements CMP'') prohibits individuals and entities from offering or transferring remuneration to Medicare or Medicaid beneficiaries that the individual or entity knows or should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any Medicare or Medicaid item or service. There are existing exceptions to the Beneficiary Inducements CMP at section 1128A(i)(6) of the Act.

4. Prohibition on Hospital Payments to Physicians To Induce Reduction or Limitation of Services (Sections 1128A(b)(1) and (2) of the Act)

Sections 1128A(b)(1) and (2) of the Act (42 U.S.C. 1320a–7a(b)(1) and (2), the ''Gainsharing CMP'') apply to certain payment arrangements between hospitals and physicians, including arrangements commonly referred to as ''gainsharing'' arrangements. Under section 1128A(b)(1) of the Act, a hospital is prohibited from making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments (sections 1128A(b)(1) and (2) of the Act).

D. Summary of Public Input Opportunities

Since passage of the Affordable Care Act, the U.S. Department of Health and Human Services (DHHS) has offered numerous opportunities for the public to provide input into the design and operation of ACOs and waivers necessary to carry out the provisions of the Shared Savings Program, most recently through the Waiver Designs Notice described previously in this IFC. In addition, CMS issued a Request for Information Regarding Accountable Care Organizations and the Shared Saving Program on November 10, 2010,[3] and held multiple listening sessions with stakeholders. CMS, OIG, and the Federal Trade Commission held a joint workshop on October 5, 2010, entitled ''Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws.''[4] We also received and reviewed written public comments in connection with the workshop.[5] Finally, we received public comments related to the waivers in response to the Waiver Designs Notice and the Shared Savings Program proposed rule. Through these means, DHHS has received public input representing a wide spectrum of views.

E. Contents of Waiver Designs Notice

The Waiver Designs Notice proposed several waivers related to ACOs in the Shared Savings Program and also solicited public comments on a range of issues. The proposed waivers included waivers of certain provisions of the Physician Self-Referral Law and the Federal anti-kickback statute to distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) To or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program. We also proposed to waive certain provisions of the Federal anti-kickback statute with respect to any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

We also proposed to waive certain provisions of the Gainsharing CMP with respect to two scenarios: (1) Distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program in circumstances where the distributions are made from a hospital to a physician, provided that the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services, and the hospital and physician are ACO participants or ACO providers/suppliers, or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; and (2) any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exception at 42 CFR 411.355 through 411.357.

The Waiver Designs Notice recognized that the proposed waivers might not cover all of the possible arrangements involved with setting up and operating an ACO. As such, we solicited comments on waivers, modifications, or additions that would be necessary to carry out the provisions of the Shared Savings Program. We specifically solicited comments on how waivers should address: arrangements related to establishing the ACO; arrangements between or among ACO participants and/or ACO providers/suppliers related to ongoing operations of the ACO and achieving ACO goals; other arrangements for which a waiver would be necessary; the duration of the waivers; and the scope of the waivers.

III. Summary of Public Comments to the Waiver Designs Notice and Relevant Sections of the Shared Savings Program Proposed Rule

We received comments related to the proposed waivers and solicitation of comments on other waiver design considerations in response to both the Waiver Designs Notice and the Shared Savings Program proposed rule. We summarize the comments in this section of the IFC. Section V. of this IFC explains the waivers in more detail and responds to comments.

A. Threshold Qualifications for Waiver

Commenters requested that we clarify whether we will be issuing waivers that are uniform across all ACOs

[3] 75 FR 70165 (2010).

[4] Information about the workshop is available on CMS's Web site at *http://www.cms.gov/center/physician.asp.*

[5] The public comments are available on the FTC's Web site at *http://www.ftc.gov/os/comments/aco/index.shtm.*

participating in the Shared Savings Program. At least one commenter recommended that we retain some provision for individualized review while others requested that waivers apply uniformly to all participants.

B. Scope of Proposed Waivers

We received numerous comments about the appropriate scope of the waivers. The great majority of commenters supported broader waivers. Many of those commenters indicated that the proposed waivers would be insufficient to foster the innovation and relationships necessary for participation in the Shared Savings Program. However, some commenters expressed concern that the proposed waivers were too broad, or that expanded waivers could lead to program abuses.

1. General Issues

Many commenters stated that the applicable fraud and abuse laws should be waived in their entirety for ACOs participating in the Shared Savings Program because, according to the commenters, the laws are premised on a ''fee-for-service'' world that has different incentives than those that apply to the Shared Savings Program and because the Shared Savings Program incorporates monitoring, reporting, and other program features that will act as safeguards. These commenters stated that DHHS should waive these laws for entities that successfully enter and participate in the Shared Savings Program, such that the entities would be shielded from penalties for transactions related to ACO business. Many commenters stated that certain elements of the Physician Self-Referral Law exceptions and Federal anti-kickback statute safe harbors cannot sufficiently support the development of innovative ACO structures. For example, these commenters identified the ''transaction-by-transaction'' structure of the existing exceptions and safe harbors and the ''fair market value'' or ''set in advance'' elements of many of them as specific burdens.

Several commenters stated that the fraud and abuse laws should be waived for payments between ACOs enrolled in the Shared Savings Program, their ACO participants, and/or their ACO providers/suppliers, regardless of the source of funding for the payments. Some commenters asserted that the Shared Savings Program's standards for clinical integration should justify protection for payments other than shared savings distributions, if the payments are made in service of achieving Shared Savings Program goals. Others were concerned that the continued use of fee-for-service payments in the program created an incentive for overutilization.

The majority of comments generally suggested one of two broad approaches to waiving the laws: First, an ''ACO waiver'' establishing broad protections for ACO functions, or second, a total waiver of the laws for any ACO participating in the Shared Savings Program. Many commenters called for the agencies to create an ''ACO waiver'' that would cover ACO activities through the lifespan of an ACO, from arrangements leading up to formation of the ACO, through the end of the ACO's participation in the program. Other commenters advocated the creation of a ''single, comprehensive approach'' for compliance, rather than requiring a piecemeal transaction-by-transaction analysis. Some commenters requested ''blanket'' waivers for certain categories of remuneration, including non-monetary arrangements (such as IT services, EHR systems, and the provision of free care management personnel and/or services) and ''systems-level'' activities (such as medical directorships or infection prevention/antimicrobial stewardship programs).

In contrast, a minority of commenters favored waivers no broader or narrower than the proposed waivers. Some of these commenters advocated alternate approaches including: Different safeguards (discussed later in this IFC), waivers conditioned on certain qualitative limits, and more extensive monitoring (including monitoring of beneficiary access to care and cost-shifting to private insurers). Although some commenters were concerned about an overly broad waiver and cautioned against expanding beyond the proposed waiver designs, the majority of commenters believed the proposed waiver for shared savings distributions would be too narrow, particularly because an ACO, its ACO participants, and its ACO providers/suppliers will not have access to the shared savings distributions until long after the ACO has entered into its participation agreement, thus precluding use of those savings to fund start-up and operating activities.

Some commenters raised issues related to specific scenarios. For example, a commenter requested that ACOs with ''commercial motives'' be treated differently than ACOs composed of ''public health providers'' because, according to the commenter, the latter do not give rise to similar fraud and abuse concerns. Other commenters stated that the fraud and abuse laws presented a particular challenge for prospective ACOs in States with ''corporate practice of medicine'' laws because providers and suppliers could not satisfy certain important exceptions and safe harbors (including the employment exception and safe harbor) in those States.

We also received requests for clarification about the proposed waivers. Several commenters requested clarification about how the fraud and abuse laws would interact with specific Shared Savings Program rules. For example, one commenter expressed concern about the phrase ''distributions of shared savings,'' and asked the agencies to clarify whether a payment from an ACO to its ACO participants or its ACO providers/suppliers must be conditioned on the same quality and cost terms that govern the ACO's participation agreement (or whether it would be sufficient that the payment initially comes from shared savings). We also received a number of comments on the proposed ''necessary for and directly related to'' standard. Commenters overwhelmingly requested that we clarify this phrase, arguing it was too restrictive and thus did not provide sufficient assurance that ACOs could participate in the Shared Savings Program. Some commenters believed the standard was overly broad, with one expressing concern that the standard could allow arrangements that would eliminate competition. Some commenters requested concrete examples of relationships that would meet this standard, while others requested that the agencies allow greater flexibility. Commenters also suggested a range of different standards, including, for example, mandating that relationships simply be ''related'' or ''directly related'' to the ACO, making the standard subjective, or requiring payments to entities outside the ACO to be linked to quality improvement goals. Finally, some commenters stated that it would be difficult to isolate arrangements that are ''necessary for and directly related to'' the ACO because many arrangements will only be feasible if applied to all payers and/or patients.

Some commenters also raised questions about how the waivers would function practically. For example, one commenter asked whether all ACO participants or ACO providers/suppliers would endanger their Medicare fee-for-service payments if the ACO (or one of its ACO participants or ACO providers/suppliers) fails to satisfy one of the qualifications of the waiver. We also received many requests for clarification of the scope of the waiver for shared savings distributions. For example,

some commenters asked us to confirm that downstream distributions would be covered by the waiver, while others asked us to clarify whether repayment of start-up costs out of shared savings would be considered ''necessary for and directly related to'' the ACO's participation in the program.

2. Compliance With the Physician Self-Referral Law Waiver

We received several comments asking for clarification of the proposed waiver of the Federal anti-kickback statute and Gainsharing CMP for financial relationships between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO's participation in and operations under the Shared Savings Program that implicate the Physician Self-Referral Law and fully comply with an existing exception at 42 CFR 411.355 through 411.357. Several commenters requested expansion of this waiver to cover relationships that would not implicate the Physician Self-Referral Law either because the relationship would not involve designated health services or would not involve referring physicians covered by the Physician Self-Referral Law. While commenters on this topic generally welcomed the alignment of the Federal anti-kickback statute, the Gainsharing CMP, and the Physician Self-Referral Law for ACO arrangements, some expressed concern that the proposed waiver design was too limited to promote many innovative ACO arrangements.

3. Gainsharing CMP

Some commenters requested clarification of the application of the waiver of the Gainsharing CMP. For example, some commenters asked us to confirm that distributions of shared savings made from the ACO to a physician would be protected, even if the ACO is owned in part by a hospital. Some commenters urged us to adopt a narrow waiver of the Gainsharing CMP and to carefully monitor ACOs to ensure that the waiver does not lead to a reduction or limitation of medically necessary services. Many commenters requested additional clarification of the ''medically necessary'' standard that limited application of the proposed waiver of the Gainsharing CMP to arrangements that do not reduce medically necessary care. Several commenters asked us to clarify or confirm whether reliance on evidence-based protocols would be sufficient to meet the ''medically necessary'' standard. Several commenters noted that successful ACOs may reduce some types of medically necessary services by encouraging the use or ordering of alternative medically necessary services, for example, arrangements that incentivize reductions in emergency room visits by encouraging management of conditions on a non-emergency basis or arrangements that reduce inpatient admissions in favor of coordinated outpatient care. A commenter urged us to permit financial rewards that incent implementation of evidence-based treatment protocols, even though such payments may be intended to encourage clinicians to select one type of medically necessary service over another.

C. Duration of Waivers

Commenters generally objected to the proposed requirement that the waivers would apply only so long as an ACO, its ACO participants, and its ACO providers/suppliers remained in compliance with Shared Savings Program requirements. Some commenters requested that this requirement be eliminated and replaced by a simpler threshold for waiver qualification, asserting that the auditing and oversight functions at the outset of and during the Shared Savings Program are sufficient to protect against fraud and abuse.

Many commenters requested that the waivers cover periods prior to an ACO's acceptance into the Shared Savings Program. Some of these commenters also expressed a desire that the waivers cover time periods after the ACO, its ACO participants, and its ACO providers/suppliers have left the Shared Savings Program, for purposes of winding down the arrangement or otherwise ensuring continued compliance with the laws. One commenter suggested that the waivers cover a period of at least 24 months prior to the start of any agreement with CMS, with no possibility of retroactive enforcement, in order to avoid a chilling effect on innovation. Other commenters suggested that the agencies apply the waivers to payments whenever made, if the payments relate to activities leading up to or occurring within the agreement period.

D. Additional Waiver Design Considerations

1. Start-Up Costs

Many commenters stated that the fraud and abuse laws should be waived in a manner that allows participants to finance others' start-up costs. As examples, commenters identified: Infrastructure creation and provision prior to acceptance in the Shared Savings Program (for example, care coordination mechanisms; EHR systems; data reporting systems; new staff; and systems to make operational performance measurements and allocate performance results and payments accordingly); market analysis for antitrust purposes; potential novel arrangements created to facilitate integration across multiple organizations; organizational and training costs; incentives to attract primary care physicians; and any loans, capital contributions, grants and withholds.

Some commenters suggested that waivers covering start-up costs should be limited to providers that have a financial stake in the success of the ACO, or, absent this requirement, that any waiver should be limited to distributions of shared savings only.

2. Other Arrangements Among the ACO, Its ACO Participants, and Its ACO Providers/Suppliers

Most commenters on this topic stated that waivers should cover arrangements (in addition to those arising out of shared savings) among the ACO, its ACO participants, and its ACO providers/suppliers. One commenter recommended that the waivers not apply to additional arrangements unless the arrangements are necessary for or directly related to the ACO's operations under the Shared Savings Program. But the majority of commenters, supporting a broader approach to waivers, explained that waivers for other arrangements are necessary to allow for start-up, operating, and maintenance costs in the context of innovative arrangements. These commenters had various suggestions about how the laws should be waived. As noted previously, many commenters suggested that the fraud and abuse laws should be waived broadly for ACOs in the Shared Savings Program. Others suggested that the laws should be waived for compensation that is expressly conditioned on quality improvements, cost savings, or adherence to objective clinical measures, care coordination guidelines, and/or treatment models. Others suggested that waivers should cover payments that are made in connection with the operations and goals of the ACO and are commercially reasonable. Some commenters asked us to consider situations in which ACOs do not generate shared savings immediately, if at all, and pointed to the Medicare Physician Group Practice demonstration project as an example. One commenter proposed that the waiver should cover hospitals that share the proceeds of system-wide savings they achieve

outside the context of the Shared Savings Program or some other formal payer-organized shared savings program.

3. Other Arrangements With Parties Outside the ACO

Some commenters asked us to clarify the term ''outside individuals and entities'' as that term was used in the solicitation of comments on this issue. For example, commenters asked whether the waivers would cover arrangements with physicians and other providers who are not ACO participants or ACO providers/suppliers but who treat ACO patients and voluntarily comply with the ACO's policies and procedures.

Many commenters appreciated the proposed waiver for arrangements with parties outside the ACO that are funded with distributions of shared savings. However, many commenters requested that we expand the waiver to cover arrangements with individuals or entities outside the ACO even if the payments are not derived from shared savings. Some commenters suggested that covered arrangements be restricted to those that meet articulated standards (for example, only arrangements arising out of the distribution of shared savings should be waived) and that CMS monitor referrals to ensure that non-ACO participants and non-ACO providers/suppliers are not being unfairly marginalized.

4. Relationships With Private Payers/ Other Payers

Many commenters stated that the agencies should waive the fraud and abuse laws for arrangements involving payments from private payers to ACOs, including ''downstream'' arrangements between or among the ACO, ACO participants, and ACO providers/ suppliers. These commenters generally believed that limiting the waiver to arrangements involving Medicare shared savings would limit economies of scale and introduce significant complexity from the perspective of governance and management. One commenter argued that the involvement of private health plans in ACO relationships would reduce fraud and abuse concerns. Some commenters expressed concern that failure to address private payer arrangements would perpetuate uncertainty for ACOs enrolling in the Shared Savings Program that were also contemplating similar arrangements with private payers. These commenters observed that arrangements downstream of private payer incentive payment programs can be sensitive to the volume or value of ''other business generated'' for providers and suppliers and thus might not fit in existing exceptions to the Physician Self-Referral Law. One commenter representing health plans expressed concern about ACO arrangements under the Shared Savings Program that might result in cost-shifting to private plans or steerage of patients to or from Medicare managed care plans based on the services required by the patient. Some commenters stated that we should not create waivers for private payer arrangements.

Some commenters suggested that, if the final waivers do not cover relationships with private payers, the agencies should clarify how elements of existing exceptions and safe harbors may be applied to such arrangements involving ACOs. For example, commenters requested further clarification on the following: whether hospital distribution of a private payer's shared savings payments would constitute ''indirect compensation'' under the Physician Self-Referral Law; how to calculate ''fair market value'' of downstream distributions of private payer shared savings for purposes of applicable exceptions; and whether the Physician Self-Referral Law risk-sharing exception could be used. Finally, one commenter requested that the agencies integrate guidance for private payers with guidance for other non-Medicare payers, including Medicaid.

5. Appropriate Safeguards

Some commenters stated that safeguards beyond the transparency, accountability, and oversight protections built into the Shared Savings Program proposed rule are unnecessary because such safeguards adequately address patient and program abuse. A commenter stated that providing opportunities for creativity without waiver-specific, restrictive safeguards will not increase the likelihood that individuals or organizations will place their own financial interests above those of their patients; instead, it will allow them to focus on furnishing appropriate and necessary care coordination. A commenter suggested that safeguards be based on prior OIG advisory opinions or the CMS proposed incentive payment and shared savings exception.

Other commenters believed that additional safeguards are necessary and suggested, for example, requiring arrangements to meet a fair market value or commercial reasonableness standard; requiring additional disclosures to CMS and to patients; or imposing more specific requirements related to methods for distributing shared savings to address the commenters' concerns about distributions inappropriately influencing physician ordering patterns or possible stinting on care.

A commenter stated that the waiver for shared savings distributions should not protect distributions of shared savings from an ACO to an ACO participant on the basis of that ACO participant's generation of other business for another ACO participant. Some commenters suggested monitoring of referrals outside the ACO to detect improper referral patterns. One commenter requested that CMS create a system to continually assess the compliance of an ACO, its ACO participants, and its ACO providers/ suppliers with the fraud and abuse laws.

6. Two-Sided Risk

We received several comments in response to our solicitation on waiver considerations related to two-sided risk. One commenter noted that a waiver should apply equally to both one- and two-sided risk models. Other commenters recommended that CMS either extend the proposed waiver to cover hospitals' disproportionate assumption of risk or change the Shared Savings Program proposed rule to make the two-sided option voluntary or make it clear that such assumption of risk is not remuneration under the Physician Self-Referral Law. Commenters asked that we protect the means or allocation of shared savings and losses, and that we define the ''proper'' allocation of such savings or losses.

7. Existing Exception and Safe Harbor for Electronic Health Records

We sought comments in the Waiver Designs Notice addressing whether, in connection with the Shared Savings Program, we should use the authority at section 1899(f) of the Act to waive the Physician Self-Referral Law and the Federal anti-kickback statute for ACO arrangements that satisfy the existing exception and safe harbor [6] for EHR arrangements but that are expected to occur after the sunset date of 2013. Some commenters requested that the agencies waive the current sunset date of 2013 that applies to the existing EHR exception and safe harbor, and suggested that the agencies protect the EHR arrangements of ACOs in the Medicare Shared Savings Program after 2013 on the same terms as the existing exception and safe harbor. Some commenters particularly argued that the Shared Savings Program proposed rule's standard of 50 percent meaningful use

[6] 42 CFR 411.357(w) and 42 CFR 1001.952(y), respectively.

of EHRs demonstrated the need to extend the waiver to relationships intended to reach that standard.

One commenter disagreed with waiving the EHR exception and safe harbor and suggested rescinding the exception and safe harbor or specifically excluding these types of arrangements from the waiver, because the EHR incentive in American Recovery and Reinvestment Act of 2009 was sufficient to achieve the exception's and safe harbor's original purpose of promoting adoption of technology. However, most commenters addressing this topic requested that we make the exception and safe harbor permanent, extend them for several years, or protect ACOs at any time after the sunset on the same terms as the exception and safe harbor.

8. Beneficiary Inducements

Most commenters addressing this topic supported a waiver of the Beneficiary Inducements CMP, section 1128A(a)(5) of the Act, although some of them expressed opposition. Among commenters supporting a waiver, many cited the need for a waiver to promote greater preventive care, to incentivize patients to follow treatment or follow-up care regimes, and to increase participation in ACOs in order to achieve the goals of the Shared Savings Program. Several supporters of a waiver suggested that the waiver cover reduced or eliminated beneficiary cost-sharing, or other financial incentives, such as allowing beneficiaries to share in ACO cost savings. Commenters opposing a Beneficiary Inducements CMP waiver stated it could negatively impact patient choice by promoting incentives that might induce beneficiaries to seek care only within a particular ACO.

9. Timing of Waivers

Generally, commenters supported issuance of the waivers prior to or at the same time as the Shared Savings Program final rule in order to afford prospective ACOs, their ACO participants, and ACO providers/suppliers as much time as possible to prepare for application to the Shared Savings Program with known waiver protection.

10. Other Issues Related to Shared Savings Program Waivers

Commenters raised a number of other issues related to the waivers. Some commenters requested that the waivers apply to clinically integrated organizations that do not participate in the Shared Savings Program. Others raised the issue that waivers of the Physician Self-Referral Law, Federal anti-kickback statute, and Gainsharing CMP laws do not offer protection with respect to State laws. Several commenters asked the agencies to clarify how the proposed waivers would affect programs outside the Shared Savings Program. Commenters proposed that CMS should extend uniform waivers for all Medicare projects involving coordinated care, including the Independence at Home project, Bundled Payment project, and demonstrations sponsored by the Innovation Center. One commenter requested that the waiver apply to healthcare providers other than ACO participants or ACO providers/suppliers, while others requested that waivers apply to all arrangements between ACO participants and/or ACO providers/suppliers, and individuals or entities outside the Shared Savings Program.

We also received a number of comments that are outside the scope of this rulemaking. Those comments are not summarized here.

IV. Provisions of the Interim Final Rule With Comment Period: Waiver Requirements

A. Overview

Section IV.B. of this IFC sets forth the specific waivers and waiver requirements, pursuant to the authority granted under section 1899(f) of the Act. The waivers apply only to the specific provisions of the laws enumerated in the waivers and do not apply to any other provisions of Federal or State law, including, without limitation, any provisions of the IRC. We invite the public to comment on the waivers set forth in section IV.B. of this IFC.

To promote efficiency and ease of use, we crafted the waivers to apply consistently across the waived fraud and abuse laws to the extent possible. The waivers apply uniformly to each ACO, ACO participant, and ACO provider/supplier (as those terms are defined in section IV.B. of this IFC pursuant to the Shared Savings Program) participating in the Shared Savings Program. The waivers are intended to be self-implementing. Apart from meeting applicable waiver conditions, no special action (such as the submission of a separate application for a waiver) is required by parties in order to be covered by a waiver. Parties need not apply for an individualized waiver.

This IFC includes five waivers. The multiplicity of waivers is intended to afford flexibility to ACOs in varying circumstances and to be responsive to public comments outlining a wide variety of arrangements that ACOs of various types might need to undertake in order to be successful at carrying out the Shared Savings Program. While the waivers contain many common elements, there are distinctions among them tailored to address particular circumstances, including particular fraud and abuse risks. The first two waivers are an ACO pre-participation waiver and an ACO participation waiver that should, collectively, address the majority of ACO-related start-up and operating arrangements identified by public comments and the DHHS's own analysis as necessary to carry out the Shared Savings Program. Two additional waivers—for shared savings distributions and arrangements that are in compliance with the Physician Self-Referral Law—were described in the Waiver Designs Notice and are being established in this IFC with minor modifications. Many arrangements covered by these waivers could also be protected under the ACO pre-participation and ACO participation waivers. However, some parties may find these two additional waivers more suitable to their particular needs, and we have elected to make them available. The remaining waiver addresses incentives offered to beneficiaries to foster preventive health care and patient compliance with treatment regimes in order to engage patients in quality and care improvement. For ease of reference, the entire set of waivers and applicable requirements is set forth in section IV.B. of this IFC. We will also make the waiver text available on both the CMS and OIG Web sites. Because the waivers cover multiple legal authorities and to ensure that the waivers, if modified, remain consistent over time and across relevant laws, we are not codifying the waivers in the Code of Federal Regulations. We solicit comments about this approach.

Additional explanation appears in section V. of this IFC, as well as additional solicitations of comments on possible modifications to the waiver designs.

B. The Waivers and Applicable Requirements

As used in these waivers, *ACO, ACO participant,* and *ACO provider/supplier* have the meanings set forth in 42 CFR 425.20. In the context of the ACO pre-participation waiver, these terms refer to individuals or entities that would meet the definitions of the terms set forth in 42 CFR 425.20, if the ACO had a participation agreement, but for the fact that the ACO has not yet submitted the list required under 42 CFR 425.204(c)(5) to be provided with the application for the Shared Savings Program.

As used in these waivers, *participation agreement* refers to the agreement between an ACO and CMS for the ACO's participation in the Shared Savings Program that is described in 42 CFR 425.208.

As used in these waivers, *purposes of the Shared Savings Program* means one or more of the following purposes consistent with section 1899(a) and (b) of the Act: promoting accountability for the quality, cost, and overall care for a Medicare patient population as described in the Shared Savings Program, managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO, or encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries.

As used in these waivers, *start-up arrangements* means any items, services, facilities, or goods (including non-medical items, services, facilities, or goods) used to create or develop an ACO that are provided by such ACO, ACO participants, or ACO providers/suppliers.

ACO Pre-participation Waiver. Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to start-up arrangements that pre-date an ACO's participation agreement, provided all of the following conditions are met:

1. The arrangement is undertaken by a party or parties acting with the good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year (the ''target year'') and to submit a completed application to participate in the Shared Savings Program for that year. The parties to the arrangement must include, at a minimum, the ACO or at least one ACO participant of the type eligible to form an ACO (as set forth at 42 CFR 425.102(a)). The parties to the arrangement may not include drug and device manufacturers, distributors, durable medical equipment (DME) suppliers, or home health suppliers.

2. The parties developing the ACO must be taking diligent steps to develop an ACO that would be eligible for a participation agreement that would become effective during the target year, including taking diligent steps to meet the requirements of 42 CFR 425.106 and 425.108 concerning the ACO's governance, leadership, and management.

3. The ACO's governing body has made and duly authorized a *bona fide* determination, consistent with a duty to the ACO that is equivalent to the duty owed by ACO governing body members under 42 CFR 425.106(b)(3), that the arrangement is reasonably related to the purposes of the Shared Savings Program.

4. The arrangement, its authorization by the governing body, and the diligent steps to develop the ACO are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, the documentation of the authorization must be contemporaneous with the authorization, and the documentation of the diligent steps must be contemporaneous with the diligent steps. All such documentation must be retained for at least 10 years following completion of the arrangement (or, in the case of the diligent steps, for at least 10 years following the date the ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application, as described in item 6) and promptly made available to the Secretary upon request. The documentation must identify at least the following:

a. A description of the arrangement, including all parties to the arrangement; the date of the arrangement; the purpose(s) of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.

b. The date and manner of the governing body's authorization of the arrangement. The documentation of the authorization should include the basis for the determination by the ACO's governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.

c. A description of the diligent steps taken to develop an ACO, including the timing of actions undertaken and the manner in which the actions relate to the development of an ACO that would be eligible for a participation agreement.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

6. If an ACO does not submit an application for a participation agreement by the last available application due date for the target year, the ACO must submit a statement on or before the last available application due date for the target year, in a form and manner to be determined by the Secretary, describing the reasons it was unable to submit an application.

For arrangements that meet all of the preceding conditions, the pre-participation waiver applies as follows:

- The waiver period would start on—

++ The date of publication of this IFC for target year 2012; or

++ One year preceding an application due date (the ''selected application date'') for a target year of 2013 or later.

- The waiver period would end—

++ For ACOs that submit an application by the selected application date and enter into a participation agreement for the target year, on the start date for that agreement;

++ For ACOs that submit an application by the selected application date for the target year, but whose application is denied, on the date of the denial notice, except with respect to any arrangement that qualified for the waiver before the date of the denial notice, in which case the waiver period would end on the date that is 6 months after the date of the denial notice; and

++ For ACOs that fail to submit an application by the selected application due date for the target year, on the earlier of the selected application due date or the date the ACO submits a statement of reasons for failing to submit an application, except that an ACO that has been unable to submit an application, but can demonstrate a likelihood of successfully developing an ACO that would be eligible to participate in the Shared Savings Program by the next available application due date, may apply for an extension of the waiver, pursuant to procedures to be established by the Secretary in guidance. The determination whether to grant a waiver will be in the sole discretion of the Secretary and will not be reviewable.

++ An ACO may use the pre-participation waiver (including any extensions granted) only one time.

ACO Participation Waiver. Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to any arrangement of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. The ACO meets the requirements of 42 CFR 425.106 and 425.108 concerning its governance, leadership, and management.

3. The ACO's governing body has made and duly authorized a *bona fide* determination, consistent with the governing body members' duty under 42 CFR 425.106(b)(3), that the arrangement is reasonably related to the purposes of the Shared Savings Program.

4. Both the arrangement and its authorization by the governing body are documented. The documentation of the arrangement must be contemporaneous with the establishment of the arrangement, and the documentation of the authorization must be contemporaneous with the authorization. All such documentation must be retained for at least 10 years following completion of the arrangement and promptly made available to the Secretary upon request. The documentation must identify at least the following:

a. A description of the arrangement, including all parties to the arrangement; date of the arrangement; the purpose of the arrangement; the items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods); and the financial or economic terms of the arrangement.

b. The date and manner of the governing body's authorization of the arrangement. The documentation should include the basis for the determination by the ACO's governing body that the arrangement is reasonably related to the purposes of the Shared Savings Program.

5. The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary. Such public disclosure shall not include the financial or economic terms of the arrangement.

For arrangements that meet all of the preceding conditions, the waiver period will start on the start date of the participation agreement and will end 6 months following the earlier of the expiration of the participation agreement, including any renewals thereof, or the date on which the ACO has voluntarily terminated the participation agreement. However, if CMS terminates the participation agreement, the waiver period will end on the date of the termination notice.

3. Shared Savings Distribution Waiver

Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the Physician Self-Referral Law), sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to distributions or use of shared savings earned by an ACO, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement;

2. The shared savings are earned by the ACO pursuant to the Shared Savings Program;

3. The shared savings are earned by the ACO during the term of its participation agreement, even if the actual distribution or use of the shared savings occurs after the expiration of that agreement.

4. The shared savings are—

a. Distributed to or among the ACO's ACO participants, its ACO providers/suppliers, or individuals and entities that were its ACO participants or its ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or

b. Used for activities that are reasonably related to the purposes of the Shared Savings Program.

5. With respect to the waiver of sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP), payments of shared savings distributions made directly or indirectly from a hospital to a physician are not made knowingly to induce the physician to reduce or limit *medically necessary* items or services to patients under the direct care of the physician.

4. Compliance With the Physician Self-Referral Law Waiver

Pursuant to section 1899(f) of the Act, sections 1128A(b)(1) and (2) of the Act (relating to the Gainsharing CMP) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Physician Self-Referral Law, provided all of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. The financial relationship is reasonably related to the purposes of the Shared Savings Program.

3. The financial relationship fully complies with an exception at 42 CFR 411.355 through 411.357.

For arrangements that meet all of the preceding conditions, the waiver period will start on the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement has been terminated.

5. Waiver for Patient Incentives

Pursuant to section 1899(f) of the Act, section 1128A(a)(5) of the Act (relating to the beneficiary inducements CMP) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair-market-value if all four of the following conditions are met:

1. The ACO has entered into a participation agreement and remains in good standing under its participation agreement.

2. There is a reasonable connection between the items or services and the medical care of the beneficiary.

3. The items or services are in-kind.

4. The items or services—

a. Are preventive care items or services; or

b. Advance one or more of the following clinical goals:

i. Adherence to a treatment regime.

ii. Adherence to a drug regime.

iii. Adherence to a follow-up care plan.

iv. Management of a chronic disease or condition.

For arrangements that meet all of the preceding conditions, this waiver period will start on the start date of the participation agreement and will end on the earlier of the expiration of the term of the participation agreement, including any renewals thereof, or the date on which the participation agreement has been terminated, provided that a beneficiary may keep items received before the participation agreement expired or terminated, and receive the remainder of any service initiated before the participation agreement expired or terminated.

V. Provisions of the Interim Final Rule With Comment Period: Explanation of Waiver Requirements

This section explains the waivers set forth in section IV.B. of this IFC and responds to public comments. We are providing guidance in this section V. of this IFC to help stakeholders interpret

the waiver requirements. We remind readers that the waivers should be interpreted in a reasonable manner. We are soliciting comments about our approach, whether we should provide greater specificity, and, if so, how and for which waivers and waiver conditions.

A. Reasonably Related to the Purposes of the Shared Savings Program

Several waivers described in section IV.B. of this IFC require that arrangements be ''reasonably related to the purposes of the Shared Savings Program.'' We have defined ''purposes of the Shared Savings Program'' consistent with the purposes set forth in Section 1899(a) and (b) of the Act. We are using the statutory purposes of the Shared Savings Program in the waiver context because the waiver authority speaks to carrying out the Shared Savings Program. As used in these waivers, the purposes of the Shared Savings Program consist of promoting accountability for the quality, cost, and overall care for a Medicare population as described in the Shared Savings Program; managing and coordinating care for Medicare fee-for-service beneficiaries through an ACO; and encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries. As further explained in the statute and regulations, these purposes can involve, for example, promoting evidence-based medicine and patient engagement; meeting requirements for reporting on quality and cost measures; coordinating care, such as through the use of telehealth, remote patient monitoring, and other enabling technologies; establishing clinical and administrative systems for the ACO; meeting the clinical integration requirements of the Shared Savings Program; or meeting the quality performance standards of the Shared Savings Program. Additional purposes consistent with the statute and regulations include, for example, evaluating health needs of the ACO's assigned population; communicating clinical knowledge and evidence based medicine to beneficiaries; and developing standards for beneficiary access and communication, including beneficiary access to medical records.

Arrangements with similar purposes but that are unrelated to the Shared Savings Program are not covered by the term ''purposes of the Shared Savings Program.'' Arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waiver. We interpret the purpose of ''efficient service delivery'' in section 1899 of the Act to include, among other things, appropriate reduction of costs to, or growth in expenditures of, the Medicare program, consistent with quality of care, physician medical judgment, and patient freedom of choice. The definition of ''purposes of the Shared Savings Program'' applies uniformly to all waivers in which it appears.

When a waiver requires that the terms of the arrangement be ''reasonably related to the purposes of the Shared Savings Program,'' the arrangement need only be reasonably related to one enumerated purpose, although we would expect that many arrangements would relate to multiple purposes. Where a reasonable relationship exists, it should not be difficult for parties to articulate clearly the nexus between their arrangement and the purposes of the Shared Savings Program. Consistent with our goal to foster flexibility, adaptability, and innovation, we are not further describing in the waiver text the specific arrangements that will be considered reasonably related to the purposes of the Shared Savings Program or providing in the waiver text a list of acceptable arrangements. To provide additional assurance to ACOs, we have provided in this section V of this IFC an illustrative, non-exhaustive list of arrangements that constitute start-up arrangements for purposes of the pre-participation waiver.

As described previously in this IFC, public comments reflected significant variation and scope of anticipated ACO arrangements. We expect parties to apply a reasonable interpretation of the waiver terms. We are, however, soliciting comments on whether we should further define the ''reasonably related to purposes of the Shared Savings Program'' standard and, if so, how. We note that we are not using the proposed language from our Waiver Designs Notice requiring arrangements to be ''necessary for and directly related to ACO purposes.'' Several public commenters expressed concern that this language was not clear. We believe the language that we are using in the waivers is simpler and addresses public comments. We note that arrangements that are necessary for and directly related to the purposes of the Shared Savings Program would be among those that meet the ''reasonably related'' standard.

B. Eligibility for Waiver

In general, four of the five waivers set forth in this IFC are available to protect arrangements involving an ACO, its ACO participants, and/or its ACO providers/suppliers, if the ACO has a participation agreement and remains in good standing under that agreement. We are considering whether to require expressly that an ACO that is under a corrective action plan (CAP) be in compliance with the CAP as a condition of a waiver. We solicit comments on these requirements.

The fifth waiver, the ACO pre-participation waiver, is available for start-up arrangements (as defined in the waiver) provided that the ACO is making good faith efforts to form an ACO and to submit an application to participate in the Shared Savings Program, and all other conditions of the waiver are satisfied. To qualify for the pre-participation waiver, the parties to the arrangement must include, at a minimum, the ACO or at least one individual or entity that is eligible to form an ACO (as defined in the Shared Savings Program final rule). In the context of the ACO pre-participation waiver, the terms ACO, ACO participant, and ACO provider/supplier refer to individuals or entities that would meet the definitions of those terms set forth in the Shared Savings Program regulations at 42 CFR 425.20, if the ACO had a participation agreement (but for the fact that the required list under the regulations has not yet been submitted to CMS). Individuals or entities that are prospective ACO participants or ACO providers/suppliers should be those that would be on the list if it were to be submitted. The pre-participation waiver does not cover arrangements involving drug and device manufacturers, distributors, DME suppliers, or home health suppliers. Drug and device manufacturers and distributors are not Medicare enrolled suppliers and providers; DME and home health suppliers have historically posed a heightened risk of program abuse.

C. Pre-Participation and Participation Waivers

1. Scope

The intent of the pre-participation and participation waivers in this IFC is to establish pathways to protect *bona fide* ACO investment, start-up, operating, and other arrangements that carry out the Shared Savings Program, subject to certain safeguards. We do not believe it is feasible at this time to enumerate in the waiver text specific protected arrangements given the anticipated wide variation in ACO composition, size, resources, and ACO readiness, as well as the goal of the program to foster innovation, adaptability, and variation in furtherance of quality, efficiency, and

economy. We are concerned that, given the limitations of foresight in the context of a new program, a fixed list might be under-inclusive and omit arrangements that are necessary for *bona fide* ACO activities.

The pre-participation waiver covers a broad array of start-up arrangements, as defined in the waiver text and discussed in this section, subject to certain conditions. The participation waiver covers any arrangement that meets its conditions, including start-up arrangements. Many commenters observed that arrangements necessary to develop an ACO may occur both before and after the ACO enrolls in the Shared Savings Program.

Consistent with views expressed by many commenters, both the pre-participation and participation waivers rely, as a threshold matter, on the programmatic requirements of the Shared Savings Program to safeguard Medicare beneficiaries and the Medicare program. The design of the waivers is premised on our expectation that risks of fraud and abuse, such as overutilization, inappropriate utilization, and underutilization, will be mitigated, in the first instance, by the Shared Savings Program design, including, for example, the eligibility requirements, the quality of care and accountability provisions, and the program integrity provisions. In these waivers, we are adding additional safeguards in the form of governance responsibility, transparency, and a documented audit trail. These points are explained in more detail later in this IFC. We are aiming for an approach that will provide ACOs with flexibility, certainty, and latitude for beneficial innovation and variation in connection with the new Shared Savings Program, while also protecting Medicare beneficiaries and the Medicare program from fraud and abuse.

2. Start-Up Arrangements for the Pre-Participation Waiver

We are limiting the pre-participation waiver so that it applies to ''start-up arrangements.'' We define the term start-up arrangements to mean any items, services, facilities, or goods (including non-medical items, services, facilities, or goods) used to create or develop an ACO that are provided by such ACO, ACO participants, or ACO providers or suppliers. We also consider the provision of a subsidy for these items, services, facilities, or goods to be a start-up arrangement. Even though the definition of start-up arrangements is specifically included in the pre-participation waiver, we anticipate that many start-up arrangements will also take place during the participation phase of an ACO's existence; those arrangements can qualify for the participation waiver.

Based on comments received, we recognize that ACOs may have a difficult time anticipating all necessary start-up arrangements that will need waiver protection. While we are not providing a specific list of ACO start-up arrangements in the waiver text, in order to provide additional assurance to developing ACOs, we offer additional guidance in this section. By way of example only, we consider the provision of the folliowng items, services, facilities, and goods to be start-up arrangements:

(1) Infrastructure creation and provision;

(2) Network development and management, including the configuration of a correct ambulatory network and the restructuring of existing providers and suppliers to provide efficient care;

(3) Care coordination mechanisms, including care coordination processes across multiple organizations;

(4) Clinical management systems;

(5) Quality improvement mechanisms including a mechanism to improve patient experience of care;

(6) Creation of governance and management structure;

(7) Care utilization management, including chronic disease management, limiting hospital readmissions, creation of care protocols, and patient education;

(8) Creation of incentives for performance-based payment systems and the transition from fee-for-service payment system to one of shared risk of losses;

(9) Hiring of new staff, including:

a. Care coordinators including nurses, technicians, physicians, and/or non-physician practitioners;

b. Umbrella organization management;

c. Quality leadership;

d. Analytical team;

e. Liaison team;

f. IT support;

g. Financial management;

h. Contracting;

i. Risk management;

(10) Information Technology, including:

a. EHR systems;

b. Electronic health information exchanges that allow for electronic data exchange across multiple platforms;

c. Data reporting systems, including all payer claims data reporting systems;

d. Data analytics, including staff and systems, such as software tools, to perform such analytic functions;

(11) Consultant and other professional support, including:

a. Market analysis for antitrust review;

b. Legal services;

c. Financial and accounting services;

(12) Organization and staff training costs;

(13) Incentives to attract primary care physicians;

(14) Capital investments including loans, capital contributions, grants and withholds.

In order to foster innovation and creativity within ACOs, we recognize that it is impossible to create an exhaustive list of *bona fide* start-up arrangements. We solicit comments on our definition of start-up arrangements and specifically seek input as to whether this definition allows for sufficient innovation in the creation and development of ACOs.

3. Additional Safeguards

The pre-participation waiver and the participation waiver require that the governing body of the ACO make a *bona fide* determination that the arrangement for which waiver protection is sought is reasonably related to the purposes of the Shared Savings Program (as described previously in this IFC) and that the governing body duly authorize the arrangement. (For the ACO participation waiver, the governance, as well as the leadership and management of the ACO, must additionally be in compliance with the applicable rules under the Shared Savings Program final rule at 42 CFR 425.106 and 425.108.) The intent of this requirement is to ensure that any arrangement for which waiver protection is sought falls under the auspices of the ACO; is transparent within the ACO to ACO participants and members of the governing body; and is integral to the ACO's mission and plans to effectuate its role in the Shared Savings Program. This approach interposes the ACO's governing body as an intermediary responsible, in the first instance, for ensuring that all protected arrangements are in furtherance of ACO purposes and are not isolated arrangements furthering the individual financial or business interests of ACO participants or ACO providers/suppliers.

We are not specifying in the waivers how the ACO governing body makes the *bona fide* determination or duly authorizes it. The determination and authorization must be contemporaneously documented. Documentation must include the basis for the determination that the arrangement is reasonably related to the purposes of the Shared Savings Program. We note that the governing body under the Shared Savings Program final rule must have a meaningful

conflicts of interest policy for its members (42 CFR 425.106(d)). We are considering, and soliciting comments on, whether we should specify particular methods by which governing bodies make determinations and authorize arrangements to ensure that ACOs are making *bona fide,* meaningful determinations and authorizations, such that arrangements covered by these waivers are truly furthering the interests of the ACO as a whole in meeting the objectives of the Shared Savings Program. We note that the pre-participation and participation waivers are intended to cover arrangements, among others, in which an ACO might receive funding or in-kind items or services from ACO participants or ACO providers/suppliers and, subject to an independent ACO governing body determination, redistribute them to other ACO participants or ACO providers/suppliers.

An ACO governing body must make a *bona fide* determination that an arrangement is reasonably related to the purposes of the Shared Savings Program. Depending on the waiver, the ACO governing body can make this determination for a wide range of arrangements, including, without limitation, start-up arrangements and ACO operating activities, as well as performance-based compensation (''results-based'' compensation) that is dependent upon achieving quality thresholds or efficiency measures of the Shared Savings Program. Members of the ACO governing body would be well-advised to exercise diligence in ensuring that arrangements are reasonably related to one or more purposes of the Shared Savings Program and to articulate clearly the bases for their determinations and authorizations. Arrangements should be scrutinized with care to ensure that the reasonable relationship between an arrangement and the purposes of the Shared Savings Program can be clearly identified. Not every arrangement will be reasonably related to the purposes of the Shared Savings Program. For example, we do not believe that a per-referral payment (such as, expressly paying a specialist $500 for every referral generated by the specialist or paying a nursing facility staff member $100 for every patient transported to the ACO's hospital) would be reasonably related to the purposes of the Shared Savings Program. However, by way of example only, arrangements with specialists or nursing facility staff members to engage in care coordination for ACO beneficiaries or implement evidence-based protocols could be reasonably related to the purposes of the Shared Savings Program even if the arrangement were to reflect a likelihood that the patient might be referred to or within an ACO. (Importantly, parties remain obligated to comply with the provisions at 42 CFR 425.304(c) that prohibit certain required referrals and cost-shifting.)

Next, the ACO pre-participation and ACO participation waivers require an audit trail of contemporaneous documentation that identifies core characteristics of the arrangement (as listed in the waiver text), is maintained for 10 years, and is available to the Secretary, upon request. We are not specifying in the waivers any particular form of documentation, which can be in paper or electronic form. Notably, the waivers do not require an agreement signed by the parties, although such an agreement is a best documentation practice (and would typically be required for compliance with the Physician Self-Referral Law if a waiver does not apply). The core characteristics of the arrangement should be evident from the documentation with sufficient clarity that the government or another third party reviewing the documentation would be able to ascertain the material terms of the arrangement, including the information listed in item 4 of the pre-participation and participation waivers. Material amendments and modifications to the arrangement should be similarly documented and subject to governing body approval and disclosure. The pre-participation waiver also requires contemporaneous documentation of the diligent steps the parties are taking to develop the ACO. Documentation of the diligent steps must be retained for at least 10 years following that date that the ACO submits its application or the date the ACO submits its statement of reasons for failing to submit an application, as described later in this IFC. As set forth in more detail in the Shared Savings Program final rule, ACOs will be monitored, and we will make periodic requests for documentation of arrangements protected by waivers.

The third main safeguard included in these waivers is a transparency requirement that requires arrangements for which waiver protection is desired to be publicly disclosed. The public disclosure will include the description of the arrangement, but shall not include the financial or economic terms of the arrangement. Our decision to shield financial or economic terms from the public transparency requirement is premised, among other considerations, on potential antitrust implications. (We note that, while not subject to the public transparency requirement, the financial or economic terms of the arrangement are among the matters that must be documented pursuant to the documentation requirements of the waivers and made available to the Secretary upon request.)

The goals of this transparency requirement are three-fold. First, the requirement recognizes that secrecy is necessary for most criminal or fraudulent conduct, and we are declining to protect hidden arrangements. Second, the requirement makes information about waived arrangements more readily available to parties involved with the ACO, regulators, and the public.[7] Third, transparency creates an incentive for ACOs to exercise due diligence when arrangements are being established to ensure that they are waiver compliant and otherwise consistent with the ACO's mission and the duty each member of the governing body owes to make decisions in the interests of the ACO. We do not expect that the disclosure requirements, to be determined by the Secretary in additional guidance, will be onerous.

We expect that ACOs will be able to use the same disclosure process that will apply to disclosure of organizational, quality, and performance information under the Shared Savings Program final rule at 42 CFR 425.308. ACOs using the pre-participation waiver will be able to use a similar disclosure process. We are soliciting comments on additional methods for public disclosure that would be minimally burdensome, as well as the timing for disclosures. In the latter regard, we are considering whether to require disclosures on a rolling basis or on a fixed interval basis. We are also interested in comments addressing whether, in lieu of additional guidance, the disclosure requirements should be set out with greater specificity in the waiver text. Until such time as additional guidance is issued, parties seeking to use the ACO pre-participation or participation waivers should meet the disclosure requirement by posting information identifying the parties to the arrangement and the type of item, service, good, or facility provided under the arrangement on a public Web site belonging to the ACO or an individual or entity forming the ACO, clearly labeled as an arrangement for which waiver protection is sought, within 60 days of the date of the

[7] For example, currently, the government has limited information regarding actual usage of existing safe harbors and exceptions.

arrangement. The Web site must include the name of the ACO (or, if the name of the ACO is not known, the parties forming the ACO) and other identifying information sufficient to allow individuals conducting an electronic internet search using a widely available search engine to readily locate the Web site.

The current design of these waivers applies to arrangements within the ACO (that is, between or among the ACO, its ACO participants, and/or its ACO providers/suppliers), as well as ACO-related arrangements with outside providers and suppliers, such as hospitals, specialists, or post-acute care facilities that might not be part of the ACO but have a role in coordinating and managing care for ACO patients. (The pre-participation waiver excludes drug and device manufacturers, distributors, DME suppliers, and home health suppliers.) All such arrangements must be reasonably related to the purposes of the Shared Savings Program. We are soliciting comments on whether we should modify the waivers to exclude outside party arrangements. We are also seeking comments on whether we should add additional conditions to the participation waiver—such as conditions requiring commercial reasonableness or fair market value or prohibiting exclusivity—that would apply to ACO relationships with outside parties, such as laboratories, equipment or supply companies, drug and device manufacturers, or distributors or purchasing organizations.

The waiver text sets forth specific duration periods for the pre-participation waiver to account for the varying circumstances of ACOs that submit applications that are accepted, submit applications that are rejected, or are unable to submit an application. These specifications are necessary to ensure that the waiver covers only pre-participation arrangements that are closely linked to the Shared Savings Program. The ACO pre-participation waiver covers arrangements undertaken by parties acting with good faith intent to develop an ACO that will participate in the Shared Savings Program starting in a particular year (the ''target year''). For ACOs pursuing target year 2012, the waiver period starts on the date of publication of this IFC. For ACOs pursuing later target years, the waiver period would begin one year preceding an application due date for the target year (the ''selected application date''). Application due dates for these years will be established in later guidance by CMS but, by way of illustration only, if an application due date for target year 2014 were September 1, 2013, the ACO pre-participation waiver period would begin on September 1, 2012.

For an ACO that submits an application and enters into a participation agreement, the pre-participation waiver lasts until the start date of the participation agreement, at which point waiver protection merges seamlessly into the participation waiver, and no further governing body approval is required for arrangements that had been protected by the pre-participation waiver. If the application is denied, the waiver lasts until the date of the denial notice, except that waiver protection extends for 6 months after the date of the denial notice for arrangements that qualified for the waiver before the date of the denial notice. However, no newly created arrangements would be protected during the 6-month period. The waiver period will end for ACOs that fail to submit an application on the final application due date for the target year. ACOs that fail to submit an application by the final application due date must instead submit a statement describing the reasons the ACO failed to submit a timely application.

ACOs that do not submit an application for the selected application date, may apply for an extension of the waiver period. The ACO must submit documentation of its diligent steps, as required under the waiver, and make a showing that it is likely to successfully develop an ACO that would be eligible to participate in the Shared Savings Program by the next available application due date. The Secretary will establish procedures in guidance for the extension process. The determination whether to grant a waiver will be in the sole discretion of the Secretary and will not be reviewable. If an extension is granted, the next available application due date will become the selected application date and the new waiver period will end in accordance with the terms of the pre-participation waiver. An ACO may only use the pre-participation waiver one time. If an extension is not granted, the ACO may no longer rely on the pre-participation waiver.

We are considering whether to further limit the pre-participation waiver by, for example, requiring that parties submit a notice of intent to form an ACO; limiting the waiver for target years after 2013 to ACOs that file applications to enroll in the Shared Savings Program; or curtailing the availability or scope of the pre-participation waiver in future years once ACO structures have become better established.

As described previously in this IFC, for some circumstances, the pre-participation and participation waivers include a 6-month ''tail'' period applicable to protected arrangements in existence at the time the waiver expires or terminates; this ''tail'' period responds to public comments urging that waivers allow for the orderly unwinding or restructuring of arrangements as necessary to ensure continued compliance with the law. The ''tail'' periods protect only arrangements that were in place and otherwise qualified for the waiver at the time the waiver expires or terminates. No ''tail'' period applies to ACOs that CMS terminates. We considered both shorter and longer periods for the ''tail'' period and are soliciting comments on whether we should modify the ''tail'' periods of the waivers.

D. Waiver for Shared Savings Distributions

The intent behind the waiver for shared savings distributions is to protect arrangements created by the distribution of shared savings within an ACO that qualifies for the waiver, as well as arrangements created by the use of shared savings to pay parties outside such an ACO if those payments are reasonably related to the purposes of the Shared Savings Program. This waiver permits shared savings to be distributed or used within the ACO in any form or manner, including ''downstream'' distributions or uses of shared savings funds between or among the ACO, its ACO participants, and its ACO providers/suppliers. This less restrictive waiver for shared savings distributions within the ACO is premised, in part, on recognition that an award of shared savings necessarily reflects the collective achievement by the ACO and its constituent parts of the quality, efficiency, and cost reduction goals of the Shared Savings Program. These goals are consistent with interests protected by the fraud and abuse laws. This waiver also affords ACOs latitude to use shared savings in arrangements with outside parties, provided that the arrangements are reasonably related to the purposes of the Shared Savings Program.

Because the payment of shared savings by CMS to an ACO under the Shared Savings Program may not occur until after expiration of the ACO's 3-year agreement, the waiver applies to distributions and uses of shared savings earned during the term of the agreement, even if distributed subsequently. Similarly, the waiver applies to distributions of shared savings to individuals or entities that were ACO participants and ACO providers/suppliers at the time the shared savings were earned, even if they

are not part of the ACO at the time of the actual distribution.

This waiver is limited to distributions of shared savings; all other arrangements would still need to qualify for one of the other waivers outlined in section IV. of this IFC, fit in an existing exception or safe harbor, or otherwise comply with the laws. This waiver does not protect distributions of shared savings to referring physicians outside the ACO, unless those referring physicians are being compensated (using shared savings) for activities that are reasonably related to the purposes of the Shared Savings Program or were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO.

Some commenters to the Waiver Designs Notice inquired about our proposal, which we are adopting here, to exclude from the shared savings distributions waiver of the Gainsharing CMP situations in which a payment is made knowingly to reduce or limit *medically necessary* services to patients under the physician's direct care. This limitation is consistent with the quality and patient care goals of the Shared Savings Program and must be interpreted in that context. In the context of waivers designed to carry out the Shared Savings Program, distributions of shared savings by an ACO, including downstream arrangements, that incentivize the provision of *alternate and appropriate* medically necessary care consistent with the purposes of the Shared Savings Program (such as the provision of coordinated outpatient care rather than inpatient services or the use of evidence-based protocols for medically necessary care) are protected by this waiver. Knowing payments by a hospital to induce a physician to reduce or limit medically necessary care without providing acceptable alternative medically necessary care (for example, payments to discharge patients without regard to appropriate care transitions or payments to use a drug or device known to be clinically less effective) would not qualify for the waiver. We will interpret ''medical necessity'' consistent with Medicare program rules and accepted standards of practice. We also note that distributions of shared savings payments also may be structured to fit in the other waivers.

Finally, we have not included in this IFC specific waiver protection for the distribution of shared savings earned by an ACO enrolled in the Shared Savings Program under a comparable program sponsored by a commercial health plan. We recognize that ACOs participating in the Shared Savings Program may also receive similar performance-based payments from commercial plans and that those payments may reflect care coordination, quality improvement, and cost-effectiveness activities similar to those promoted by the Shared Savings Program. However, at this time, we are not persuaded that a specific waiver for such payments is necessary to carry out the Shared Savings Program. In addition, we lack an adequate basis for identifying comparable private payer arrangements of ACOs that would be subject to the waiver.

Shared savings or similar performance-based payments received from a commercial plan do not necessarily implicate the fraud and abuse laws; however, in some circumstances, funds are calculated or used in downstream arrangements in ways that influence the referring of, or ordering for, Medicare or other Federal health care program patients. Moreover, we are mindful of the concerns expressed by commenters that some private payer arrangements may be sensitive to the volume of business generated for downstream providers or suppliers and that this characteristic may have implications for the application of the Physician Self-Referral Law.

Although we are not providing a specific waiver for private payer arrangements at this time, we believe avenues exist to provide flexibility for ACOs participating in commercial plans. First, nothing precludes arrangements ''downstream'' of commercial plans (for example, arrangements between hospitals and physician groups) from qualifying for the participation waiver described in section IV. of this IFC. The participation waiver does not turn on the source of the funds for the arrangement. Second, many commercial shared savings arrangements are, or can be, structured to fit within the Physician Self-Referral Law exception for risk-sharing arrangements at 42 CFR 411.357(n) and some may be structured to fit in other exceptions. Some private payer arrangements may also fit in existing Federal anti-kickback statute safe harbors, such as the managed care safe harbors. Finally, as noted previously in this IFC, no waiver or other protection is needed for private payer arrangements that do not implicate the fraud and abuse laws.

We are soliciting comments on our approach to shared savings arrangements with commercial plans, whether our approach is consistent with the needs of ACOs participating in the Shared Savings Program, and whether a specific waiver should apply to shared savings derived from commercial plans comparable to the Shared Savings Program (and, if so, how we should define a comparable program with sufficient precision).

E. Compliance With the Physician Self-Referral Law Waiver

This waiver is intended to ease the compliance burden on providers that might elect to use existing Physician Self-Referral Law exceptions for their ACO arrangements and to reassure those with existing arrangements that already fit in such an exception that they need not undertake a separate legal review under the Federal anti-kickback statute or Gainsharing CMP. This waiver covers arrangements that otherwise implicate the Physician Self-Referral Law, meaning, for example, arrangements involving designated health services entities, as defined at 42 CFR 411.351, and referring physicians, as defined at 42 CFR 411.351. Arrangements that cannot qualify for a Physician Self-Referral Law exception because they are not within the ambit of the law, such as arrangements between facilities that do not involve referring physicians, can qualify for the other waivers described in this IFC. Ordinarily, compliance with an exception to the Physician Self-Referral Law does not operate to immunize conduct under the Federal anti-kickback statute or Gainsharing CMP, and arrangements that comply with the Physician Self-Referral Law are still subject to scrutiny under the Federal anti-kickback statute and Gainsharing CMP. Here, however, we are deviating from this general rule in view of the specific safeguards in the Shared Savings Program, the authority under section 1899(f) of the Act for the Secretary to waive the Federal anti-kickback statute and Gainsharing CMP as necessary to carry out the Shared Savings Program, and our desire to minimize burdens on entities establishing or operating ACOs under the Shared Savings Program.

This waiver is structured to apply until the participation agreement, including any renewals thereof, expires or terminates. We are considering whether it might be necessary for this particular waiver to continue for some period of time, perhaps in the range of 3 to 12 months, after expiration or termination of an ACO's participation agreement. We are soliciting comments on this consideration.

F. Waiver for Patient Incentives

As described in section III of this IFC, several public commenters indicated that, in carrying out the quality and cost reduction goals of the Shared Savings

Program, ACOs would need to engage patients in better managing their own health care, including obtaining preventive care and complying with treatment plans for chronic conditions. Therefore, in light of this need, this IFC promulgates a waiver of the Federal anti-kickback statute and Beneficiary Inducements CMP to address arrangements pursuant to which ACOs, ACO participants, and ACO providers/suppliers provide beneficiaries with free or below-fair market value items and services that advance the goals of preventive care, adherence to treatment, drug, or follow-up care regimes, or management of a chronic disease or condition. This waiver will help ACOs foster patient engagement in improving quality and lowering costs for Medicare and beneficiaries by removing any perceived obstacles presented by the Beneficiary Inducements CMP or Federal anti-kickback statute. Beneficiary compliance with care management programs is critical to the success of ACOs, and ACOs should have the flexibility to develop incentives to that end, with certain safeguards. In the interest of promoting broad improvement in care coordination and quality for all beneficiaries and in light of the mechanisms for assigning beneficiaries under the Shared Savings Program final rule, at this time we are not limiting this waiver to beneficiaries assigned to the ACO. However, we are soliciting comments on whether the waiver could and should be limited to beneficiaries assigned to the ACO.

In order to balance the goal of beneficiary compliance with care management programs against the risk that ACOs could use extravagant incentives to steer beneficiaries, we are requiring that there be a reasonable connection between the incentives and the medical care of the individual. By way of example, the waiver would cover blood pressure cuffs for hypertensive patients, but not beauty products or theatre tickets. The waiver will protect incentives that are in-kind items or services, but not financial incentives, such as waiving or reducing patient cost sharing amounts (that is, copayment or deductible), which we believe are prone to greater abuse. We note that the Shared Savings Program at 42 CFR 425.304(a)(1) itself prohibits ACOs, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities from providing gifts or other remuneration to beneficiaries as inducements for receiving items or services from, or remaining in, an ACO or with providers in a particular ACO or receiving items or services from ACO participants or ACO providers/suppliers; clearly then, such incentives are not covered by this waiver. As further provided in the Shared Savings Program final rule, 42 CFR 425.304(a)(2) permits certain incentives that are consistent with the requirements of 42 CFR 425.304(a)(1) and the terms of this waiver. This waiver applies only to the application of the Federal anti-kickback statute and Gainsharing CMP; nothing in this waiver supplants any applicable requirement in the Shared Savings Program final rule or other Medicare payment or coverage rules. We are not defining preventive care for purposes of this waiver in order to provide some flexibility as care models develop in the Shared Savings Program and evidence-based care programs are adopted by ACOs. However, we are soliciting comments on whether we should provide a specific definition.

This waiver does not protect the provision of free or below fair market value items or services by manufacturers or other vendors to beneficiaries, the ACO, ACO participants, or ACO providers/suppliers. The patient incentives waiver would cover ACOs, ACO participants, and ACO provider/suppliers that give beneficiaries items or services that they have received from manufacturers at discounted rates. However, the waiver would not cover the discount arrangement (or any arrangement for free items and services) between the manufacturer and the ACO, ACO participant, or ACO provider/supplier.

This waiver applies during the term of the ACO's participation agreement. However, to ensure continuity of care for beneficiaries if an ACO's agreement terminates or is not renewed, we are providing that a beneficiary may keep any items received during the term of the ACO's participation agreement pursuant to the waiver and may continue to receive any service initiated during the term of the ACO's participation agreement pursuant to the waiver, if the service was in progress when the participation agreement terminated. Illustrative examples could include, but would not be limited to, a post-surgical patient receiving free home visits to coordinate in-home care during the recovery period, a hypertensive patient using home telehealth monitoring of blood pressure, or a beneficiary halfway through a normal course of smoking cessation treatment. Nothing precludes ACOs, ACO participants, or ACO providers/suppliers from offering patient incentives to promote their clinical care if the incentives fit in an applicable safe harbor or exception or do not otherwise violate the Federal anti-kickback statute and Beneficiary Inducements CMP. For example, many such arrangements may fit in the exception to the Beneficiary Inducements CMP for incentives given to individuals to promote the delivery of preventive care at section 1128A(i)(6)(D) of the Act; 42 CFR 1003.101.

G. Application of Waivers to Innovation Center Demonstrations

Several commenters inquired about the application of these waivers to ACO demonstration programs sponsored by the Innovation Center, including application to the Pioneer ACOs. The waivers in this IFC are promulgated under section 1899(f) of the Act and, as set forth in the statute, are limited to the Shared Savings Program. Section 3021 of the Affordable Care Act includes a similar waiver authority that may be exercised for Innovation Center demonstration programs, including the Pioneer ACOs. We will address the exercise of that waiver authority in guidance relevant to those programs. As noted previously in this IFC, the waivers in this IFC will apply to ACOs participating in the Advance Payment Initiative because those ACOs also participate in the Shared Savings Program.

H. Additional Policy Considerations and Solicitation of Comments

The waivers adopted in this IFC take into account the specific redesigned care delivery incentives and processes of the Shared Savings Program, as well as the obligation of ACOs, ACO participants, and ACO providers/suppliers to comply with the Shared Savings Program rules, including requirements addressing governance, management, leadership, transparency, data, quality, performance, compliance, patient freedom of choice, and others. Moreover, the Shared Savings Program requires ACOs and their constituent parts to demonstrate a meaningful commitment to the Shared Savings Program. The waivers emanate from the expectation that ACOs and their constituent parts will act in compliance with program rules and in the best interests of patients and the Medicare program, including the Shared Savings Program. The waivers are an attempt to promote a high degree of certainty, innovation, and variation in the development of ACOs to improve quality of care, as well as economy and efficiency in the Medicare program.

The government's enforcement experience reflects that, to varying degrees, all Federal health care

programs are susceptible to fraud and abuse. These waivers should not be read to reflect any diminution of our commitment to protect programs and beneficiaries from harms associated with kickbacks and referral payments, including overutilization, increased costs, and substandard or poor quality care. DHHS will monitor ACOs and the Shared Savings Program as a whole for fraud or abuse, such as billing for medically unnecessary or upcoded services, submitting false or fraudulent data, or providing worthless or substandard care. If these or other problematic practices are found, the government has a number of tools to address the problem. In appropriate cases, we will use these tools to protect the interests of beneficiaries and the Medicare program.

We intend to closely monitor ACOs entering the program in 2012 through June 2013. We plan to narrow the waivers established in this IFC unless the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements.[8] In particular, if we find that undesirable effects (for example, aberrant patterns of utilization) have occurred because of the waivers, we will revise this IFC to address those problems by narrowing the waivers. Modifications to the waivers would apply to future ACO applicants beyond July 2013 and to ACOs that renew their participation agreements. There are several options for modifying the waivers to address problems that may arise. Should we identify specific areas of fraud and abuse resulting from arrangements covered by the waivers, we could modify the waivers to add or substitute conditions tailored to address specific abusive conduct. We could also limit ACO arrangements involving referral sources to those that are fair market value or commercially reasonable or involve services performed by the referral source. This approach could include exceptions for specified arrangements, including, for example, a limited amount of start-up costs, information technology, medical training, care coordination, or goods or services provided to referral sources' patients. In addition, we could preclude waiver protection for arrangements that involve individuals or entities that are not part of the ACO or we could include a requirement that ACOs submit reports to the Secretary regarding their arrangements. We solicit comments in this rulemaking regarding these narrow waivers. We also seek comments on additional categories of arrangements that would require protection through a waiver and how the categories should be defined and what limits, if any, should be imposed.

We are establishing waivers under section 1899(f) of the Act to foster the success of the Shared Savings Program, the purposes of which are to promote accountability for a Medicare patient population, manage and coordinate care for Medicare fee-for-service beneficiaries, and encourage redesigned care processes to improve quality. Our goal is to balance effectively the need for ACO certainty, innovation, and flexibility in the Shared Savings Program with protections for beneficiaries and the Medicare program. It is our expectation that the waivers promulgated in this IFC will be used for their intended purposes to carry out the Shared Savings Program. We will closely monitor the program and ACO conduct. We plan to narrow the waivers in this IFC unless information gathered through monitoring or other means suggests that the waivers in this IFC are adequately protecting the Medicare program and beneficiaries from the types of harms associated with referral payments or payments to reduce or limit services. We are soliciting comment on the specific narrowed waivers described above.

VI. Procedural Rulemaking Matters

A. Waiver of Proposed Rulemaking

Under the Administrative Procedures Act (5 U.S.C. 553(b)), an agency may waive publication of a notice of proposed rulemaking if the agency finds good cause that the notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and the agency incorporates into the rule a statement of, and the reasons for, such a finding. For the reasons discussed later in this IFC, we find that it would be unnecessary, impracticable, and contrary to the public interest to delay the issuance of the waivers granted in this IFC until after a public notice and comment process is completed.

In section 1899(a)(1) of the Act, Congress expressly required the Secretary to establish the Shared Savings Program no later than January 1, 2012. As noted earlier in this document, Congress authorized the Secretary to waive the requirements of sections 1128A and 1128B and title XVIII of the Act as may be necessary to carry out the Shared Savings Program. The Physician Self-Referral Law, the Federal anti-kickback statute, the Gainsharing CMP, and the Beneficiary Inducements CMP, discussed elsewhere in this IFC, are important tools to protect patients and the Federal health care programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other harms.

We recognize, however, that these laws may prohibit or significantly restrict certain arrangements necessary for the formation of ACOs under the Shared Savings Program. Moreover, the significant financial consequences of noncompliance with these laws (and the potential False Claims Act liability) will likely have a chilling effect on the willingness of health care providers to participate in the Shared Savings Program at its inception if these provisions are not waived. Delaying the issuance of final waivers would effectively delay the program's establishment well beyond the statutory deadline and delay the savings that the program is expected to achieve at a time when reducing the Federal budget is a critical priority. For this reason, it is impracticable and contrary to the public interest to issue the waivers of these laws only after additional months of notice and comment rulemaking. In addition, the failure to simultaneously issue the Shared Savings Program final rule and the waivers promulgated in this IFC would impede development of the innovative integrated-care models envisioned by the Shared Savings Program and deny Medicare beneficiaries the opportunity to benefit from a new approach to the delivery of health care that is designed to result in better care for individuals, and better health for populations, as well as lower growth in expenditures. Neither result is in the public interest.

We also believe it is unnecessary to offer what would essentially be a second opportunity to comment on these waivers and thereby delay finalizing waivers that will permit arrangements that are essential to the implementation success of the Shared Savings Program. On April 7, 2011, we published the Waiver Designs Notice. That notice solicited public comment regarding possible waivers of the application of the Physician Self-Referral Law, the Federal anti-kickback statute, and certain civil monetary penalties law provisions to specified arrangements involving ACOs under the Shared Savings Program. This IFC responds to public comments received on that notice. Moreover, the public will nonetheless receive an opportunity to

[8] As described in section III of this IFC, several commenters suggested that we establish either narrow waivers or none at all; some commenters suggested specific additional conditions for waivers that we have not adopted,

comment on the specific policy choices made in this rule because we are publishing it as an IFC. In accordance with section 1871(a)(3) of the Act, we are obligated to consider comments and publish a final rule addressing those comments within 3 years.

Finally, we note that in the absence of final program rules, it would have been impracticable, if not impossible, to issue a comprehensive notice of proposed rulemaking on fraud and abuse waivers that would adequately support the Shared Savings Program. As we stated in the Waiver Designs Notice, the requirements of the final program rules regarding the structure and operations of ACOs under the Shared Savings Program would affect the scope of the waivers. For this reason, we indicated in the Waiver Designs Notice that, in drafting the final waivers, we would consider comments received on the Shared Savings Program proposed rule and the terms of the final rule. We have, in fact, done so in creating the waivers set forth in this IFC. Simply put, the proposal of definitive waivers was not possible until now.

For the reasons noted previously in this IFC, we believe that it would be impracticable and contrary to the public interest to delay the issuance of final waivers until after the receipt and analysis of additional public comments. Therefore, we find good cause to waive prior notice and comment procedure and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

B. Waiver of Delayed Effective Date

Section 1871(e)(1) of the Act generally requires that a final rule become effective at least 30 days after the issuance or publication of the rule. This requirement for a 30-day delayed effective date can be waived, however, if the Secretary finds that waiver of the 30-day period is necessary to comply with statutory requirements or that the requirement for a delayed effective date is contrary to the public interest.

As indicated previously in this IFC, section 1899 of the Act expressly requires the Secretary to establish the Shared Savings Program no later than January 1, 2012. Prospective ACOs that wish to participate in the Medicare Shared Savings Program in 2012 must submit an application and enter into a participation agreement with CMS that commences on April 1, 2012 or July 1, 2012. We expect that the application deadline for participation agreements with an April 1, 2012 start date will be no later than January 1, 2012. Based on the comments submitted in response to the Waiver Designs Notice, we believe that a significant number of ACO applicants for the Shared Savings Program would forego applying to participate in the Shared Savings Program until final waivers have become effective and sufficient time has elapsed to allow the applicants to use the waivers in a manner that would support their applications and the purposes of the program. We believe that a 30-day delay in the effective date for the final waivers could jeopardize an ACO's ability to submit timely an application for a participation agreement commencing in 2012. For this reason, we find that waiver of the requirement for a delayed effective date is necessary to comply with a statutory requirement.

We also find that a delayed effective date would be contrary to the public interest. The success of the Shared Savings Program depends in no small part on allowing prospective ACOs sufficient time to prepare for application to the program and to build the innovative, cost effective, integrated healthcare delivery models envisioned by the Shared Savings Program. Delaying the effective date of this rule would be contrary to the public interest because it would effectively delay the timely implementation of the Shared Savings Program, thereby denying the public the benefits of a new approach to health care delivery that is designed to result in better care for individuals, and better health for populations, as well as lower growth in expenditures.

In addition, we find that it is not in the public interest to delay the effective date of a rule that does not impose a burden upon anyone. This IFC waives the aforementioned authorities, provided certain conditions are met. In short, the rule rescinds, rather than adds, restrictions with which prospective ACOs, their prospective ACO participants, and their prospective ACO providers/suppliers must comply. Accordingly, a delay in the effective date of this IFC is unnecessary and contrary to the public interest.

VII. Collection of Information Requirements

While this IFC does include information collection and record keeping requirements, section 3022 of the Affordable Care Act provides that Chapter 35 of title 44, United States Code, shall not apply to the Shared Savings Program. Consequently, the information collection requirements contained in this IFC need not be reviewed by the Office of Management and Budget.

VIII. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $7.0 million to $34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this IFC will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this IFC will not have a significant impact on the

operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately $136 million. This rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

For the reasons set forth in this preamble, the Centers for Medicare & Medicaid Services and the Office of the Inspector General are implementing this interim final rule under the authority of section 1899 of the Act.

Authority: Section 1899(f) of the Act.

Dated: October 6, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 19, 2011.

Daniel R. Levinson,

Inspector General, Department of Health and Human Services.

Approved: October 19, 2011.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2011–27460 Filed 10–20–11; 11:15 am]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

Medicare Program; Advanced Payment Model; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5505–N]

Medicare Program; Advanced Payment Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the testing of the Advance Payment Model for certain accountable care organizations participating in the Medicare Shared Savings Program scheduled to begin in 2012, and provides information about the model and application process.

DATES: *Application Submission Deadline:* Applicants must submit both the application for the Medicare Shared Savings Program and the application for the Advance Payment Model by the Shared Savings Program deadline(s). Additional information is available on the Innovation Center Web site at *http://www.innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/.*

FOR FURTHER INFORMATION CONTACT: Questions regarding the Advance Payment Model or the application process should be sent to *advpayaco@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Centers for Medicare & Medicaid Services (CMS) is committed to achieving the three-part aim of better health, better health care, and reduced expenditures through continuous improvement for Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries. One potential mechanism for achieving this goal is for CMS to partner with groups of health care providers of services and suppliers with a mechanism for shared governance that have formed an Accountable Care Organization (ACO) through which they work together to coordinate care for a specified group of patients. We will pursue such partnerships through complementary efforts, including the Medicare Shared Savings Program and initiatives undertaken by the Center for Medicare and Medicaid Innovation (Innovation Center).

The Advance Payment Model is an Innovation Center initiative designed for participants in the Medicare Shared Savings Program in need of prepayment of expected shared savings to build their capacity to provide high quality, coordinated care and generate cost savings. The Advance Payment Model will test whether and how pre-paying a portion of future shared savings could increase participation in the Medicare Shared Savings Program, and whether advance payments will increase the amount of and speed at which ACOs can effectively coordinate care to generate Medicare savings. More information about the initiative, including instructions on how to apply, is available on the Innovation Center Web site at *http://www.innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment.*

II. Provisions of the Notice

Consistent with its authority under section 1115A of the Social Security Act (the Act) to test innovative payment and service delivery models that reduce spending under Medicare, Medicaid, or CHIP, while preserving or enhancing the quality of care, the Innovation Center aims to achieve the following goals through implementation of the Advance Payment Model:

- Test whether advance payments will increase the amount of and speed at which ACOs in the Medicare Shared Savings Program can generate Medicare savings.
- Test whether and how pre-paying a portion of future shared saving could increase participation in the Medicare Shared Savings Program.

The Advance Payment model is intended for organizations in need of additional access to capital to make investments necessary for coordinating care, including rural and physician-led ACOs. Not every participant in the Shared Savings Program will be eligible to receive an advance payment. Additional information about eligibility requirements is available in the solicitation available on the Innovation Center Web site—*http://www.innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/.*

Selected ACOs will receive three types of payments: (1) An upfront, fixed payment; (2) an upfront, variable payment; and (3) a monthly payment of varying amount depending on the number of Medicare beneficiaries historically attributed to the ACO. Payments to selected ACOs will begin at the start of the first performance year and end at the settlement scheduled at the end of that performance year in June 2014. In most cases, advance payments will be recouped through the ACO's earned shared savings. An ACO that does not complete the full agreement period and does not earn shared savings will be required to repay the advance payment.

Organizations must be accepted for participation in the Medicare Shared Savings Program before they can be considered for the Advance Payment Model. For more information on the Medicare Shared Savings Program see the Medicare Shared Savings Program final rule published elsewhere in this issue of the **Federal Register.** Additional information about the initiative and the application process is available on the Innovation Center Web site at *http://www.innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/.*

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act provides that the requirements of the Paperwork Reduction Act of 1995 do not apply to the testing and evaluation or expansion of new payment and service delivery models under section 1115A of the Act.

Authority: Section 1115A of the Social Security Act.

Dated: October 6, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–27458 Filed 10–20–11; 11:15 am]

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Part V

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Part 1

Federal Acquisition Regulation; Federal Acquisition Circular 2005–54; Introduction; Interim and Final Rules and Notice

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket FAR 2011–0076; Sequence 6]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–54; Introduction

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of final and interim rules.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rules agreed to by DoD, GSA, and NASA in this Federal Acquisition Circular (FAC) 2005–54. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC. The FAC, including the SECG, is available via the Internet at *http://www.regulations.gov.*

DATES: For effective dates and comment dates, see separate documents, which follow.

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below in relation to each FAR case. Please cite FAC 2005–54 and the specific FAR case numbers. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755.

LIST OF RULES IN FAC 2005–54

Item	Subject	FAR case	Analyst
I	Notification of Employee Rights Under the National Labor Relations Act	2010–006	McFadden.
II	Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions	2008–025	Robinson.
III	Small Disadvantaged Business Program Self-Certification	2009–019	Morgan.
IV	Certification Requirement and Procurement Prohibition Relating to Iran Sanctions	2010–012	Davis.
V	Representation Regarding Export of Sensitive Technology to Iran (Interim)	2010–018	Davis.
VI	Set-Asides for Small Business (Interim)	2011–024	Morgan.
VII	Sudan Waiver Process	2009–041	Davis.
VIII	Successor Entities to the Netherlands Antilles	2011–014	Davis.
IX	Labor Relations Costs	2009–006	Chambers.
X	Technical Amendments.		

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these FAR cases, refer to the specific item numbers and subject set forth in the documents following these item summaries. FAC 2005–54 amends the FAR as specified below:

Item I—Notification of Employee Rights Under the National Labor Relations Act (FAR Case 2010–006)

This rule adopts as final, without change, the interim rule that published in the **Federal Register** at 75 FR 77723 on December 13, 2010, implementing Executive Order (E.O.) 13496, Notification of Employee Rights Under Federal Labor Laws, as implemented by the Department of Labor (DOL). The E.O. requires contractors to display a notice for employees of their rights under Federal labor laws, and the DOL has determined that the notice shall include employee rights under the National Labor Relations Act.

Item II—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions (FAR Case 2008–025)

This final rule amends the FAR to address personal conflicts of interest by employees of Government contractors, as required by section 841(a) of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417) (now codified at 41 U.S.C. 2303). This rule requires the contractor to take the steps necessary to identify and prevent personal conflicts of interest for employees that perform acquisition functions closely associated with inherently governmental functions. The contracting officer shall consult with agency legal counsel for advice and recommendations on a course of action when the contractor reports a personal conflict of interest violation by a covered employee or when the contractor violates the clause requirements.

Item III—Small Disadvantaged Business Program Self-Certification (FAR Case 2009–019)

This rule adopts as final, without change, an interim rule that implements revisions made by the Small Business Administration (SBA) in its Small Disadvantaged Business (SDB) regulations. The FAR interim rule was published in the **Federal Register** at 75 FR 77737 on December 13, 2010, to allow SDBs to self-represent their SDB status to prime contractors in good faith when seeking Federal subcontracting opportunities. This FAR revision removed an administrative burden for SDB subcontractors to obtain SBA certification, as well as prime contractors, who were required to confirm that SDB subcontractors had obtained SBA certification.

Item IV—Certification Requirement and Procurement Prohibition Relating to Iran Sanctions (FAR Case 2010–012)

This rule adopts as final, with minor changes, an interim rule. The interim rule implemented sections 102 and 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. Section 102 requires certification that each offeror, and any person owned or controlled by the offeror, does not engage in any activity for which sanctions may be imposed under section 5 of the Iran Sanctions Act of 1996. Section 106 imposes a procurement prohibition relating to contracts with persons that export certain sensitive technology to Iran. This rule will have little effect on domestic small business concerns, because such dealings with Iran are already generally prohibited under U.S. law.

Item V—Representation Regarding Export of Sensitive Technology to Iran (FAR Case 2010–018) (Interim)

This interim rule amends the FAR to include additional requirements to implement section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, Public Law 111–195. To enhance

enforcement of section 106, the FAR will require each offeror to complete a representation that the offeror does not export certain sensitive technology to the government of Iran or any entities or individuals owned or controlled by or acting on behalf or at the direction of the government of Iran. This rule will have little effect on domestic small business concerns, because such dealings with Iran are already generally prohibited in the United States.

Item VI—Set-Asides for Small Business (FAR Case 2011–024) (Interim)

This interim rule amends the FAR to implement section 1331 of Pub. L. 111–240, the Small Business Jobs Act of 2010, providing agencies with the legal authority to set aside or reserve multiple-award contracts and orders.

Specifically, section 1331 authorizes agencies to (1) Set aside part or parts of multiple-award contracts; (2) set aside orders placed against multiple-award contracts; and (3) reserve one or more multiple-award contracts for small business concerns that are awarded using full and open competition.

The interim rule gives agencies an additional procurement tool to increase opportunities for small businesses to compete in the Federal marketplace.

Item VII—Sudan Waiver Process (FAR Case 2009–041)

This final rule amends the FAR to revise section 25.702, Prohibition on contracting with entities that conduct restricted business operations in Sudan. The rule adds specific criteria, including foreign policy aspects, that an agency must address when applying to the President or his appointed designee for a waiver of the prohibition on awarding a contract to a contractor that conducts restricted business operations in Sudan, in accordance with the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110–174). The rule also describes the consultation process that will be used by the Office of Federal Procurement Policy in support of the waiver review. The rule does not impose any requirements on small businesses.

Item VIII—Successor Entities to the Netherlands Antilles (FAR Case 2011–014)

This final rule amends FAR parts 25 and 52 to revise the definitions of ''Caribbean Basin country'' and ''designated country'' due to the change in status of the islands that comprised the Netherlands Antilles. On October 10, 2010, the Netherlands Antilles dissolved into five separate successor entities. The rule does not impose any requirements on small businesses.

Item IX—Labor Relations Costs (FAR Case 2009–006)

This final rule amends the FAR to implement Executive Order (E.O.) 13494, Economy in Government Contracting, issued on January 30, 2009, and amended on October 30, 2009. This E.O. treats as unallowable the costs of any activities undertaken to persuade employees, whether employees of the recipient of Federal disbursements or of any other entity, to exercise or not to exercise, or concerning the manner of exercising, the right to organize and bargain collectively through representatives of the employee's own choosing.

Item X—Technical Amendments

Editorial changes are made at FAR 1.106, 4.604, and 8.501.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Federal Acquisition Circular (FAC) 2005–54 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator for the National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2005–54 is effective November 2, 2011, except for Items II, VII, and IX which are effective December 2, 2011.

Dated: October 20, 2011.

Richard Ginman,

Director, Defense Procurement and Acquisition Policy.

Dated: October 21, 2011.

Mindy S. Connolly, CPCM,

Chief Acquisition Officer U.S. General Services Administration.

Dated: October 20, 2011.

Leigh Pomponio,

Procurement Analyst, National Aeronautics and Space Administration.

[FR Doc. 2011–27778 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 2, 22, and 52

[FAC 2005–54; FAR Case 2010–006; Item I; Docket 2010–0106; Sequence 1]

RIN 9000–AL76

Federal Acquisition Regulation; Notification of Employee Rights Under the National Labor Relations Act

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA have adopted as final, without change, an interim rule amending the Federal Acquisition Regulation (FAR) to implement the Department of Labor (DOL) regulations that implemented the Executive Order (E.O.), Notification of Employee Rights Under Federal Labor Laws.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Clare McFadden, Procurement Analyst, at (202) 501–0044, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2010–006.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published an interim rule in the **Federal Register** at 75 FR 77723 on December 13, 2010, to implement E.O. 13496, Notification of Employee Rights Under Federal Labor Laws, as implemented by the DOL. The E.O. requires contractors to display a notice for employees of their rights under Federal labor laws, and the DOL has determined that the notice shall include employee rights under the National Labor Relations Act. Public comments were due on or before February 11, 2011. Three respondents submitted nine comments on the interim rule.

II. Discussion and Analysis of the Public Comments

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the

development of the final rule. A discussion of the comments and the changes made to the rule as the result of those comments are provided as follows:

A. General Comments

Comment: One respondent stated support for the interim rule and urged that a final rule be adopted as quickly as possible. The respondent noted that the need to facilitate timely implementation of the E.O. constitutes a compelling reason for issuance of an interim rule.

Response: An interim rule was published to facilitate the implementation of the E.O., and this rule is being converted to a final rule, herein.

Comment: Another respondent referred to the interim rule as an ''invasion of privacy,'' comparing this to a requirement to post the Constitution, Bill of Rights, or tax laws.

Response: The comment is noted but does not warrant a change to the FAR. The FAR is implementing a requirement of the E.O. and the DOL regulations. The E.O. is premised on the policy that it is beneficial to the Government to rely on contractors whose employees are informed of their rights under Federal labor laws.

B. Comment on the FAR Text

Comment: A respondent recommended deleting the phrase at FAR 22.1605(a) ''including acquisitions for commercial items and commercially available off-the-shelf items.''

Response: DOL is the regulatory agency with primary responsibility for implementation of the E.O. The DOL final rule does not provide an exception for the acquisition of commercial items, including commercially available off-the-shelf items. Therefore, the FAR rule must be consistent with the DOL rule in its application to commercial items.

C. Comments on FAR Clause 52.212–5

Comment: A respondent noted that the clause should be listed as subsection (28), not (27), at FAR 52.212–5(b).

Response: The correction to the number has been made.

Comment: A respondent requested the deletion of the phrase ''flow down required in accordance with paragraph (f) of FAR clause 52.222–40'' at 52.212–5(e)(1)(vii) and 52.212–5 Alternate II(e)(1)(ii)(G).

Response: As noted earlier (see response at section II.B. above), the FAR is implementing the DOL final rule. The DOL rule very specifically set the requirements for flow down of the requirement for posting the National Labor Relations Act poster to subcontracts at all tiers that exceed $10,000.

D. Comments on FAR Clause 52.222–40

Comment: A respondent requested clarification of the clause at FAR 52.222–40 so that it is obvious whether contractors and subcontractors are required to use the DOL poster or have permission to create a company-specific poster, as long as the latter meets the DOL's size, form, and content requirements.

Response: The language at FAR 22.1602(a) and at FAR 52.222–40(a) indicates that an employer does not have to use the DOL poster but can use its own poster as long as it includes the requisite information—the DOL's size, form, and content requirements.

Comment: A respondent suggested revising FAR 52.222–40(a)(1) to read as follows:

> ''Physical posting of the employee notice shall be in conspicuous places in and about the plants and offices of contractors and subcontractors, in the languages employees speak, so that the notice is prominent and readily seen by employees who are covered by the National Labor Relations Act and engage in activities related to the performance of the contract.''

The respondent stated that the following language at FAR 52.222–40(a), regarding where the poster must be posted and what languages must be used in the poster, is redundant:

> ''* * * in conspicuous places in and about its plants and offices where employees covered by the National Labor Relations Act engage in activities relating to the performance of the contract, including all places where notices to employees are customarily posted both physically and electronically, in the languages employees speak, in accordance with 29 CFR 471.2 (d) and (f).''

Response: DOL's final rule was published in the **Federal Register** at 75 FR 28368 on May 20, 2010, and it incorporated that agency's requirements for implementation of the E.O. at 29 CFR 471. The FAR is being updated to incorporate the DOL requirements into corresponding sections of the FAR. Since DOL has the primary responsibility for implementation of the E.O., it is not appropriate to make any substantive change in the FAR clause.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule implements the Department of Labor's (DOL) final rule that implemented E.O. 13496, Notification of Employee Rights Under Federal Labor Laws. This E.O. requires contractors to display a notice to employees of their rights under Federal labor laws, and the DOL has determined that the notice shall include employee rights under the National Labor Relations Act. DOL certified in its final rule (published in the **Federal Register** at 75 FR 28368 on May 20, 2010, with an effective date of June 21, 2010) that its rule would not have a significant economic impact on a substantial number of small entities. After reviewing DOL's certification, DoD, GSA, and NASA concurred that no regulatory flexibility analysis was needed. DoD, GSA, and NASA did not receive comments from small entities in response to the invitation to do so included in the FAR interim rule that published in the **Federal Register** at 75 FR 77723 on December 13, 2010.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 1, 2, 22, and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Interim Rule Adopted as Final Without Change

Accordingly, the interim rule amending 48 CFR parts 1, 2, 22, and 52, which was published in the **Federal Register** at 75 FR 77723 on December 13, 2010, is adopted as a final rule without change.

[FR Doc. 2011–27779 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 3, 12, and 52

[FAC 2005–54; FAR Case 2008–025; Item II; Docket 2009–0039, Sequence 1]

RIN 9000–AL46

Federal Acquisition Regulation; Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to address personal conflicts of interest by employees of Government contractors as required by statute.

DATES: *Effective Date:* December 2, 2011.

Applicability Date: Except for contracts, including task or delivery orders, for the acquisition of commercial items, this rule applies to—

- Contracts issued on or after the effective date of this rule; and
- Task or delivery orders awarded on or after the effective date of the rule, regardless of whether the contracts, pursuant to which such task or delivery orders are awarded, were awarded before, on, or after the effective date of this rule.

Contracting officers shall modify, on a bilateral basis, in accordance with FAR 1.108(d)(3), existing task- or delivery-order contracts to include the FAR clause for future orders. In the event that a contractor refuses to accept such a modification, the contractor will not be eligible to receive further orders under such contract.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Robinson, Procurement Analyst, at (202) 501–2658, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2008–025.

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I. Background

Section 841(a) of the Duncan Hunter National Defense Authorization Act (NDAA) for Fiscal Year 2009 (Pub. L. 110–417), now codified at 41 U.S.C. 2303, requires that the Office of Federal Procurement Policy (OFPP) develop policy to prevent personal conflicts of interest by contractor employees performing acquisition functions closely associated with inherently governmental functions for, or on behalf of, a Federal agency or department. The NDAA also requires OFPP to develop a personal conflicts-of-interest clause for inclusion in solicitations, contracts, task orders, and delivery orders. To address the requirements of section 841(a) in the most effective manner possible, OFPP collaborated with DoD, GSA, and NASA on this case to develop regulatory guidance, including a new subpart under FAR part 3, and a new clause for contracting officers to use in contracts to prevent personal conflicts of interest for contractor employees performing acquisition functions for, or on behalf of, a Federal agency or department.

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 74 FR 58584 on November 13, 2009. OFPP and DoD, GSA, and NASA proposed a policy that would require each contractor that has employees performing acquisition functions closely associated with inherently governmental functions to identify and prevent personal conflicts of interest for such employees. In addition, such contractors would be required to prohibit covered employees with access to non-public Government information from using it for personal gain. The proposed rule also made contractors responsible for—

- Having procedures to screen for potential personal conflicts of interest;
- Informing covered employees of their obligations with regard to these policies;
- Maintaining effective oversight to verify compliance;
- Reporting any personal conflicts-of-interest violations to the contracting officer; and
- Taking appropriate disciplinary action with employees who fail to comply with these policies.

Comments were received from 19 respondents; these are analyzed in the following sections.

II. Discussion and Analysis of the Public Comments

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) have reviewed the public comments in development of the final rule. As a result of this review, the Councils have incorporated some changes in the final rule, including the following more significant changes:

- Revised the definition of ''covered employee'' to clarify applicability to subcontracts.
- Revised the contracting officer procedures at FAR 3.1103(a)(1) and (a)(3), and (b)(3).
- Revised the discussion of violations at FAR 3.1105.
- Added a new paragraph FAR 3.1106(c) to provide additional clarification on use of FAR clause 52.203–16 when contracting with a self-employed individual.
- Amended 12.503(a) to clarify that the statute does not apply to contracts for the acquisition of commercial items.
- Revised the clause at FAR 52.203–16 by—
  - Clarifying the financial disclosure requirements in paragraph (b)(1), including deletion of the requirement for an annual update of the disclosure statement;
  - Adding to the list of possible personal conflicts-of-interest violations in (b)(6);
  - Removing the list of remedies in paragraph (d); and
  - Clarifying the clause flowdown.

A. General

Comments: Several respondents commented on general elements of the proposed coverage. Some supported implementing the proposed coverage, while others stated that the proposed

rule is not necessary, is duplicative, or should not apply to certain organizations, such as DoD-sponsored Federally Funded Research and Development Centers (FFRDCs).

Response: The Councils concur with those respondents who support the rule. In addition to implementing a statutory requirement, contained in section 841(a) of the NDAA for FY 2009, the proposed coverage fills a current gap in the FAR, which contains very little coverage on preventing personal conflicts of interest for contractor employees. The proposed coverage is not duplicative of current organizational conflicts-of-interest coverage, or the current coverage in FAR subpart 3.10 regarding the contractor Code of Business Ethics, and should not be limited to exclude FFRDCs.

Comments: Several respondents addressed the issue of whether personal conflicts-of-interest coverage for contractor employees should mirror the ethics rules that apply to Government employees.

Response: The Councils recognize that most of the ethics statutes that apply to Government employees are not applicable to contractor employees. The differences between the coverage here and the ethics standard applicable to Federal employees reflect those differences in the underlying statutes.

B. Definitions

1. Acquisition Function Closely Associated With Inherently Governmental Functions

Comments: Some respondents suggested that the definition be limited, either by explicitly restricting it to actions performed on behalf of the Government or by removing the term ''supporting'' from the definition. Some respondents argued that the proposed definition was problematic because it was inconsistent with current FAR coverage or the statutory language in the NDAA. Two respondents suggested waiting to issue a final rule until the Office of Management and Budget's (OMB) review of inherently governmental functions was complete, to ensure compatibility with any definitions issued as a result of that review. One of these respondents recommended publication of a revised proposed rule rather than a final rule.

Response: Contextual text and applicability already limit the definition to an appropriate class of actions, and striking the word ''supporting'' would imply that contractors were performing inherently governmental tasks, which is prohibited by law and regulation. While the definition provided is not identical to that provided in FAR 7.503(c)(12) or to the summary definition provided in the NDAA, it builds on both of those definitions and is not inconsistent with them, and no changes were made to the final rule that would require that it be delayed or published as a revised proposed rule. Finally, if changes will be required as a result of future OMB guidance regarding work closely associated with inherently governmental functions, a separate case will be opened to implement them.

2. Covered Employee

a. Prime Contractor Should Not Be Responsible for Employees Other Than Own Employees

Comments: Several respondents were concerned that the definition of ''covered employee'' could be interpreted to include employees of contractors, subcontractors, consultants, and partners. Respondents were concerned that assuming responsibility for all of these employees would create an unreasonable burden because the prime contractor could not impose disciplinary actions against other companies' employees or adequately identify or address personal conflicts of interest with respect to such employees.

Response: The Councils have modified the definition to clarify that the contractor is not directly responsible for the employees of subcontractors. The subcontract flowdown portion of the clause at FAR 52.203–16(e) will ensure that subcontractor employees are adequately covered while making sure that the subcontractor bears responsibility for its employees.

b. Self-Employed Individual

Comment: One respondent stated that in the case of a self-employed individual, the disclosure forms would be submitted to the same person filling out the form.

Response: The Councils have addressed this issue in the final rule. When a self-employed individual is a subcontractor and that individual is personally performing the acquisition function closely associated with inherently governmental functions, rather than having an employee of the subcontractor perform the function, then the self-employed individual will be treated as a covered employee of the prime contractor for purposes of this rule and the clause will not flow down. In such case, the clause could not meaningfully flow down to the subcontractor, because there is no employer/employee relationship involved at the subcontract level of performance. The individual completing the disclosure form and the individual accepting and reviewing those forms cannot be one and the same. The definition of ''covered employee'' was modified to reflect this.

Similarly, the clause cannot meaningfully apply at the prime level if the functions are to be performed by a self-employed individual, rather than a contractor employee. Since a self-employed individual is a legal entity, conflicts of interest relating to a prime contract with an entity (whatever its composition) are covered under the organizational conflicts of interest coverage at FAR subpart 9.5.

c. Limit Covered Employee to Those Specifically Performing the Acquisition Functions Under the Contract

Comment: One respondent raised the concern that agencies might interpret ''covered employee'' to mean all employees who work for a Government contractor, and suggested that the definition should be revised to clarify that a covered employee is an employee that is remunerated specifically to perform acquisition functions closely associated with inherently governmental functions.

Response: The definition, as amended, is clear that an employee is only covered under the rule if the employee performs acquisition functions closely associated with inherently governmental functions. Further, ''acquisition function closely associated with governmental functions'' is defined to tie directly to support of the activities of a Federal agency.

3. Non-Public Government Information

Comments: One respondent suggested that the definition of ''non-public Government information'' be limited by providing more specific guidance. One specific approach that was suggested involved requiring that any protected information be explicitly designated as such in writing by the Government. Another respondent suggested that the rule should be broadened to prohibit contractor employees from using any information related to the contract on which they work. This respondent stated that anything less would ''open the floodgates'' for mitigation or waivers, and debates over timelines of when information was publicly available.

Response: It would be overly burdensome to require that all such information be explicitly marked by the Government. The definition of ''non-public Government information'' was intended to have a broad meaning, including proprietary data belonging to another contractor as well as

information that could confer an unfair competitive advantage to a contractor for whom the employees work. This proposed definition requires the use of judgment on the part of contractors. A contractor employee should presume that all information given to a contractor has not been made public unless facts clearly indicate the contrary.

Further, the definition of ''non-public Government information'' is similar to the standard Government employees use executing their jobs—a standard that is particularly appropriate when tasks involve acquisition functions closely associated with inherently governmental functions.

This topic is relevant to other pending and forthcoming FAR cases, and for that reason, some structural changes have been made to the definition to harmonize this case with potential future usage. Specifically, the qualification that the information be accessed through performance on a Government contract has been removed from the definition, but has been applied in the rule text in appropriate places.

4. Personal Conflict of Interest

Comments: Many respondents commented on the definition of ''personal conflict of interest'' in proposed FAR 3.1101 and also in the clause at FAR 52.203–16(a).

One cautioned against defining the term ''personal conflict of interest'' by relying solely on terminology used in the Government's Standards of Conduct for Employees of the Executive Branch (Standards), at 5 CFR part 2635, urging the Councils to take differences between the Government and contractor workforce into account.

Several other respondents considered the proposed definition of ''personal conflict of interest'' to be imprecise. Each of these respondents identified terms in the definition that are undefined or that they deemed ambiguous or overly broad, including ''personal activity,'' ''relationship,'' ''close family members,'' ''other members of the household,'' other employment or financial relationships,'' ''gifts,'' ''compensation,'' and ''consulting relationships.'' Although one of these organizations counseled against relying too heavily on language in the Government's standards, as discussed above, four others recommended that the Councils borrow from comparable definitions in existing Government regulations.

One respondent suggested an alternative definition of the term ''personal conflict of interest'' that it considered an amalgam of the proposed definition and definitions in the ethics regulations and the Troubled Asset Relief Program regulations at 31 CFR 31.201, while another respondent urged that the definition of ''personal conflict of interest'' not rely on a listing of examples that is incomplete, yet not specifically designated as non-exclusive.

One respondent urged that the rule ''incorporate some element of contemporaneous 'knowledge' on the part of the covered employee before the PCI requirements are triggered,'' and that coverage be included to exclude *de minimis* ownership or partnership interests. On the other hand, another respondent recommended that the definition of ''personal conflict of interest'' be expanded in scope to capture personal conflicts of interest that can arise from prior work or employment undertaken in support of Government acquisition functions.

Response: As explained in the preamble to the proposed rule, the Councils considered various sources of guidance when developing the definition of ''personal conflict of interest.'' The definition of ''personal conflict of interest'' provided by the rule clearly borrowed from the Government ethics provisions. On the other hand, the Councils intentionally did not create a mirror image of either 18 U.S.C. 208 or the Government's impartiality provision. The Government's impartiality standard judges a public servant's circumstances from the perspective of a ''reasonable person,'' whereas the FAR standard focuses on the contractor's obligation to the Government and defines a ''personal conflict of interest'' as a situation ''that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract.'' (A verb other than ''impair'' was inadvertently used in the proposed contract clause. The Councils have corrected this error to make the clause consistent with the rule text.)

Similar to the Government's approach in its ethics regulations, the proposed definition of ''personal conflict of interest'' listed ''sources'' of conflicts, including the financial interests of an employee and other members of his or her household, and then listed types of financial interests in subparagraphs (2)(i) through (2)(viii). In response to several comments, the Councils have decided to revise the wording of paragraph (2) of the definition to make it clear that this listing is intended to amplify the term ''financial interest'' as used earlier in the definition. The Councils have also inserted the words ''[f]or example'' at the beginning of paragraph (2) to clearly indicate that the listing in subparagraphs (2)(i) through (2)(viii) is not exhaustive.

The Councils have not attempted to further define other terms or phrases used within the definition of ''personal conflict of interest.'' The Councils consider the proposed terminology adequate to enable a contractor to develop screening procedures that will elicit relevant information from its covered employees. In the definition of ''personal conflict of interest'', the regulation affords flexibility regarding *de minimis* interest, since it may be determined that a *de minimis* interest would not ''impair the employee's ability to act'' with the required objectivity. Separately, although no ''knowledge'' element has been added, the Councils acknowledge that neither a contractor nor its employees can apply the impartiality standard if it cannot yet be known what interests may be affected by a particular acquisition.

C. Applicability

Comments: One respondent recommended that specific language be added to the proposed rule limiting its application to those contractor employees who directly support Government buying offices.

Response: Section 841(a) of the NDAA for FY 2009 required that policy be developed to prevent personal conflicts of interest by all contractor employees performing acquisition functions closely associated with inherently governmental functions for, or on behalf of, a Federal agency or department, and not all such work occurs in direct support of a buying office.

Comment: One respondent stated that the statutory requirement that the clause be included in task or delivery orders is not recognized in the rule.

Response: The applicability to task or delivery orders against existing contracts is addressed under the applicability date in this preamble. Such transitional issues are not included as part of the regulation, because they are only temporary, until the clause is included in most existing contracts.

D. Contractor Procedures

1. Screening of Covered Employees (Including Financial Disclosure)

Comments: More than half the respondents commented on this issue, and provided a variety of concerns and suggestions, which are addressed more specifically in the following response.

Response: In response to these comments, the Councils have narrowed the scope of the required disclosures in

a number of ways. First, in response to concern that the word ''including'' in FAR 3.1103(a) created ambiguity, the Councils have substituted the word ''by,'' to indicate that disclosure is the mandated screening mechanism. Next, in response to a wide variety of comments regarding the breadth of required disclosures, the Councils have made several revisions to FAR 3.1103(a)(1) to make it clear that contractors are afforded some flexibility in determining how to implement the screening requirement (*i.e.,* one method of effective screening might require each covered employee to review a list of entities affected by the upcoming work and either disclose any conflict or confirm that he or she has none), and to allow that disclosures be limited to financial interests ''that might be affected by the task to which the employee has been assigned.'' Finally, the Councils recognized that other potential sources of conflicts, including employment or gifts, should be covered by these procedures as well.

The Councils have also made changes in response to a number of respondents that noted inconsistencies and other concerns regarding updates to employee financial disclosures. These changes include ensuring that the language in FAR part 3 is consistent with the language in the clause, and that both require an update only when ''an employee's personal or financial circumstances change in such a way that a new personal conflict of interest might occur because of the task the covered employee is performing.'' If it is the task that changes, rather than the financial circumstances, the situation will be covered by the requirement to obtain information from a covered employee ''when the employee is initially assigned to the task under the contract.'' Implementing ''as needed'' disclosure addresses one respondent's concern about selling and repurchasing assets to avoid personal conflict of interest requirements, and also eliminates the need for disclosure on an annual basis.

Comments: In addition, several respondents addressed other areas related to the financial disclosure requirement. Several respondents were generally critical of the burden involved in the requirement to screen employees for conflicts of interest, arguing that it is short-sighted and ''has an element of impossibility,'' or that it would be ''onerous and unproductive'' to require disclosure, for example, every time a covered employee's retirement portfolio, or that of his or her spouse, might include potential contractors. Other respondents stated that the financial disclosure requirement is intrusive, and would provide employers with ''unprecedented insight into employee private financial data'' that would give the employer leverage during negotiations about salary, benefits, and work conditions.

Response: The Councils carefully considered the comments that were critical of the burdensome or intrusive nature of the screening process involving financial disclosure, but have determined that the concerns expressed are outweighed by the importance of assuring the integrity of the Government's acquisition process.

Comments: Finally, two respondents recommended clarification of roles and responsibilities concerning the review of financial disclosure statements. One recommended that the rule should specify that contractors acting in good faith may rely on the information submitted by their employees or that the rule specify that review by the employee's supervisor and legal counsel or ethics officer is sufficient. The other recommended that the contractor should be required to designate an official to solicit and review financial disclosure statements, but also suggested that the Government's contracting officer should review the statements and be able to access the services of subject matter experts to assist with the review. The same respondent also suggested that the rule should require that the covered employee's submission ''be accompanied by a certification as to the accuracy, completeness and truthfulness of the submission.''

Response: The Councils consider that it is the contractor's responsibility to decide how to review employee disclosures. Government contracting officers have not been assigned the responsibility to review disclosures of financial interests. Further, there is a statutory prohibition on adding non-statutory certification requirements to the FAR without express written approval by the Administrator for Federal Procurement Policy (see FAR 1.107).

2. Prevent Personal Conflicts of Interest (Including Nondisclosure Agreements)

a. Preventing Personal Conflicts of Interest

Comments: Some respondents provided comments in this area concerning the role of the Government in contractor processes. For example, one respondent pointed out that the requirement to reassign tasks does not oblige the contractor to report known or reported conflicts of interest to the contracting officer in order for reassignment to occur. Others suggested that the required non-disclosure agreements be submitted to the contracting officer for review and approval.

Response: It is up to the contractor to manage its employees, and to assign them in a way that prevents personal conflicts of interest. The Government only needs to be informed if violations occur, or if the contractor needs approval for a mitigation plan or requests a waiver. Similarly, while employer/employee non-disclosure agreements will be available for Government inspection for recordkeeping compliance purposes, it is the contractor's responsibility to ensure that such agreements are enacted and enforced.

b. Non-Disclosure Agreements (NDAs)

Comments: One respondent stated that the proposed rule did not provide any specific guidance concerning the NDA requirement. This respondent requested that the Councils address—

- Which parties are required to sign an NDA;
- Whether the contractor and/or the contractor employee are required to execute the NDA for each entity that provides information to which it will have access;
- Whether an entity that submitted non-public information is entitled to know who has signed an NDA relating to that information; and
- Whether there is a required duration for the NDA. If an NDA is not indefinite, how should a contractor address protection of non-public information when the NDA expires?

Response: The rule requires that each employee sign an NDA with respect to information obtained during the course of the work being performed under the contract. The agreements should be structured to protect the interests of the information owner(s), the contractor, and the contractor employee, including protection of appropriate length (often indefinitely or until the information is otherwise made public). Since these agreements will be executed between each individual contractor and that contractor's employees, and contractors are not required to provide any notice of those agreements, there will be no means of providing an entity with a listing of those who have signed NDAs which cover their information.

3. Appearance of a Conflict

Comments: Several respondents expressed concern about the difficulty contractors face in identifying circumstances that suggest ''even the

appearance of personal conflicts of interest.'' These respondents state that the standard is vague and too difficult for contractors and their employees to implement. One respondent points out that there are likely different standards in the ''healthcare, defense, or transportation industries'' and suggests limiting language along the lines of ''consistent with industry norms.''

Response: The rule requires that contractors inform covered employees of their obligation to avoid even the appearance of personal conflicts of interest. That same obligation is imposed on Government employees by FAR 3.101–1. Nothing in this rule requires a report of an ''appearance of conflict.'' Concern about how to deal with an ''appearance of a conflict,'' where in fact there is actually no conflict, is difficult, but once sensitized to the issue of appearances, contractors and contracting officers can develop solutions to the appearance questions that will protect the public's trust in the acquisition system.

The Councils do not concur with the suggestion that the rule incorporate industry norms as a standard. While there very well may be different ways of doing business in the healthcare, defense, and transportation industries, the threshold provided here is the minimum level of coverage required across all industries regarding personal conflicts of interest and the appearance of such conflicts.

4. Report Violations to the Contracting Officer

a. Timing of the Report

Comments: Various respondents raised concerns regarding the report to the contracting officer. They pointed out that the proposed rule both required a report of a conflict ''as soon as it is identified'' and also requires a full description of the violation and the actions taken. The respondents suggested that the rule permit some time for investigation and consideration of action before reporting the conflict. Another suggestion was to allow for a specified number of days to report.

Response: In response to these comments, the Councils have clarified that the initial report of immediate actions taken may be followed with a report of subsequent corrective action. The respondents correctly pointed to the apparent dilemma presented in the proposed rule which requires a report, as soon as the conflict is identified, and yet requires that the report include a full description and a contractor resolution. The rule necessarily requires that the contractor notify the contracting officer about a conflict ''as soon as it is identified'' so that, if necessary, the contracting officer can take immediate steps to protect the Government.

The violation has not been ''identified'' until the Contractor has performed sufficient investigation to confirm that a violation has occurred. Practically speaking, we would expect contractors will be able to identify the conflict, initially assess its scope, and even evaluate potential corrective actions relatively quickly. We would also expect that in proposing corrective action, it will be necessary in many cases that the contractor takes the time to evaluate the seriousness of the matter and develop a solution acceptable to the Government, as well as the employee in some circumstances (where the violation was inadvertent, for instance). The final rule better reflects the requirements of such situations.

b. Report Violations to the Inspector General

Comments: Several agency respondents recommend that the report be made to the Inspector General, as well as the contracting officer.

Response: Not all employee personal conflict-of- interest violations are violations of criminal law or nefarious. The contractor's report is treated here as a contractual issue to be addressed first by the contractor and then by the contracting officer. There is no reason to add a third party, such as the Inspector General, unless violation of Federal criminal law has occurred. In those cases, a report to the Inspector General will already be required in accordance with FAR 52.203–13(b)(3). On the other hand, nothing in this rule prevents individual agencies and their Inspector General from establishing internal procedures for coordinating contractor reports.

5. Specify Period of Record Retention

Comments: One respondent recommended that the proposed rule should include language requiring that contractors maintain records of financial disclosures and all actions taken in response to an alleged personal conflict of interest for a certain period of time (perhaps 3 or 5 years).

Response: FAR 4.703 provides requirements for retention of contractor records (generally 3 years after final payment). Subpart 4.7 applies to records generated under contracts that contain either of the FAR audit and records clauses (FAR 52.214–26 or FAR 52.215–2). Pursuant to these clauses, contractors must generally make records available to satisfy contract negotiation, administration, and audit requirements of the contracting agencies and the Comptroller General.

E. Mitigation or Waiver

Comments: One respondent recommended removing the requirement that any mitigation or waiver be limited to exceptional circumstances. At the other end of the spectrum, one respondent suggested that mitigation and waiver not be allowed at all.

Response: While the goal of the rule is to prevent personal conflicts of interest, making provision for mitigation or waiver in exceptional circumstances is necessary to prevent potential negative consequences to the Government. Balancing these goals is achieved by requiring that any mitigation or waiver be approved in writing, including a description of why such action is in the best interest of the Government.

Regarding the suggestion to allow approval of mitigation at the chief of the contracting office level, mitigation and waiver should only be employed in exceptional circumstances, and one means of ensuring this is requiring the approval of the head of the contracting activity.

F. Violations/Remedies

1. Description of Violations by Covered Employees (FAR 3.1103(a)(6) and FAR 52.203–16(b)(6))

Comment: One respondent recommended several changes to this section, which are addressed more specifically in the following response.

Response: While the Councils do not concur with recommendations to create a definitive list of violations to replace the examples, or to alter the requirement to report violations to tie specifically to a failure to update the required financial disclosure form, the Councils do concur with the suggestion to include ''Failure of a covered employee to comply with the terms of a non-disclosure agreement,'' in the list of violations. This covers situations where the inappropriate disclosure of information might not be due to a personal conflict of interest or for personal gain, but instead results from thoughtless or careless action. Furthermore, this is parallel to the construction of the requirements in FAR 3.1103(a)(2)(iii).

2. Violations by the Contractor

a. Clarification of Contractor Liability

Comments: Two respondents expressed concern about the imposition of liability upon contractors, and suggested that an employer should only be sanctioned when it fails to address

issues within its control, not as a guarantor of flawless performance by its employees in the area of personal conflicts of interest.

Response: A contractor should only be held liable for a violation if the contractor fails to comply with paragraphs (b), (c)(3), or (d) of the clause at FAR 52.203–16. There is nothing in the clause that establishes contractor liability for a violation by an employee, as long as the contractor followed the appropriate steps to uncover and report the violation.

Because the rule addresses both violations by a covered employee and violations by the contractor, the Councils have clarified in each instance what type of violation is being addressed (FAR 3.1103(a)(6) and (b); FAR 3.1105(a) and (b); and FAR 52.203–16(b)(6)). This should help the concern of the respondent that the contractor may be subject to remedies for violations by covered employees, rather than compliance with the clause requirements.

In addition, the Councils have adopted two suggested changes to the text of FAR 3.1105(b). ''Pursue'' has been changed to ''consider,'' to more accurately reflect the contracting officer's obligation. The Councils also deleted the term ''sufficient'' before the word ''evidence'' in describing the conditions for considering appropriate remedies. If the contracting officer finds evidence of a violation, the contracting officer should consider appropriate remedies. The term ''evidence'' on its own presents the requirement for a level of certainty beyond a mere rumor or suspicion.

3. Remedies for Violations by the Contractor

Comment: One respondent objected to inclusion of the list of remedies in the clause at FAR 52.203–16(d), stating that the FAR contains adequate remedies to address non-compliance with any material requirement of a contract, which includes the proposed FAR clause 52.203–16.

Response: While the list of remedies included within FAR 52.203–16 specifically identified those remedies available for violations involving potential conflicts, it was not intended to create new remedies. For this reason, the Councils have removed the paragraph regarding remedies from the clause. Removal of this section also addresses comments from several respondents related to individual remedies included in the list.

Comment: One respondent recommended adding a provision stating that certain violations should immediately be entered into the new Federal Awardee Performance and Integrity Information System (FAPIIS).

Response: Inclusion in the FAPIIS database is already adequately covered. For violations that result in suspension, debarment, or termination of the contract for default or cause, such actions will be entered into FAPIIS in accordance with the requirements published in the **Federal Register** at 75 FR 14059 on March 23, 2010. The other violations are of a type that would be entered in FAPIIS through the contracting officer performance evaluation of the contractor.

G. Clause Flowdown

1. Flowdown Requirements Should Mirror Clause

Comments: Respondents were concerned that the proposed rule requires the prime contractor to be responsible for subcontractor personnel, and that the requirements for inclusion in a subcontract are broader than the requirements for including the clause in a prime contract.

Response: The Councils have made changes to clarify the flowdown requirements. First, the definition of ''covered employee'' has been clarified to indicate that the prime contractor is not responsible for screening subcontractor employees. See also the response to comment B.2., definition of ''covered employee.'' Additionally, the flowdown provision, which stated that the clause should be included in subcontracts that ''may'' involve performance of certain work in the proposed rule, has been revised to only apply to subcontracts that ''will'' involve such work, for consistency with the requirements for inclusion in prime contracts.

2. Subcontract Threshold

Comment: The flowdown of the clause should be conditioned on subcontracts that exceed the simplified acquisition threshold, rather than specifying $150,000.

Response: The threshold for application to subcontracts will not be subject to change during the performance of the contract, if the simplified acquisition threshold changes, so stating a dollar amount is preferable. When the simplified acquisition threshold changes, the clause will be changed for future contracts, but those changes will not be imposed on existing contracts.

H. Cost and Administrative Burden

1. Costs of Ethics Compliance Program

Comment: Several respondents expressed concerns about the costs involved with establishing a comprehensive compliance program to comply with the requirements of this rule.

Response: While the Councils recognize that there will be some administrative costs associated with implementation of this program, the Government anticipates that when preparing proposals for Government contracts vendors will account for these costs appropriately and through their normal procedures. Subcontractors also are expected to include their anticipated costs in their offered price to the prime contractor. The anticipated costs, therefore, are likely to be passed on to the Government.

2. Information Collection Requirements

Comments: One respondent stated that the estimates of the Paperwork Reduction Act burdens (information collection requirements) appear to be significantly underestimated, and do not take into account the many levels of internal reviews that would be required as well as efforts associated with coordinating with legal counsel, program staff, *etc.,* as necessary.

Another respondent, in response to the notice published in the **Federal Register** at 76 FR 27648 on May 12, 2011, questioned the accuracy and currency of the supporting statement for the information collection requirement for the subject rule.

Response: In response, the Councils updated the data used in the supporting statement, including current Federal Procurement Data System data. This resulted in minor or non-material changes in the estimated number of responses. For example, the estimate for the ratio of violations reported to the Department of Justice compared to the base of estimated number of Federal employees was doubled, due to correcting the base to include only Federal civilian employees. However, this approach only increased the estimated number of annual contractor employee violations from 10 to 22.

In addition, the Councils considered the comment that the hours per response are underestimated, due to the many levels of internal reviews that would be required as well as efforts associated with coordinating with legal counsel or program staff, as necessary. Although the Councils did not have specific data as to how much increase these reviews would require, the Councils doubled the previous estimates

of 2 hours for reporting a violation and 4 hours for requesting mitigation, resulting in an estimate of 4 hours per violation report and 8 hours per mitigation request. As with any estimate of an average number, there will be a large range between the high end (as in a large corporation) and the low end where only a few people may be involved.

These revisions result in an increase of the estimated response burden hours from 1,820 hours in the proposed rule to 3,688 hours. The estimated recordkeeping hours remain unchanged at 61,200 hours.

I. Miscellaneous Comments

The Councils considered, but did not implement, a variety of additional comments. These included suggestions that the rule require the following:

- Use of a standard non-disclosure agreement form, to be published by the Government.
- Use of a standards financial disclosure form, to be published by the Government.
- Placement of responsibility for compliance at a ''high level'' within the contractor organization.
- Use of established structures required for implementation of the Contractor Code of Business Ethics for implementation of these requirements.
- Certification from the contractor that no personnel have a personal conflict of interest.
- Establishment of training programs for contractor personnel.

In each of these cases, implementation of the recommendation is neither necessary nor desirable, because establishing additional structural requirements would eliminate the flexibilities provided to contractors. The proposed rule sets out the requirements with which each contractor must comply, but allows latitude for the application of business judgment in structuring internal programs to achieve that compliance.

Comment: Finally, one respondent suggested that the proposed rule should require ''that a contractor certify that * * * no covered personnel have a personal conflict of interest.''

Response: A certification requirement would not add any substantial protections not already present in the rule.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the requirements of the clause are not significantly burdensome. The requirement to obtain and retain information on employees' potential conflicts of interest is limited to service contractors whose employees are performing acquisition functions closely associated with inherently governmental functions for, or on behalf of, Federal agencies. This class is a minority of Government contractors and is becoming smaller as Government agencies bring more such functions back in house. Further, there is no requirement to report the information collected to the Government. It is not a significant economic burden to report to the contracting officer personal conflict-of-interest violations by covered employees and the corrective actions taken. The final rule has also reduced potential burden by—

1. Not including a certification requirement;
2. Not requiring a formal training program;
3. Clarifying that the rule does not apply to commercial items;
4. Removing the requirement for an annual update of the financial disclosure statement; and
5. Allowing mitigation under exceptional circumstances.

Comments on impact on small business: Three respondents expressed concern about the potential impact this rule could have on small businesses and specifically that the reporting, prevention, and oversight requirement could be a burden for small businesses such that they might reconsider pursuing Federal contracts. One respondent believed that small businesses will be most affected by this rule because it could force divestitures.

Response: The Councils agree that the reporting, prevention and oversight requirements may cause some burden for small businesses. The rule requires that prime contractors have procedures in place to screen covered employees and requires avoidance or mitigation of any potential conflicts. It may be difficult for smaller companies to avoid or mitigate the conflict (*e.g.,* remove the employee from that position on the contract when the business only has a few employees). However, the burden on small business is reduced because the rule—

- Provides the contractor with discretion on how best to implement its procedures;
- Does not hold the prime contractor liable for violations by employees, as long as the contractor has procedures in place and deals appropriately with the violations;
- Clarifies the meaning of ''covered employee'' and requires a flowdown to all subcontracts involving performance of acquisition related functions by employees, so that the prime contractor is not directly responsible for assessing the subcontractor employee personal conflicts of interest, as many respondents feared; and
- Provides the contracting officer with discretion on the handling of personal conflicts of interest violations.

Further, the public law did not create an exception for small businesses with respect to implementation and it would be inconsistent with the purpose and intent of the public law to not apply the rules relating to personal conflicts of interest to any particular group of contracts where personnel are performing acquisition functions closely associated with inherently governmental functions.

V. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) applies. The final rule contains information collection requirements. OMB has cleared this information collection requirement under OMB Control Number 9000–0181, titled: Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions.

List of Subjects in 48 CFR Parts 1, 3, 12, and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 1, 3, 12, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 3, 12, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 1—FEDERAL ACQUISITION REGULATORY SYSTEM

1.106 [Amended]

■ 2. Amend section 1.106, in the table following the introductory text, by adding FAR segments ''3.11'' and ''52.203–16'' and the corresponding OMB Control Number ''9000–0181.''

PART 3—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

■ 3. Add Subpart 3.11 to read as follows:

Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions

Sec.
3.1100 Scope of subpart.
3.1101 Definitions.
3.1102 Policy.
3.1103 Procedures.
3.1104 Mitigation or waiver.
3.1105 Violations.
3.1106 Contract clause.

Subpart 3.11—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions

3.1100 Scope of subpart.

This subpart implements the policy on personal conflicts of interest by employees of Government contractors as required by section 841(a) of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417) (41 U.S.C. 2303).

3.1101 Definitions.

As used in this subpart—

Acquisition function closely associated with inherently governmental functions means supporting or providing advice or recommendations with regard to the following activities of a Federal agency:

(1) Planning acquisitions.

(2) Determining what supplies or services are to be acquired by the Government, including developing statements of work.

(3) Developing or approving any contractual documents, to include documents defining requirements, incentive plans, and evaluation criteria.

(4) Evaluating contract proposals.

(5) Awarding Government contracts.

(6) Administering contracts (including ordering changes or giving technical direction in contract performance or contract quantities, evaluating contractor performance, and accepting or rejecting contractor products or services).

(7) Terminating contracts.

(8) Determining whether contract costs are reasonable, allocable, and allowable.

Covered employee means an individual who performs an acquisition function closely associated with inherently governmental functions and is—

(1) An employee of the contractor; or

(2) A subcontractor that is a self-employed individual treated as a covered employee of the contractor because there is no employer to whom such an individual could submit the required disclosures.

Personal conflict of interest means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract. (A *de minimis* interest that would not ''impair the employee's ability to act impartially and in the best interest of the Government'' is not covered under this definition.)

(1) Among the sources of personal conflicts of interest are—

(i) Financial interests of the covered employee, of close family members, or of other members of the covered employee's household;

(ii) Other employment or financial relationships (including seeking or negotiating for prospective employment or business); and

(iii) Gifts, including travel.

(2) For example, financial interests referred to in paragraph (1) of this definition may arise from—

(i) Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;

(ii) Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, or serving as an expert witness in litigation);

(iii) Services provided in exchange for honorariums or travel expense reimbursements;

(iv) Research funding or other forms of research support;

(v) Investment in the form of stock or bond ownership or partnership interest (excluding diversified mutual fund investments);

(vi) Real estate investments;

(vii) Patents, copyrights, and other intellectual property interests; or

(viii) Business ownership and investment interests.

3.1102 Policy.

The Government's policy is to require contractors to—

(a) Identify and prevent personal conflicts of interest of their covered employees; and

(b) Prohibit covered employees who have access to non-public information by reason of performance on a Government contract from using such information for personal gain.

3.1103 Procedures.

(a) By use of the contract clause at 52.203–16, as prescribed at 3.1106, the contracting officer shall require each contractor whose employees perform acquisition functions closely associated with inherently Government functions to—

(1) Have procedures in place to screen covered employees for potential personal conflicts of interest by—

(i) Obtaining and maintaining from each covered employee, when the employee is initially assigned to the task under the contract, a disclosure of interests that might be affected by the task to which the employee has been assigned, as follows:

(A) Financial interests of the covered employee, of close family members, or of other members of the covered employee's household.

(B) Other employment or financial relationships of the covered employee (including seeking or negotiating for prospective employment or business).

(C) Gifts, including travel; and

(ii) Requiring each covered employee to update the disclosure statement whenever the employee's personal or financial circumstances change in such a way that a new personal conflict of interest might occur because of the task the covered employee is performing.

(2) For each covered employee—

(i) Prevent personal conflicts of interest, including not assigning or allowing a covered employee to perform any task under the contract for which the Contractor has identified a personal conflict of interest for the employee that the Contractor or employee cannot satisfactorily prevent or mitigate in consultation with the contracting agency;

(ii) Prohibit use of non-public information accessed through

performance of a Government contract for personal gain; and

(iii) Obtain a signed non-disclosure agreement to prohibit disclosure of non-public information accessed through performance of a Government contract.

(3) Inform covered employees of their obligation—

(i) To disclose and prevent personal conflicts of interest;

(ii) Not to use non-public information accessed through performance of a Government contract for personal gain; and

(iii) To avoid even the appearance of personal conflicts of interest;

(4) Maintain effective oversight to verify compliance with personal conflict-of-interest safeguards;

(5) Take appropriate disciplinary action in the case of covered employees who fail to comply with policies established pursuant to this section; and

(6) Report to the contracting officer any personal conflict-of-interest violation by a covered employee as soon as identified. This report shall include a description of the violation and the proposed actions to be taken by the contractor in response to the violation, with follow-up reports of corrective actions taken, as necessary.

(b) If a contractor reports a personal conflict-of-interest violation by a covered employee to the contracting officer in accordance with paragraph (b)(6) of the clause at 52.203–16, Preventing Personal Conflicts of Interest, the contracting officer shall—

(1) Review the actions taken by the contractor;

(2) Determine whether any action taken by the contractor has resolved the violation satisfactorily; and

(3) If the contracting officer determines that the contractor has not resolved the violation satisfactorily, take any appropriate action in consultation with agency legal counsel.

3.1104 Mitigation or waiver.

(a) In exceptional circumstances, if the contractor cannot satisfactorily prevent a personal conflict of interest as required by paragraph (b)(2)(i) of the clause at 52.203–16, Preventing Personal Conflicts of Interest, the contractor may submit a request, through the contracting officer, for the head of the contracting activity to—

(1) Agree to a plan to mitigate the personal conflict of interest; or

(2) Waive the requirement to prevent personal conflicts of interest.

(b) If the head of the contracting activity determines in writing that such action is in the best interest of the Government, the head of the contracting activity may impose conditions that provide mitigation of a personal conflict of interest or grant a waiver.

(c) This authority shall not be redelegated.

3.1105 Violations.

If the contracting officer suspects violation by the contractor of a requirement of paragraph (b), (c)(3), or (d) of the clause at 52.203–16, Preventing Personal Conflicts of Interest, the contracting officer shall contact the agency legal counsel for advice and/or recommendations on a course of action.

3.1106 Contract clause.

(a) Insert the clause at 52.203–16, Preventing Personal Conflicts of Interest, in solicitations and contracts that—

(1) Exceed the simplified acquisition threshold; and

(2) Include a requirement for services by contractor employee(s) that involve performance of acquisition functions closely associated with inherently governmental functions for, or on behalf of, a Federal agency or department.

(b) If only a portion of a contract is for the performance of acquisition functions closely associated with inherently governmental functions, then the contracting officer shall still insert the clause, but shall limit applicability of the clause to that portion of the contract that is for the performance of such services.

(c) Do not insert the clause in solicitations or contracts with a self-employed individual if the acquisition functions closely associated with inherently governmental functions are to be performed entirely by the self-employed individual, rather than an employee of the contractor.

PART 12—ACQUISITION OF COMMERCIAL ITEMS

■ 4. Amend section 12.503 by adding paragraph (a)(9) to read as follows:

12.503 Applicability of certain laws to Executive agency contracts for the acquisition of commercial items.

(a) * * *

(9) Public Law 110–417, section 841(a), Policy on Personal Conflicts of Interest by Employees of Federal Government Contractors 41 U.S.C. 2303 (see subpart 3.11).

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 5. Add section 52.203–16 to read as follows:

52.203–16 Preventing Personal Conflicts of Interest.

As prescribed in 3.1106, insert the following clause:

Preventing Personal Conflicts of Interest (DEC 2011)

(a) *Definitions.* As used in this clause—

Acquisition function closely associated with inherently governmental functions means supporting or providing advice or recommendations with regard to the following activities of a Federal agency:

(1) Planning acquisitions.

(2) Determining what supplies or services are to be acquired by the Government, including developing statements of work.

(3) Developing or approving any contractual documents, to include documents defining requirements, incentive plans, and evaluation criteria.

(4) Evaluating contract proposals.

(5) Awarding Government contracts.

(6) Administering contracts (including ordering changes or giving technical direction in contract performance or contract quantities, evaluating contractor performance, and accepting or rejecting contractor products or services).

(7) Terminating contracts.

(8) Determining whether contract costs are reasonable, allocable, and allowable.

Covered employee means an individual who performs an acquisition function closely associated with inherently governmental functions and is—

(1) An employee of the contractor; or

(2) A subcontractor that is a self-employed individual treated as a covered employee of the contractor because there is no employer to whom such an individual could submit the required disclosures.

Non-public information means any Government or third-party information that—

(1) Is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552) or otherwise protected from disclosure by statute, Executive order, or regulation; or

(2) Has not been disseminated to the general public and the Government has not yet determined whether the information can or will be made available to the public.

Personal conflict of interest means a situation in which a covered employee has a financial interest, personal activity, or relationship that could impair the employee's ability to act impartially and in the best interest of the Government when performing under the contract. (A *de minimis* interest that would not ''impair the employee's ability to act impartially and in the best interest of the Government'' is not covered under this definition.)

(1) Among the sources of personal conflicts of interest are—

(i) Financial interests of the covered employee, of close family members, or of other members of the covered employee's household;

(ii) Other employment or financial relationships (including seeking or negotiating for prospective employment or business); and

(iii) Gifts, including travel.

(2) For example, financial interests referred to in paragraph (1) of this definition may arise from—

(i) Compensation, including wages, salaries, commissions, professional fees, or fees for business referrals;

(ii) Consulting relationships (including commercial and professional consulting and service arrangements, scientific and technical advisory board memberships, or serving as an expert witness in litigation);

(iii) Services provided in exchange for honorariums or travel expense reimbursements;

(iv) Research funding or other forms of research support;

(v) Investment in the form of stock or bond ownership or partnership interest (excluding diversified mutual fund investments);

(vi) Real estate investments;

(vii) Patents, copyrights, and other intellectual property interests; or

(viii) Business ownership and investment interests.

(b) *Requirements.* The Contractor shall—

(1) Have procedures in place to screen covered employees for potential personal conflicts of interest, by—

(i) Obtaining and maintaining from each covered employee, when the employee is initially assigned to the task under the contract, a disclosure of interests that might be affected by the task to which the employee has been assigned, as follows:

(A) Financial interests of the covered employee, of close family members, or of other members of the covered employee's household.

(B) Other employment or financial relationships of the covered employee (including seeking or negotiating for prospective employment or business).

(C) Gifts, including travel; and

(ii) Requiring each covered employee to update the disclosure statement whenever the employee's personal or financial circumstances change in such a way that a new personal conflict of interest might occur because of the task the covered employee is performing.

(2) For each covered employee—

(i) Prevent personal conflicts of interest, including not assigning or allowing a covered employee to perform any task under the contract for which the Contractor has identified a personal conflict of interest for the employee that the Contractor or employee cannot satisfactorily prevent or mitigate in consultation with the contracting agency;

(ii) Prohibit use of non-public information accessed through performance of a Government contract for personal gain; and

(iii) Obtain a signed non-disclosure agreement to prohibit disclosure of non-public information accessed through performance of a Government contract.

(3) Inform covered employees of their obligation—

(i) To disclose and prevent personal conflicts of interest;

(ii) Not to use non-public information accessed through performance of a Government contract for personal gain; and

(iii) To avoid even the appearance of personal conflicts of interest;

(4) Maintain effective oversight to verify compliance with personal conflict-of-interest safeguards;

(5) Take appropriate disciplinary action in the case of covered employees who fail to comply with policies established pursuant to this clause; and

(6) Report to the Contracting Officer any personal conflict-of-interest violation by a covered employee as soon as it is identified. This report shall include a description of the violation and the proposed actions to be taken by the Contractor in response to the violation. Provide follow-up reports of corrective actions taken, as necessary. Personal conflict-of-interest violations include—

(i) Failure by a covered employee to disclose a personal conflict of interest;

(ii) Use by a covered employee of non-public information accessed through performance of a Government contract for personal gain; and

(iii) Failure of a covered employee to comply with the terms of a non-disclosure agreement.

(c) *Mitigation or waiver.* (1) In exceptional circumstances, if the Contractor cannot satisfactorily prevent a personal conflict of interest as required by paragraph (b)(2)(i) of this clause, the Contractor may submit a request through the Contracting Officer to the Head of the Contracting Activity for—

(i) Agreement to a plan to mitigate the personal conflict of interest; or

(ii) A waiver of the requirement.

(2) The Contractor shall include in the request any proposed mitigation of the personal conflict of interest.

(3) The Contractor shall—

(i) Comply, and require compliance by the covered employee, with any conditions imposed by the Government as necessary to mitigate the personal conflict of interest; or

(ii) Remove the Contractor employee or subcontractor employee from performance of the contract or terminate the applicable subcontract.

(d) *Subcontract flowdown.* The Contractor shall include the substance of this clause, including this paragraph (d), in subcontracts—

(1) That exceed $150,000; and

(2) In which subcontractor employees will perform acquisition functions closely associated with inherently governmental functions (*i.e.,* instead of performance only by a self-employed individual).

(End of clause)

[FR Doc. 2011–27780 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 2, 19, and 52

[FAC 2005–54; FAR Case 2009–019; Item III; Docket 2010–0108; Sequence 1]

RIN 9000–AL77

Federal Acquisition Regulation; Small Disadvantaged Business Self-Certification

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA have adopted as final, without change, an interim rule amending the Federal Acquisition Regulation (FAR) to incorporate changes made by the Small Business Administration (SBA) to its small disadvantaged business (SDB) program.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Karlos Morgan, Procurement Analyst, at (202) 501–2364, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2009–019.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published an interim rule in the **Federal Register** at 75 FR 77737 on December 13, 2010, to implement in the FAR revisions made by the SBA regarding certification of Federal subcontractors. The FAR revisions, as identified in the interim rule, allow for small disadvantaged businesses (SDBs) to self-represent their SDB status to prime contractors in good faith when seeking Federal subcontracting opportunities.

Previously under the FAR, Federal prime contractors were required to confirm that subcontractors representing themselves as small disadvantaged businesses were certified by the SBA as SDB firms. DoD, GSA, and NASA received no comments in response to the interim rule.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs

and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the FAR change removes the requirement for Federal prime contractors to confirm that small disadvantaged business subcontractors have obtained SDB certification from the SBA. This change will also be beneficial to SDB firms because they will no longer have to incur the costs associated with the formal certification process.

IV. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 2, 19, and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Interim Rule Adopted as Final Without Change

Accordingly, the interim rule amending 48 CFR parts 2, 19, and 52, which was published in the **Federal Register** at 75 FR 77737 on December 13, 2010, is adopted as a final rule without change.

[FR Doc. 2011–27782 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 4, 25, and 52

[FAC 2005–54; FAR Case 2010–012; Item IV; Docket 2010–0102, Sequence 1]

RIN 9000–AL71

Federal Acquisition Regulation; Certification Requirement and Procurement Prohibition Relating to Iran Sanctions

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA have adopted as final, with changes, an interim rule amending the Federal Acquisition Regulation (FAR) to implement sections 102 and 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. Section 102 requires certification that each offeror, and any person owned or controlled by the offeror, does not engage in any activity for which sanctions may be imposed under section 5 of the Iran Sanctions Act of 1996 (the Iran Sanctions Act). Section 106 imposes a procurement prohibition relating to contracts with persons that export certain sensitive technology to Iran. There will be further implementation of section 106 in FAR Case 2010–018, Representation Regarding Export of Sensitive Technology to Iran.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, at (202) 219–0202, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2010–012.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published an interim rule in the **Federal Register** at 75 FR 60254 on September 29, 2010, to implement section 102 and to partially implement section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. FAR Case 2010–018, Representation Regarding Export of Sensitive Technology to Iran, will provide further implementation of section 106 by adding a representation regarding export of sensitive technology to Iran and a waiver provision.

Two respondents submitted comments on the interim rule.

II. Discussion and Analysis of the Public Comments

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. A discussion of the comments and the changes made to the rule as a result of those comments are provided as follows:

A. Applicability to Construction

Comment: One respondent was concerned that the prescription at FAR 25.1103, which requires use of the FAR provision at 52.225–25, Prohibition on Engaging in Sanctioned Activities Relating to Iran—Certification, in ''each solicitation for the acquisition of products or services'' could be interpreted to exclude construction. The respondent suggested changing the prescription to require use in ''all solicitations.''

Response: The phrase ''products or services'' was intended to include construction, as indicated in the FAR clause matrix. DoD, GSA, and NASA have agreed to change the final rule to require use of the provision in ''all solicitations.''

B. Commercial Database of Persons Doing Business With Iran

Comment: One respondent provided information about the commercial Iran Economic Interest database of persons doing business with Iran, provided by World-Check, a provider of data services to organizations, including Government contractors. This respondent believed that this data set provided by his company is the only standard that would allow Government contractors the ability to comply with the provisions of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. He suggested that the Government should require or recommend that contractors should have this data available before they ''self-certify.''

Response: The Government does not generally promote the use of particular commercial services. DoD, GSA, and NASA have not changed the final rule in response to this comment.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule will only have impact on an offeror that is engaging in an activity for which sanctions may be imposed under section 5 of the Iran Sanctions Act or that is exporting sensitive technology to Iran. This rule will have little effect on domestic small business concerns, because such dealings with Iran are already generally prohibited under U.S. law. Due to current restrictions on trade with Iran, domestic entities are generally prohibited from engaging in activity that would cause them to be subject to the procurement bans described in this rule (see *e.g.,* Department of the Treasury Office of Foreign Assets Control regulations at 31 CFR part 560). Accordingly, it is expected that the number of domestic entities, both large and small, significantly impacted by this rule will be minimal, if any.

Although this rule mainly affects foreign entities, the Regulatory Flexibility Act is for the protection of domestic small entities, not foreign entities. For the definition of ''small business'', the Regulatory Flexibility Act refers to the Small Business Act, which in turn allows the Small Business Administration (SBA) Administrator to specify detailed definitions or standards (5 U.S.C. 601(3) and 15 U.S.C. 632(a)). The SBA regulations at 13 CFR 121.105 discuss who is a small business: ''(a)(1) Except for small agricultural cooperatives, a business concern eligible for assistance from SBA as a small business is a business entity organized for profit, with a place of business located in the United States, and which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor.'' Therefore, the impact assessment does not include the impact on foreign entities.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 4, 25, and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Interim Rule Adopted as Final With Change

Accordingly, the interim rule amending 48 CFR parts 4, 25, and 52 which was published in the **Federal Register** at 75 FR 60254 on September 29, 2010, is adopted as final with the following change:

PART 25—FOREIGN ACQUISITION

■ 1. The authority citation for 48 CFR part 25 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

■ 2. Amend section 25.1103 by revising paragraph (e) to read as follows:

25.1103 Other provisions and clauses.

* * * * *

(e) The contracting officer shall include in all solicitations the provision at 52.225–25, Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification.

[FR Doc. 2011–27783 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 4, 25, and 52

[FAC 2005–54; FAR Case 2010–018; Item V; Docket 2010–0018, Sequence 1]

RIN 9000–AL91

Federal Acquisition Regulation; Representation Regarding Export of Sensitive Technology to Iran

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule.

SUMMARY: DoD, GSA, and NASA are issuing an interim rule amending the Federal Acquisition Regulation (FAR) to add a representation to implement section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. Section 106 imposes a procurement prohibition relating to contracts with persons that export certain sensitive technology to Iran.

DATES: *Effective Date:* November 2, 2011.

Comment Date: Interested parties should submit written comments to the Regulatory Secretariat at one of the addresses shown below on or before January 3, 2012 to be considered in the formulation of the final rule.

ADDRESSES: Submit comments identified by FAC 2005–54, FAR Case 2010–018 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by inputting ''FAR Case 2010–018'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''FAR Case 2010–018.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''FAR Case 2010–018'' on your attached document.

- *Fax:* (202) 501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Hada Flowers, 1275 First Street, NE., 7th Floor, Washington, DC 20417.

Instructions: Please submit comments only and cite FAC 2005–54, FAR Case 2010–018, in all correspondence related

to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, at (202) 219–0202, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2010–018.

SUPPLEMENTARY INFORMATION:

I. Background and Discussion

This interim rule expands upon the interim rule published in the **Federal Register** at 75 FR 60254 on September 29, 2010, under FAR Case 2010–012, Certification Requirement and Procurement Prohibition Relating to Iran Sanctions. FAR Case 2010–012 implementation of section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Pub. L. 111–195), included imposing a procurement prohibition relating to contracts with persons that export certain sensitive technology to Iran. To further implement section 106, the rule adds at FAR 25.703–3(b) a requirement for a representation that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran.

The interim rule provides an exception to the representation requirement for offerors that are providing eligible products in acquisitions that are subject to trade agreements.

The waiver procedure at FAR 25.703–2(d) is moved to FAR 25.703–4, so that waiver of section 106 can be addressed along with the procedures for waiver of section 102 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010.

The representation that the offeror does not export sensitive technology to Iran is incorporated into the certification at FAR 52.225–25, now titled ''Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification,'' in order to include the representation and clarify that the prohibition is against contracting with sanctioned entities. Along with the statutory definition of ''sensitive technology,'' an email address is included in the provision, so that offerors can refer questions concerning sensitive technology to the Department of State, prior to making the representation.

This representation requirement is also applied to acquisition of commercial items at FAR 52.212–3, Offeror Representations and Certifications—Commercial Items, paragraph (o) (see section III, Determinations of Applicability).

Offerors will be able to make an annual certification through the Online Representations and Certifications Application, if the offeror is registered in the Central Contractor Registration database. Therefore, conforming changes have been made to FAR part 4 and the FAR clause at 52.204–8, Annual Representations and Certifications.

The interim rule includes two additional changes:

- FAR 25.703–2(b)—Adds an authority for termination—FAR part 49 and a cite to FAR 12.403 for termination of commercial contracts.
- FAR 52.225–25(d)—Adds two more examples of trade agreement provisions that may be included in the solicitation to indicate the applicability of trade agreements to the acquisition.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Determinations of Applicability

The Federal Acquisition Regulatory Council (FAR Council) has made a determination to apply the requirement of section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, to contracts at or below the simplified acquisition threshold (SAT), contracts for the acquisition of commercial items, and contracts for the acquisition of commercially available off-the-shelf (COTS) items.

1. Applicability to Contracts at or Below the SAT

41 U.S.C. 1905 governs the applicability of laws to contracts or subcontracts in amounts not greater than the SAT. It is intended to limit the applicability of laws to them. 41 U.S.C. 1905 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt contracts or subcontracts at or below the SAT, the law will apply to them. Therefore, given that the requirements of sections 102 and 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 were enacted to widen the sanctions against Iran, the FAR Council has determined that it is in the best interest of the Federal Government to apply this rule to all acquisitions including contracts at or below the SAT, as defined at FAR 2.101. An exception for acquisitions at or below the SAT would exclude a significant portion of Federal contracting and the contractors who provide these products and services, thereby undermining the overarching public policy purpose of the law.

2. Applicability to Contracts for the Acquisition of Commercial Items

41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial items, and is intended to limit the applicability of laws to contracts for the acquisition of commercial items. 41 U.S.C. 1906 provides that if a provision of law contains criminal or civil penalties, or if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial item contracts, the provision of law will apply to contracts for the acquisition of commercial items.

Therefore, given that the requirements of sections 102 and 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 were enacted to widen the sanctions against Iran, the FAR Council has determined that it is in the best interest of the Federal Government to apply the rule to contracts for the acquisition of commercial items, as defined at FAR 2.101. An exception for contracts for the acquisition of commercial items would exclude a significant portion of Federal contracting and the contractors who provide these products and services, thereby undermining the overarching public policy purpose of the law.

3. Applicability to Contracts for the Acquisition of COTS Items

41 U.S.C. 1907 governs the applicability of laws to contracts for the acquisition of COTS items, and is intended to limit the applicability of

laws to them. 41 U.S.C. 1907 provides that if a provision of law contains criminal or civil penalties, or if the Administrator for Federal Procurement Policy makes a written determination that it is not in the best interest of the Federal Government to exempt contracts for the acquisition of COTS items, the provision of law will apply. Therefore, given that the requirements of sections 102 and 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 were enacted to widen the sanctions against Iran, the Administrator for Federal Procurement Policy has determined that it is in the best interest of the Federal Government to apply the rule to contracts for the acquisition of COTS items, as defined at FAR 2.101. An exception for contracts for the acquisition of COTS items would exclude a significant portion of Federal contracting and the contractors who provide these products and services, thereby undermining the overarching public policy purpose of the law.

IV. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because this rule will only have an impact on an offeror that is exporting sensitive technology to Iran. Domestic entities are generally prohibited from engaging in activity that would cause them to be subject to the procurement bans described in this rule due to current restrictions on trade with Iran (see, *e.g.,* Department of the Treasury Office of Foreign Assets Control regulations at 31 CFR part 560).

Although this rule mainly affects foreign entities, the Regulatory Flexibility Act is for the protection of domestic small entities, not foreign entities. For the definition of ''small business,'' the Regulatory Flexibility Act refers to the Small Business Act, which in turn allows the U.S. Small Business Administration (SBA) Administrator to specify detailed definitions or standards (5 U.S.C. 601(3) and 15 U.S.C. 632(a)). The SBA regulations at 13 CFR 121.105 discuss who is a small business: ''(a)(1) Except for small agricultural cooperatives, a business concern eligible for assistance from SBA as a small business is a business entity organized for profit, with a place of business located in the United States, and which operates primarily within the United States or which makes a significant contribution to the U.S. economy through payment of taxes or use of American products, materials or labor.''

Therefore, an Initial Regulatory Flexibility Analysis has not been performed because the number of domestic entities significantly impacted by this rule will be minimal. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAC 2005–54, FAR Case 2010–018), in correspondence.

V. Paperwork Reduction Act

The interim rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

VI. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense (DoD), the Administrator of General Services (GSA), and the Administrator of the National Aeronautics and Space Administration (NASA) that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. FAR Case 2010–012 implemented section 102 and partially implemented section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Pub. L. 111–195). This interim rule is necessary because the rule further implements section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, which was signed on July 1, 2010. Section 106 was effective upon enactment, which imposed a procurement prohibition relating to contracts with persons that export certain sensitive technology to Iran entered into or renewed on or after September 29, 2010. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD, GSA, and NASA will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 4, 25, and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 4, 25, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 4, 25, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 4—ADMINISTRATIVE MATTERS

■ 2. Amend section 4.1202 by revising paragraph (y) to read as follows:

4.1202 Solicitation provision and contract clause.

* * * * *

(y) 52.225–25, Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification.

* * * * *

PART 25—FOREIGN ACQUISITION

■ 3. Amend section 25.703–1 by—

■ a. Revising the section heading;

■ b. Adding an introductory paragraph; and

■ c. Adding, in alphabetical order, the definition ''Sensitive technology''.

The revised and added text reads as follows:

25.703–1 Definitions.

As used in this subpart—

* * * * *

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

■ 4. Amend section 25.703–2 by revising paragraphs (a)(1) and (b)(1); and removing paragraph (d).

The revised text reads as follows:

25.703–2 Iran Sanctions Act.

(a) * * *

(1) As required by the Iran Sanctions Act (50 U.S.C. 1701 note), unless an exception applies in accordance with paragraph (c) of this section, or a waiver

is granted in accordance with 25.703–4, each offeror must certify that the offeror, and any person owned or controlled by the offeror, does not engage in any activity for which sanctions may be imposed under section 5 of the Iran Sanctions Act.

* * * * *

(b) * * *

(1) The contracting officer may terminate the contract in accordance with procedures in part 49, or for commercial items, 12.403.

* * * * *

■ 5. Revise section 25.703–3 to read as follows:

25.703–3 Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, section 106.

(a) The head of an Executive agency may not enter into or extend a contract for the procurement of goods or services with a person that exports certain sensitive technology to Iran, as determined by the President and listed on the Excluded Parties List System at *http://www.epls.gov.*

(b) Each offeror must represent that it does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran.

(c) *Exception for trade agreements.* The representation requirement of paragraph (b) of this subsection does not apply with respect to the procurement of eligible products, as defined in section 308(4) of the Trade Agreements Act of 1974 (19 U.S.C. 2518(4)), of any foreign country or instrumentality designated under section 301(b) of that Act (19 U.S.C. 2511(b)) (see subpart 25.4).

■ 6. Add section 25.703–4 to read as follows:

25.703–4 Waiver.

(a) An agency or contractor seeking a waiver of these requirements, consistent with section 6(b)(5) of the Iran Sanctions Act or section 401(b) of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (Pub. L. 111–195), and the Presidential Memorandum of September 23, 2010 (75 FR 67025), shall submit the request to the Office of Federal Procurement Policy, allowing sufficient time for review and approval.

(b) Agencies may request a waiver on an individual or class basis; however, waivers are not indefinite and can be cancelled, if warranted.

(1) A class waiver may be requested only when the class of supplies or equipment is not available from any other source and it is in the national interest.

(2) Prior to submitting the waiver request, the request must be reviewed and cleared by the agency head.

(c) In general, all waiver requests should include the following information:

(1) Agency name, complete mailing address, and point of contact name, telephone number, and email address.

(2) Offeror's name, complete mailing address, and point of contact name, telephone number, and email address.

(3) Description/nature of product or service.

(4) The total cost and length of the contract.

(5) Justification, with market research demonstrating that no other offeror can provide the product or service and stating why the product or service must be procured from this offeror, as well as why it is in the national interest for the President to waive the prohibition on contracting with this offeror that—

(i) Conducts activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; or

(ii) Exports sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran.

(6) Documentation regarding the offeror's past performance and integrity (see the Past Performance Information Retrieval System and the Federal Awardee Performance Information and Integrity System at *http://www.ppirs.gov,* and any other relevant information).

(7) Information regarding the offeror's relationship or connection with other firms that—

(i) Conduct activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act; or

(ii) Export sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran.

(8) Describe—

(i) The activities in which the offeror is engaged for which sanctions may be imposed under section 5 of the Iran Sanctions Act; or

(ii) The sensitive technology and the entity or individual to which it was exported (*i.e.,* the government of Iran or an entity or individual owned or controlled by, or acting on behalf or at the direction of, the government of Iran).

■ 7. Amend section 25.1103 by revising paragraph (e) to read as follows:

25.1103 Other provisions and clauses.

* * * * *

(e) The contracting officer shall include in all solicitations the provision at 52.225–25, Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 8. Amend section 52.204–8 by revising the date of the provision and paragraph (c)(1)(xx) to read as follows:

52.204–8 Annual Representations and Certifications.

* * * * *

Annual Representations and Certifications (NOV 2011)

* * * * *

(c) * * *

(1) * * *

(xx) 52.225–25, Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification. This provision applies to all solicitations.

* * * * *

■ 9. Revise section 52.212–3 by—

■ a. Revising the date of the provision;

■ b. In paragraph (a), adding, in alphabetical order, the definition ''Sensitive technology''; and

■ c. Revising paragraph (o).

The revised and added text reads as follows:

52.212–3 Offeror Representations and Certifications—Commercial Items.

* * * * *

Offer Representations and Certifications—Commercial Items (NOV 2011)

* * * * *

(a) *Definitions.* * * *

* * * * *

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

* * * * *

(o) *Sanctioned activities relating to Iran.* (1) The offeror shall email questions concerning sensitive technology to the Department of State at *CISADA106@state.gov.*

(2) *Representation and Certification.* Unless a waiver is granted or an exception applies as provided in paragraph (o)(3) of this provision, by submission of its offer, the offeror—

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran; and

(ii) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act.

(3) The representation and certification requirements of paragraph (o)(2) of this provision do not apply if—

(i) This solicitation includes a trade agreements certification (*e.g.,* 52.212–3(g) or a comparable agency provision); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products.

* * * * *

■ 10. Revise section 52.225–25 to read as follows:

52.225–25 Prohibition on Contracting with Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification.

As prescribed at 25.1103(e), insert the following provision:

Prohibition on Contracting With Entities Engaging in Sanctioned Activities Relating to Iran—Representation and Certification (NOV 2011)

(a) *Definitions.* As used in this provision—

Person—

(1) Means—

(i) A natural person;

(ii) A corporation, business association, partnership, society, trust, financial institution, insurer, underwriter, guarantor, and any other business organization, any other nongovernmental entity, organization, or group, and any governmental entity operating as a business enterprise; and

(iii) Any successor to any entity described in paragraph (1)(ii) of this definition; and

(2) Does not include a government or governmental entity that is not operating as a business enterprise.

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

(b) The offeror shall email questions concerning sensitive technology to the Department of State at *CISADA106@state.gov.*

(c) Except as provided in paragraph (d) of this provision or if a waiver has been granted in accordance with 25.703–4, by submission of its offer, the offeror—

(1) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran; and

(2) Certifies that the offeror, or any person owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Iran Sanctions Act. These sanctioned activities are in the areas of development of the petroleum resources of Iran, production of refined petroleum products in Iran, sale and provision of refined petroleum products to Iran, and contributing to Iran's ability to acquire or develop certain weapons or technologies.

(d) *Exception for trade agreements.* The representation requirement of paragraph (c)(1) and the certification requirement of paragraph (c)(2) of this provision do not apply if—

(1) This solicitation includes a trade agreements notice or certification (*e.g.,* 52.225–4, 52.225–6, 52.225–12, 52.225–24, or comparable agency provision); and

(2) The offeror has certified that all the offered products to be supplied are designated country end products or designated country construction material.

(End of provision)

[FR Doc. 2011–27784 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 8, 12, 16, 19, 38, and 52

[FAC 2005–54; FAR Case 2011–024; Item VI; Docket 2011–0024, Sequence 01]

RIN 9000–AM12

Federal Acquisition Regulation; Set-Asides for Small Business

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule.

SUMMARY: DoD, GSA, and NASA are issuing an interim rule amending the Federal Acquisition Regulation (FAR) to implement section 1331 of the Small Business Jobs Act of 2010 (Jobs Act). Section 1331 addresses set-asides of task- and delivery-orders under multiple-award contracts, partial set-asides under multiple-award contracts, and the reserving of one or more multiple-award contracts that are awarded using full and open competition. Within this same context, section 1331 also addresses the Federal Supply Schedules Program managed by GSA. DoD, GSA, and NASA are coordinating with the Small Business Administration (SBA) on the development of an SBA proposed rule that will provide greater detail regarding implementation of section 1331 authorities.

DATES: *Effective Date:* November 2, 2011.

Comment Date: Interested parties should submit written comments to the Regulatory Secretariat on or before January 3, 2012 to be considered in the formation of a final rule.

Applicability Date: Contracting officers are encouraged to modify, on a bilateral basis, existing multiple-award contracts in accordance with FAR 1.108(d)(3), if the remaining period of performance extends at least six months after the effective date, and the amount of work or number of orders expected under the remaining performance period is substantial.

ADDRESSES: Submit comments identified by FAC 2005–54, FAR Case 2011–024, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by inputting ''FAR Case 2011–024'' under the heading ''Enter Keyword or ID'' and selecting ''Search.'' Select the link ''Submit a Comment'' that corresponds with ''FAR Case 2011–024.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''FAR Case 2011–024'' on your attached document.
- *Fax:* (202) 501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Hada Flowers, 1275 First Street, NE., 7th Floor, Washington, DC 20417.

Instructions: Please submit comments only and cite FAC 2005–54, FAR Case 2011–024, in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Karlos Morgan, Procurement Analyst, at (202) 501–2364, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2011–024.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past 15 years, Federal agencies have increasingly used multiple award contracts—including the Federal Supply Schedules managed by GSA, governmentwide acquisition contracts, multi-agency contracts, and agency-specific indefinite-delivery, indefinite-quantity (IDIQ) contracts—to acquire a wide range of products and services. This trend has created challenges for agencies seeking to provide maximum opportunity for small businesses. Although set-asides are one of the most effective tools agencies have at their disposal to help small businesses participate in Government contracting opportunities, the FAR is silent on how to apply set-asides at the task-or-delivery order level.

In September 2010, the Interagency Task Force on Small Business Contracting, created by the President in April of that year, issued a report recommending that the rules on set-asides, including for multiple-award contracts, be clarified, and that legislation be developed where it is determined that statutory changes are warranted. The Task Force noted that set-asides accounted for approximately half of all small business contract awards in FY 2009, yet ''there has been no attempt to create a comprehensive policy for orders placed under either general task- and delivery-order contracts or schedule contracts that rationalizes and appropriately balances the need for efficiency with the need to maximize opportunities for small businesses.'' For a copy of the report, go to *http://www.sba.gov/sites/default/files/contracting_task_force_report_0.pdf.*

The same month as the Task Force report was issued, the President signed the Jobs Act (Pub. L. 111–240) into law to protect the interests of small businesses and expand their opportunities in the Federal marketplace. Section 1331 of the Jobs Act amends section 15 of the Small Business Act (Pub. L. 85–536) to add a new subsection (r) stating, in pertinent part, that:

The Administrator, Office of Federal Procurement Policy (OFPP) and the Administrator, U.S. Small Business Administration (SBA), in consultation with the Administrator of the General Services, shall, by regulation, establish guidance under which Federal agencies may, at their discretion—

(1) Set aside part or parts of a multiple-award contract for small business concerns, including the subcategories of small business concerns identified in subsection (g)(2) of the Small Business Act;

(2) Notwithstanding the fair opportunity requirements under section 2304c(b) of Title 10, United States Code, and section 303J(b) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253j(b)) (subsequently recodified as 41 U.S.C. 4106), set aside orders placed against multiple-award contracts for small business concerns, including the subcategories of small business concerns identified in subsection (g)(2) of the Small Business Act; and

(3) Reserve one or more contract awards for small business concerns under full and open multiple-award procurements, including the subcategories of small business concerns identified in subsection (g)(2) of the Small Business Act.

SBA and OFPP, which are vested under section 1331 with the authority to issue regulations, in consultation with the Administrator of GSA, have requested that DoD, GSA, and NASA publish this interim rule in order to provide agencies with guidance that they can use in taking advantage of this important tool, while SBA completes the drafting and coordination of a proposed rule that will set forth more specific guidance. This interim rule amends—

- FAR subpart 8.4 to make clear that order set-asides may be used in connection with the placement of orders and blanket purchase agreements under Federal Supply Schedules;
- FAR subpart 12.2 to acknowledge that discretionary set-asides may be used if placing an order under a multiple-award contract;
- FAR subpart 16.5 to acknowledge that set-asides may be used in connection with the placement of orders under multiple-award contracts, notwithstanding the requirement to provide each contract holder a fair opportunity to be considered;
- FAR part 19 to add a new section authorizing agencies to (1) use set-asides under multiple-award contracts—including set-asides for small businesses participating in the small business programs identified in FAR 19.000(a)(3); and (2) reserve one or more contract awards under multiple-award contracts for small businesses, including any of the socio-economic groups; and
- FAR subpart 38.1 to add a reference to FAR 8.405–5 to make clear that order set-asides may be used in connection with the placement of orders and blanket purchase agreements under Federal Supply Schedules.

This interim rule also amends existing solicitation provisions and contract clauses, including FAR 52.219–6 to provide notice of total set-asides and partial set-asides under multiple-award contracts, and revises existing contract clauses to address limitations on subcontracting for small businesses under multiple award contracts.

DoD, GSA, and NASA expect agencies to take advantage of set-asides under multiple-award contracts by: (1) Identifying existing or prospective multiple-award contracts with small business contract holders where order set-asides may be appropriate, and (2) maximizing opportunities for small business by utilizing order set-asides under the Federal Supply Schedule Program.

II. Executive Order 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

The change may have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act 5 U.S.C. 601, *et seq.* The Initial Regulatory Flexibility Analysis (IRFA) is summarized as follows:

The Administrator of the Office of Management and Budget's Office of Federal Procurement Policy requested that DoD, GSA, and NASA amend the FAR to provide preliminary implementation of section 1331 of the Small Business Jobs Act of 2010 (Jobs Act).

DoD, GSA, and NASA are amending the FAR to implement the authority to (1) set aside part or parts of a multiple-award contract for small business concerns; (2) set aside orders placed against multiple-award contracts, including Federal Supply Schedules, for small business concerns; and (3) reserve one or more contract awards under full and open multiple-award procurements, for small business concerns.

The objective of this rule is to provide an additional tool for agencies to increase opportunities for small business to compete in the Federal marketplace. The statutory authority for this action is Small Business

Jobs Act of 2010, Pub. L. 111–240, 15 U.S.C. 644(r).

This rule may have a significant positive economic impact on any small business entity that wishes to participate in the Federal procurement arena. Analysis of the Central Contractor Registration database indicates there are over 351,203 small business registrants that can potentially benefit from the implementation of this rule.

This rule does not impose any new reporting, recordkeeping, or other compliance requirements. The rule does not duplicate, overlap, or conflict with any other Federal rules.

The Regulatory Secretariat will be submitting a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAC 2005–54, FAR Case 2011–024) in correspondence.

IV. Paperwork Reduction Act

The interim rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

V. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense (DoD), the Administrator of General Services (GSA), and the Administrator of the National Aeronautics and Space Administration (NASA) that urgent and compelling reasons exist to promulgate this interim rule without prior opportunity for public comment. This action is necessary because section 1331 of the Jobs Act calls for the issuance, within one year of the law's enactment (September 27, 2010), of ''a regulation, to establish guidance under which Federal agencies may, at their discretion—'' set aside task-and-delivery orders under multiple-award contracts, use partial set-asides under multiple-award contracts, and reserve one or more contracts under procurements awarded using full and open competition.

Despite the progress agencies have made over the past two years in increasing the amount of contracting dollars awarded to small businesses, the set-aside authority for multiple-award contracts conveyed by this interim rule may serve as the linchpin to closing the remaining shortfall agencies are experiencing in meeting their small business contracting goals. As such, valuable opportunities to help small businesses through set-asides and reserves under multiple-award contracts will be lost while the rulemaking process moves forward. Issuing an interim rule that is effective upon publication, prior to the receipt of public comment, will allow agencies to immediately begin taking advantage of set-asides under multiple-award contracts, as envisioned by the Jobs Act, to increase awards to small businesses. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), DoD, GSA, and NASA will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 8, 12, 16, 19, 38, and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 8, 12, 16, 19, 38, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 8, 12, 16, 19, 38, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES

■ 2. Amend section 8.405–5 by revising paragraph (a); and redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively; and adding a new paragraph (b) to read as follows:

8.405–5 Small business.

(a) Although the preference programs of part 19 are not mandatory in this subpart, in accordance with section 1331 of Public Law 111–240 (15 U.S.C. 644(r))—

(1) Ordering activity contracting officers may, at their discretion—

(i) Set aside orders for any of the small business concerns identified in 19.000(a)(3); and

(ii) Set aside BPAs for any of the small business concerns identified in 19.000(a)(3).

(2) When setting aside orders and BPAs—

(i) Follow the ordering procedures for Federal Supply Schedules at 8.405–1, 8.405–2, and 8.405–3; and

(ii) The specific small business program eligibility requirements identified in part 19 apply.

(b) Orders placed against schedule contracts may be credited toward the ordering activity's small business goals. For purposes of reporting an order placed with a small business schedule contractor, an ordering agency may only take credit if the awardee meets a size standard that corresponds to the work performed. Ordering activities should rely on the small business representations made by schedule contractors at the contract level.

* * * * *

PART 12—ACQUISITION OF COMMERCIAL ITEMS

■ 3. Amend section 12.207 by revising paragraph (b)(1)(i)(C) to read as follows:

12.207 Contract type.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(C) The fair opportunity procedures in 16.505 (including discretionary small business set-asides under 16.505(b)(2)(i)(F)), if placing an order under a multiple-award delivery-order contract; and

* * * * *

PART 16—TYPES OF CONTRACTS

■ 4. Amend section 16.505 by—

■ a. Revising the introductory text of paragraph (b);

■ b. Adding paragraph (b)(2)(i)(F);

■ c. Revising the introductory text of paragraph (b)(2)(ii); and

■ d. Revising paragraph (b)(2)(ii)(D)(*5*).

The revised and added text reads as follows:

16.505 Ordering.

* * * * *

(b) Orders under multiple-award contracts—

* * * * *

(2) * * *

(i) * * *

(F) In accordance with section 1331 of Public Law 111–240 (15 U.S.C. 644(r)), contracting officers may, at their discretion, set aside orders for any of the small business concerns identified in 19.000(a)(3). When setting aside orders for small business concerns, the specific small business program eligibility requirements identified in part 19 apply.

(ii) The justification for an exception to fair opportunity shall be in writing as

specified in paragraphs (b)(2)(ii)(A) or (B) of this section. No justification is needed for the exception described in paragraph (b)(2)(i)(F) of this section.

* * * * *

(D) * * *

(*5*) The posting requirement of this section does not apply—

(*i*) When disclosure would compromise the national security (*e.g.,* would result in disclosure of classified information) or create other security risks; or

(*ii*) To a small business set-aside under paragraph (b)(2)(i)(F).

* * * * *

PART 19—SMALL BUSINESS PROGRAMS

19.502–4 and 19.502–5 [Redesignated as 19.502–5 and 19.502–6]

■ 5a. Redesignate sections 19.502–4 and 19.502–5 as sections 19.502–5 and 19.502–6, respectively.

■ 5b. Add a new section 19.502–4 to read as follows:

19.502–4 Multiple-award contracts and small business set-asides.

In accordance with section 1331 of Public Law 111–240 (15 U.S.C. 644(r)) contracting officers may, at their discretion—

(a) When conducting multiple-award procurements using full and open competition, reserve one or more contract awards for any of the small business concerns identified in 19.000(a)(3). The specific program eligibility requirements identified in this part apply;

(b) Set aside part or parts of a multiple-award contract for any of the small business concerns identified in 19.000(a)(3). The specific program eligibility requirements identified in this part apply; or

(c) Set aside orders placed under multiple-award contracts for any of the small business concerns identified in 19.000(a)(3). For orders placed under the Federal Supply Schedules Program see 8.405–5. For all other multiple-award contracts see 16.505.

* * * * *

■ 6. Amend section 19.508 by revising paragraphs (c), (d), and (e); and adding paragraph (f) to read as follows:

19.508 Solicitation provisions and contract clauses.

* * * * *

(c) The contracting officer shall insert the clause at 52.219–6, Notice of Total Small Business Set-Aside, in solicitations and contracts involving total small business set-asides or reserves. This includes multiple-award contracts when orders may be set aside for any of the small business concerns identified in 19.000(a)(3), as described in 8.405–5 and 16.505(b)(2)(i)(F). The clause at 52.219–6 with its Alternate I will be used when the acquisition is for a product in a class for which the Small Business Administration has waived the nonmanufacturer rule (see 19.102(f)(4) and (5)). Use the clause at 52.219–6 with its Alternate II when including FPI in the competition in accordance with 19.504.

(d) The contracting officer shall insert the clause at 52.219–7, Notice of Partial Small Business Set-Aside, in solicitations and contracts involving partial small business set-asides. This includes part or parts of multiple-award contracts, including those described in 38.101. The clause at 52.219–7 with its Alternate I will be used when the acquisition is for a product in a class for which the Small Business Administration has waived the nonmanufacturer rule (see 19.102(f)(4) and (5)). Use the clause at 52.219–7 with its Alternate II when including FPI in the competition in accordance with 19.504.

(e) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in solicitations and contracts for supplies, services, and construction, if any portion of the requirement is to be set aside or reserved for small business and the contract amount is expected to exceed $150,000. This includes multiple-award contracts when orders may be set aside for small business concerns, as described in 8.405–5 and 16.505(b)(2)(i)(F).

(f) The contracting officer shall insert the clause at 52.219–13, Notice of Set-Aside of Orders, in solicitations and contracts to notify offerors if an order or orders are to be set aside for any of the small business concerns identified in 19.000(a)(3).

■ 7. Amend section 19.811–3 by revising paragraph (e) to read as follows:

19.811–3 Contract clauses.

* * * * *

(e) The contracting officer shall insert the clause at 52.219–14, Limitations on Subcontracting, in any solicitation and contract resulting from this subpart. This includes multiple-award contracts when orders may be set aside for 8(a) concerns as described in 8.405–5 and 16.505(b)(2)(i)(F).

■ 8. Amend section 19.1304 by revising paragraphs (b) and (c) to read as follows:

19.1304 Exclusions.

* * * * *

(b) Orders under indefinite-delivery contracts (see subpart 16.5). (But see 16.505(b)(2)(i)(F) for discretionary set-asides of orders);

(c) Orders against Federal Supply Schedules (see subpart 8.4). (But see 8.405–5 for discretionary set-asides of orders);

* * * * *

19.1308 [Amended]

■ 9. Amend section 19.1308 by removing from the first sentence of paragraph (b) ''of Total Hubzone'' and adding ''of Hubzone'' in its place.

■ 10. Amend section 19.1309 by revising the introductory text of paragraph (a) to read as follows:

19.1309 Contract clauses.

(a) The contracting officer shall insert the clause 52.219–3, Notice of HUBZone Set-Aside or Sole Source Award, in solicitations and contracts for acquisitions that are set aside, or reserved for, or awarded on a sole source basis to, HUBZone small business concerns under 19.1305 or 19.1306. This includes multiple-award contracts when orders may be set aside for HUBZone small business concerns as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

■ 11. Amend section 19.1404 by revising paragraphs (b) and (c) to read as follows:

19.1404 Exclusions.

* * * * *

(b) Orders under indefinite-delivery contracts (see subpart 16.5). (But see 16.505(b)(2)(i)(F) for discretionary set-asides of orders);

(c) Orders against Federal Supply Schedules (see subpart 8.4). (But see 8.405–5 for discretionary set-asides of orders); or

* * * * *

■ 12. Revise section 19.1407 to read as follows:

19.1407 Contract clauses.

The contracting officer shall insert the clause 52.219–27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside, in solicitations and contracts for acquisitions that are set aside or reserved for, or awarded on a sole source basis to, service-disabled veteran-owned small business concerns under 19.1405 and 19.1406. This includes multiple-award contracts when orders may be set aside for service-disabled veteran-owned small business concerns as described in 8.405–5 and 16.505(b)(2)(i)(F).

■ 13. Amend section 19.1504 by revising paragraphs (c) and (d) to read as follows:

19.1504 Exclusions.

* * * * *

(c) Orders under indefinite-delivery contracts (see subpart 16.5). (But see 16.505(b)(2)(i)(F) for discretionary set-asides of orders); or (d) Orders against Federal Supply Schedules (see subpart 8.4). (But see 8.405–5 for discretionary set-asides of orders.)

■ 14. Amend section 19.1506 by revising paragraphs (a) and (b) to read as follows:

19.1506 Contract clauses.

(a) The contracting officer shall insert the clause 52.219–29, Notice of Set-Aside for Economically Disadvantaged Women-owned Small Business Concerns, in solicitations and contracts for acquisitions that are set aside or reserved for economically disadvantaged women-owned small business (EDWOSB) concerns under 19.1505(b). This includes multiple-award contracts when orders may be set aside for EDWOSB concerns as described in 8.405–5 and 16.505(b)(2)(i)(F).

(b) The contracting officer shall insert the clause 52.219–30, Notice of Set-Aside for Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program, in solicitations and contracts for acquisitions that are set aside or reserved for women-owned small business (WOSB) concerns under 19.1505(c). This includes multiple-award contracts when orders may be set aside for WOSB concerns eligible under the WOSB program as described in 8.405–5 and 16.505(b)(2)(i)(F).

PART 38—FEDERAL SUPPLY SCHEDULE CONTRACTING

38.101 [Amended]

■ 15. Amend section 38.101 by removing from paragraph (e) ''(except see 8.404).'' and adding ''(except see 8.404 and 8.405–5).'' in its place.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 16. Amend section 52.212–5 by—

■ a. Revising the date of the clause and paragraphs (b)(8) and (b)(11);

■ b. Redesignating paragraphs (b)(15) through (b)(49) as paragraphs (b)(16) through (b)(50), respectively;

■ c. Adding a new paragraph (b)(15); and

■ d. Revising newly redesignated paragraphs (b)(16), (b)(21), (b)(23), and (b)(24).

The revised and added text reads as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Items (NOV 2011)

* * * * *

(b) * * *

__(8) *52.219–3,* Notice of HUBZone Set-Aside or Sole-Source Award (NOV 2011) (*15 U.S.C. 657a*).

* * * * *

__(11)(i) 52.219–6, Notice of Total Small Business Set-Aside (NOV 2011) (*15 U.S.C. 644*).

__(ii) Alternate I (NOV 2011).

__(iii) Alternate II (NOV 2011).

* * * * *

__(15) 52.219–13, Notice of Set-Aside of Orders (NOV 2011) (15 U.S.C. 644(r)).

__(16) *52.219–14,* Limitations on Subcontracting (NOV 2011) (*15 U.S.C. 637(a)(14)*).

* * * * *

__(21) *52.219–27,* Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (NOV 2011) (*15 U.S.C. 657f*).

* * * * *

__(23) *52.219–29,* Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business Concerns (NOV 2011).

__(24) *52.219–30,* Notice of Set-Aside for Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (NOV 2011).

* * * * *

■ 17. Amend section 52.219–3 by—

■ a. Revising the section heading, the clause heading, and the date of the clause;

■ b. Redesignating paragraphs (b) through (f) as paragraphs (c) through (g), respectively;

■ c. Adding a new paragraph (b);

■ d. Removing from the newly redesignated paragraph (e) ''in paragraph (c) of'' and adding ''in paragraph (d) of'' in its place;

■ e. Removing from the newly redesignated paragraph (f) ''Paragraphs (e)(1) and (e)(2) of'' and adding ''Paragraphs (f)(1) and (f)(2) of'' in its place; and

■ f. In Alternate I, revising the date and introductory text; and redesignating paragraphs (c)(3) and (c)(4) as paragraphs (d)(3) and (d)(4), respectively.

The revised and added text reads as follows:

52.219–3 Notice of HUBZone Set-Aside or Sole Source Award.

* * * * *

Notice of HUBZone Set-Aside or Sole Source Award (NOV 2011)

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been set aside or reserved for, or awarded on a sole source basis to, HUBZone small business concerns;

(2) Part or parts of a multiple-award contract that have been set aside for HUBZone small business concerns; and

(3) Orders set-aside for HUBZone small business concerns under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

Alternate I (NOV 2011). As prescribed in *19.1309*(a)(1), substitute the following paragraphs (d)(3) and (d)(4) for paragraphs (d)(3) and (d)(4) of the basic clause:

* * * * *

■ 18. Amend section 52.219–6 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d), respectively;

■ c. Adding a new paragraph (b);

■ d. In Alternate I, revising the date; and removing from the end of the paragraph ''delete paragraph (c).'' and adding ''delete paragraph (d).'' in its place; and

■ e. In Alternate II, revising the date and introductory text; and redesignating paragraph (b) as paragraph (c), respectively.

The revised and added text reads as follows:

52.219–6 Notice of Total Small Business Set-Aside.

* * * * *

Notice of Total Small Business Set-Aside (NOV 2011)

* * * * *

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been totally set aside or reserved for small business concerns; and

(2) Orders set aside for small business concerns under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

Alternate I (NOV 2011). * * *

Alternate II (NOV 2011). As prescribed in *19.508*(c), substitute the following paragraph (c) for paragraph (c) of the basic clause:

* * * * *

■ 19. Add section 52.219–13 to read as follows:

52.219–13 Notice of Set-Aside of Orders.

As prescribed in 19.508(f), insert the following clause:

Notice of Set-Aside of Orders (Nov 2011)

The Contracting Officer will give notice of the order or orders, if any, to be set aside for small business concerns identified in 19.000(a)(3) and the applicable small

business program. This notice, and its restrictions, will apply only to the specific orders that have been set aside for any of the small business concerns identified in 19.000(a)(3).

(End of clause)

■ 20. Amend section 52.219–14 by—
■ a. Revising the date of the clause;
■ b. Redesignating paragraph (b) as paragraph (c; and
■ c. Adding a new paragraph (b) to read as follows:

52.219–14 Limitations on Subcontracting.

* * * * *

Limitations on Subcontracting (Nov 2011)

* * * * *

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been set aside or reserved for small business concerns or 8(a) concerns;

(2) Part or parts of a multiple-award contract that have been set aside for small business concerns or 8(a) concerns; and

(3) Orders set aside for small business or 8(a) concerns under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

■ 21. Amend section 52.219–27 by—
■ a. Revising the section heading, the clause heading, and the date of the clause;
■ b. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively; and
■ c. Adding a new paragraph (b).

The revised and added text reads as follows:

52.219–27 Notice of Service-Disabled Veteran-Owned Small Business Set-Aside.

* * * * *

Notice of Service-Disabled Veteran-Owned Small Business Set-Aside (Nov 2011)

* * * * *

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been set aside or reserved for service-disabled veteran-owned small business concerns;

(2) Part or parts of a multiple-award contract that have been set aside for service-disabled veteran-owned small business concerns; and

(3) Orders set aside for service-disabled veteran-owned small business concerns under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

■ 22. Amend section 52.219–29 by—
■ a. Revising the section heading, the clause heading, and the date of the clause;
■ b. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively;
■ c. Adding a new paragraph (b); and
■ d. Removing from the newly redesignated paragraph (e)(4) ''paragraph (c) above'' and adding ''paragraph (d) above'' in its place.

The revised and added text reads as follows:

52.219–29 Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business Concerns.

* * * * *

Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business Concerns (Nov 2011)

* * * * *

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been set aside or reserved for EDWOSB concerns;

(2) Part or parts of a multiple-award contract that have been set aside for EDWOSB concerns; and

(3) Orders set aside for EDWOSB concerns under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

■ 23. Amend section 52.219–30 by—
■ a. Revising the section heading, the clause heading, and the date of the clause;
■ b. Redesignating paragraphs (b) through (e) as paragraphs (c) through (f), respectively;
■ c. Adding a new paragraph (b); and
■ d. Removing from the newly redesignated paragraph (e)(4) ''paragraph (c) above'' and adding ''paragraph (d) above'' in its place.

The revised and added text reads as follows:

52.219–30 Notice of Set-Aside for Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program.

* * * * *

Notice of Set-Aside for Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program (Nov 2011)

* * * * *

(b) *Applicability.* This clause applies only to—

(1) Contracts that have been set aside or reserved for WOSB concerns eligible under the WOSB Program;

(2) Part or parts of a multiple-award contract that have been set aside for WOSB concerns eligible under the WOSB Program; and

(3) Orders set aside for WOSB concerns eligible under the WOSB Program, under multiple-award contracts as described in 8.405–5 and 16.505(b)(2)(i)(F).

* * * * *

[FR Doc. 2011–27786 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 25

[FAC 2005–54; FAR Case 2009–041; Item VII; Docket 2010–0105, Sequence 1]

RIN 9000–AL65

Federal Acquisition Regulation; Sudan Waiver Process

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to revise the prohibition on contracting with entities that conduct restricted business operations in Sudan. This rule adds specific criteria including foreign policy aspects that an agency must address when applying to the President or his appointed designee for a waiver of the prohibition on awarding a contract to a contractor that conducts restricted business operations in Sudan. The rule also describes the consultation process that will be used by the Office of Federal Procurement Policy (OFPP) in support of the waiver request review.

DATES: *Effective Date:* December 2, 2011.

FOR FURTHER INFORMATION CONTACT: Cecelia L. Davis, Procurement Analyst, at (202) 219–0202, for clarification of content. For information pertaining to status or publication schedules, contact the FAR Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2009–041.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 75 FR 62069 on October 7, 2010, to revise FAR 25.702, Prohibition on contracting with entities that conduct restricted business operations in Sudan, to add specific criteria including foreign policy aspects that an agency must address when applying to the President or his appointed designee for a waiver of the prohibition on awarding a contract to a contractor that conducts restricted business operations in Sudan. The rule also describes the consultation process that will be used by OFPP in support of the waiver review. No comments were received by the close of

the public comment period on December 6, 2010.

DoD, GSA, and NASA published a final rule, FAR Case 2008–004, Prohibition on Restricted Business Operations in Sudan and Imports from Burma, in the **Federal Register** at 74 FR 40463 on August 11, 2009, amending the FAR to implement section 6 of the Sudan Accountability and Divestment Act of 2007 (the Act), Public Law 110–174.

Section 6(a) of the Act requires that each contract entered into by an Executive agency include a certification that the contractor does not conduct certain business operations in Sudan as described in section 3(d) of the Act. Pursuant to section 6(c), the President may waive this certification requirement on a case-by-case basis if the President determines and certifies to the appropriate congressional committees that it is in the national interest to do so.

Section 6 of the Act was implemented in the FAR but did not include a waiver consultation process and specific criteria for the waiver request. With the addition of these changes, the FAR will provide consistent guidance on specific criteria that must be included in the waiver request for consideration, and establish a consultation process to ensure all waiver requests are reviewed by the appropriate agency experts.

OFPP will be required to consult with the President's National Security Council, Office of African Affairs and the Department of State Sudan Office and Sanctions Office on foreign policy matters relevant to the waiver request and include this information in the recommendation to the President. All waiver requests must clearly explain why the product or service must be procured from the offeror for which the waiver is requested and why it is in the national interest to waive the statutory prohibition against contracting with an offeror that conducts restricted business operations in Sudan. In addition, the waiver request must address any humanitarian efforts engaged in by the offeror, the human rights impact of doing business with that offeror, and the extent of the offeror's business operations in Sudan. All of the information required to be included in the waiver request will be considered in determining whether to recommend that the President waive the prohibition.

Additionally, individual and class waiver requests will be considered for a specific contract or class of contracts, as long as the waiver request has been reviewed and cleared by the agency head prior to submitting it to OFPP and the request includes the appropriate waiver information specified at FAR 25.702–4(c)(3). However, a waiver will not be issued for an indefinite period of time, and may be cancelled, if warranted.

In accordance with section 6 of the Act, the Administrator of OFPP is required to submit semiannual reports, on April 15th and October 15th, to Congress, on waivers approved by the President.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because the rule does not impose any additional requirements on small businesses.

IV. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 25

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 25 as set forth below:

PART 25—FOREIGN ACQUISITION

■ 1. The authority citation for 48 CFR part 25 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

■ 2. Amend section 25.702–4 by revising paragraph (b); and adding paragraphs (c) and (d) to read as follows:

25.702–4 Waiver.

* * * * *

(b) An agency seeking waiver of the requirement shall submit the request to the Administrator of the Office of Federal Procurement Policy (OFPP), allowing sufficient time for review and approval. Upon receipt of the waiver request, OFPP shall consult with the President's National Security Council, Office of African Affairs, and the Department of State Sudan Office and Sanctions Office to assess foreign policy aspects of making a national interest recommendation.

(c) Agencies may request a waiver on an individual or class basis; however, waivers are not indefinite and can be cancelled if warranted.

(1) A class waiver may be requested only when the class of supplies is not available from any other source and it is in the national interest.

(2) Prior to submitting the waiver request, the request must be reviewed and cleared by the agency head.

(3) All waiver requests must include the following information:

(i) Agency name, complete mailing address, and point of contact name, telephone number, and email address;

(ii) Offeror's name, complete mailing address, and point of contact name, telephone number, and email address;

(iii) Description/nature of product or service;

(iv) The total cost and length of the contract;

(v) Justification, with market research demonstrating that no other offeror can provide the product or service and stating why the product or service must be procured from this offeror, as well as why it is in the national interest for the President to waive the prohibition on contracting with this offeror that conducts restricted business operations in Sudan, including consideration of foreign policy aspects identified in consultation(s) pursuant to 25.702–4(b);

(vi) Documentation regarding the offeror's past performance and integrity (see the Past Performance Information Retrieval System including the Federal Awardee Performance Information and Integrity System at *http://www.ppirs.gov* and any other relevant information);

(vii) Information regarding the offeror's relationship or connection with

other firms that conduct prohibited business operations in Sudan; and

(viii) Any humanitarian efforts engaged in by the offeror, the human rights impact of doing business with the offeror for which the waiver is requested, and the extent of the offeror's business operations in Sudan.

(d) The consultation in 25.702–4(b) and the information in 25.702–4(c)(3) will be considered in determining whether to recommend that the President waive the requirement of subsection 25.702–2. In accordance with section 6(c) of the Sudan Accountability and Divestment Act of 2007, OFPP will semiannually submit a report to Congress, on April 15th and October 15th, on the waivers granted.

[FR Doc. 2011–27788 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 25 and 52

[FAC 2005–54; FAR Case 2011–014; Item VIII; Docket 2011–0014, Sequence 1]

RIN 9000–AM11

Federal Acquisition Regulation; Successor Entities to the Netherlands Antilles

AGENCIES: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to revise the definitions of ''Caribbean Basin country'' and ''designated country'' due to the change in status of the islands that comprised the Netherlands Antilles.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, at (202) 219–0202, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2011–014.

SUPPLEMENTARY INFORMATION:

I. Background

The Netherlands Antilles was designated as a beneficiary country under the Caribbean Basin Initiative (see 19 U.S.C. 2702). According to the initiative, successor political entities remain eligible as beneficiary countries. On October 10, 2010, Curacao and Sint Maarten became autonomous territories of the Kingdom of the Netherlands. Bonaire, Saba, and Sint Eustatius now fall under the direct administration of the Netherlands. Additional information about this change is available at *http://www.state.gov/r/pa/ei/bgn/22528.htm.*

With this change, the definitions have been revised to replace ''Netherlands Antilles'' with the five separate successor entities—Bonaire, Curacao, Saba, Sint Eustatius, and Sint Maarten.

This final rule amends definitions of ''Caribbean Basin country'' and ''designated country'' at FAR 25.003, and FAR clauses 52.225–5, Trade Agreements; 52.225–11, Buy American Act—Construction Materials under Trade Agreements; and 52.225–23, Required Use of American Iron, Steel, and Manufactured Goods—Buy American Act—Construction Materials Under Trade Agreements.

II. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

III. Regulatory Flexibility Act

The Regulatory Flexibility Act does not apply to this rule because this final rule does not constitute a significant FAR revision within the meaning of FAR 1.501–1 and 41 U.S.C. 1707 and does not require publication for public comment.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. chapter 35) does apply; however, these changes to the FAR do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 9000–0141 titled: Buy American Act—Construction.

List of Subjects in 48 CFR Parts 25 and 52

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 25 and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 25 and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 25—FOREIGN ACQUISITION

■ 2. Amend section 25.003 by revising the definition ''Caribbean Basin country'' and paragraph (4) in the definition ''Designated country'' to read as follows:

25.003 Definitions.

* * * * *

Caribbean Basin country means any of the following countries: Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago.

* * * * *

Designated country * * *

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

* * * * *

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. Amend section 52.212–5 by revising the date of the clause and paragraph (b)(39) to read as follows:

52.212–5 Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items.

* * * * *

Contract Terms and Conditions Required to Implement Statutes or Executive Orders—Commercial Items (NOV 2011)

* * * * *

(b) * * *

__(39) 52.225–5, Trade Agreements (NOV 2011) (19 U.S.C. 2501, *et seq.,* 19 U.S.C. 3301 note).

■ 4. Amend section 52.225–5 by revising the date of the clause; and in paragraph (a), by revising paragraph (4) in the definition ''Designated country'' to read as follows:

52.225–5 Trade Agreements.

* * * * *

Trade Agreements (NOV 2011)

(a) *Definitions.* * * *

* * * * *

Designated country * * *

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

* * * * *

■ 5. Amend section 52.225–11 by revising the date of the clause; and in paragraph (a), by revising paragraph (4) in the definition ''Designated country'' to read as follows:

52.225–11 Buy American Act—Construction Materials under Trade Agreements.

* * * * *

Buy American Act—Construction Materials Under Trade Agreements (NOV 2011)

(a) *Definitions.* * * *

* * * * *

Designated country * * *

(4) A Caribbean Basin country ((Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

* * * * *

■ 6. Amend section 52.225–23 by revising the date of the clause, and paragraph (4) in the definition ''Designated country'' to read as follows:

52.225–23 Required Use of American Iron, Steel, and Manufactured Goods—Buy American Act—Construction Materials Under Trade Agreements.

* * * * *

Required Use of American Iron, Steel, and Manufactured Goods—Buy American Act—Construction Materials Under Trade Agreements (NOV 2011)

* * * * *

Designated country * * *

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

* * * * *

[FR Doc. 2011–27789 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 31

[FAC 2005–54; FAR Case 2009–006; Item IX; Docket 2010–0084, Sequence 1]

RIN 9000–AL39

Federal Acquisition Regulation; Labor Relations Costs

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: DoD, GSA, and NASA are issuing a final rule amending the Federal Acquisition Regulation (FAR) to implement the Executive Order (E.O.) on Economy in Government Contracting, issued on January 30, 2009, and amended on October 30, 2009. This E.O. treats as unallowable the costs of any activities undertaken to persuade employees, whether employees of the recipient of Federal disbursements or of any other entity, to exercise or not to exercise, or concerning the manner of exercising, the right to organize and bargain collectively through representatives of the employee's own choosing.

DATES: *Effective Date:* December 2, 2011.

FOR FURTHER INFORMATION CONTACT: Mr. Edward N. Chambers, Procurement Analyst, at (202) 501–3221, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755. Please cite FAC 2005–54, FAR Case 2009–006.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 75 FR 19345 on April 14, 2010, to implement E.O. 13494, Economy in Government Contracting, dated January 30, 2009, published in the **Federal Register** at 74 FR 6101 on February 4, 2009, as amended on October 30, 2009 (published in the **Federal Register** at 74 FR 57239 on November 5, 2009). This E.O. promotes economy and efficiency in Government contracting by providing that certain costs that are not directly related to the contractor's provision of goods and services to the Government shall be unallowable for payment, thereby directly reducing Government expenditures and reinforcing the fiscally responsible handling of taxpayer funds. Specifically, this E.O. states that the costs of the activities of preparing and distributing materials, hiring or consulting legal counsel or consultants, holding meetings (including paying the salaries of the attendees at meetings held for this purpose), and planning or conducting activities by managers, supervisors, or union representatives during work hours, when they are undertaken to persuade employees to exercise or not to exercise, or concern the manner of exercising, rights to organize and bargain collectively are unallowable costs.

In order to implement E.O. 13494, DoD, GSA, and NASA have amended FAR 31.205–21, the cost principle addressing labor relations costs. Currently, this cost principle states that costs incurred in maintaining satisfactory relations between the contractor and its employees, including costs of shop stewards, labor management committees, employee publications, and other related activities, are allowable. To implement the requirements of the E.O., DoD, GSA, and NASA issued a proposed rule that would amend this cost principle by adding a new paragraph addressing the handling of persuader activities—that is, activity involving the persuading of employees to exercise or not exercise their rights to organize and bargain collectively. By doing so, the proposed rule differentiated the handling of costs incurred through persuader activities, which are unallowable, from those incurred in maintaining satisfactory labor relations, which remain allowable. Specifically, the proposed rule stated that the costs of any activities undertaken to persuade employees, of any entity, to exercise or not to exercise, or concerning the manner of exercising, the right to organize and bargain collectively through representatives of

the employees' own choosing are unallowable. The proposed rule also identified examples of activities the costs of which are unallowable when performed in connection with persuader activities: (1) Preparing and distributing materials, (2) hiring or consulting legal counsel or consultants, (3) meetings (including paying the salaries of the attendees at meetings held for this purpose), and (4) planning or conducting activities by managers, supervisors, or union representatives during work hours. Based on a careful review of public comments, discussed below, DoD, GSA, and NASA have concluded that the proposed rule should be finalized with just one minor editorial change. Consistent with section 8 of the E.O. and standard FAR conventions (see FAR 1.108(d)), this rule shall apply to contracts resulting from solicitations issued on or after the rule's effective date.

II. Discussion and Analysis of the Public Comments

The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (the Councils) reviewed the public comments in the development of the final rule. Fourteen respondents submitted comments on the proposed rule. These responses included a total of 28 comments on 12 issues. Several respondents strongly supported the rule, with one respondent urging the proposed rule be finalized as soon as possible. Other respondents raised concerns which are addressed below.

A. Favors Unions

Comment: Two respondents asserted that the rule favors unions and penalizes contractors.

Response: Under this rule, the Government will treat as unallowable the costs of specified ''persuader'' activities that are not directly related to the contractor's provision of goods and services to the Government, in order to promote economy and efficiency in Government contracting. Moreover, certain costs undertaken by contractors that are incurred in maintaining satisfactory relations between the contractor and its employees continue to be allowable, whether or not the contractor's employees are represented by a union. In addition, certain activities undertaken with the union that are not otherwise unlawful, including costs associated with negotiating or administering collective bargaining agreements, are allowable under section 3 of E.O. 13494 and paragraph (a) of FAR 31.205–21 because they involve the maintenance of satisfactory labor relations between the contractor and its employees. Costs related to the development, implementation, and enforcement of neutrality agreements would also be allowable provided that none of the costs attributed to the agreements include unreasonable costs or costs of unallowable persuader activities or activities that are otherwise unlawful. (See comment ''F'' for additional discussion of neutrality agreements.) No change to the rule has been made in response to this comment.

B. Prohibits Certain Protected Contractor Activities

Comment: A number of respondents interpreted the rule to prohibit certain protected contractor activities, such as an employers' right to engage in speech that does not violate the National Labor Relations Act (NLRA). See 29 U.S.C. 158(c). As such, these respondents argued that E.O. 13494 is preempted by the NLRA, particularly in light of *Chamber of Commerce* v. *Brown,* 554 U.S. 60 (2008), in which the United States Supreme Court held that a State statute was preempted by the NLRA because it attempted regulation of speech about union-related activity that was within the zone of conduct intended by Congress to be left to market forces.

Response: This rule does not prohibit or otherwise regulate persuader activities; it only disallows the reimbursement of the costs of these activities under Federal contracts. The purpose of the rule is to promote economy and efficiency in Government contracting by excluding certain costs from reimbursement by the Government that are not directly related to the contractors' provision of goods and services to the Government. By doing so, the rule promotes the fiscally responsible handling of taxpayer funds. The State law at issue in *Brown* was rooted in ''California's policy judgment that partisan employer speech necessarily interferes with an employee's choice about whether to join or to be represented by a union.'' 554 U.S. at 69 (internal quotation omitted). By contrast here, neither the E.O. nor the rule in any way restrict the manner in which recipients of Federal funds may expend funds they receive from the Government or any other of their own funds, including funds a recipient received as a Government contractor for providing goods and services under Federal contracts. Instead, this rule preserves a contractor's freedom to spend its own funds however it wishes, whereas the State statute in *Brown* made it exceedingly difficult for employers to demonstrate that they had not used State funds for non-reimbursable purposes. (554 U.S. at 71–73). Moreover, unlike the State statute in *Brown,* this rule does not contain a ''formidable enforcement scheme'' involving ''compliance costs and litigation risks * * * calculated to make union-related advocacy prohibitively expensive for employers.'' *Id.* at 63, 71. To the contrary, the E.O. and this rule merely identify types of costs that are not allowed for reimbursement under the well-established Federal procurement scheme, which already contains mechanisms for submission to and review of contract costs by Federal agencies designed to avoid unnecessary Government expenditures. No additional enforcement burden or employer liability is established by the E.O. or this rule. As a result, this rule is consistent with the Court's holding in *Brown,* and does not run afoul of the NLRA.

C. Unclear Language

Comment: Several respondents stated that the proposed rule contained confusing or conflicting language or that the rule was unclear as to what costs are disallowed.

Response: The language added to the labor relations cost principle does not conflict with the existing language. As explained in section II.A. of this preamble, the existing language, now identified as FAR 31.205–21(a), identifies when costs are allowable. The language addressing the E.O., added at a new FAR paragraph 31.205–21(b), addresses costs incurred through persuader activities, which are unallowable.

D. Imposes Significant Compliance Burdens

Comment: A number of respondents contended that the rule imposes significant compliance burdens and accounting costs, including those incurred in distinguishing between allowable and unallowable costs.

Response: FAR 31.201–6 requires contractors to have an accounting system to segregate unallowable costs. The incremental costs of implementing and tracking an additional unallowable cost element will be minimal. No changes in the rule have been made in response to this comment.

E. Conflicts With 29 U.S.C. 433

Comment: One respondent believed that the proposed rule was in conflict with 29 U.S.C. 433, which requires that employers file reports with the Secretary of Labor if they engage in certain ''persuader activities'' defined in

that section. The respondent stated that section 433 defines these activities differently and more narrowly than E.O. 13494.

Response: The policies codified in the Labor-Management Reporting and Disclosure Act of 1959 (LMRDA), 29 U.S.C. 401 *et seq.,* and the E.O. are not in conflict. Nothing in the E.O. or the rule affects the scope of employer reporting obligations for purposes of section 203 of the LMRDA, 29 U.S.C. 433. As discussed above, the E.O. is designed to promote the policies of economy and efficiency in Federal Government contracting established in the Federal Property and Administrative Services Act, by excluding certain costs that are not directly related to the contractor's provision of goods and services to the Government, and to do so in a neutral manner that is consistent with that reflected in 29 U.S.C. 433.

F. Unreimbursable Costs

Comment: A respondent stated that unreimbursable costs, as addressed in the proposed rule, are too broad and ignore the realities that employers frequently reimburse employees for time spent in collective bargaining and further ignore the rise and prevalence of neutrality pacts between employers and unions, used by the parties to minimize labor disputes. The respondent further stated that employers and unions frequently cooperate to encourage employees to ratify a collective bargaining agreement reached by the employer and the employees' bargaining representative. The respondent suggested that the list of reimbursable expenses in FAR 31.205–21(a) be amended by adding immediately after the words ''employee publications'' the following: ''the costs of preparing for and conducting collective bargaining and the cost attributable to the ratification of collective bargaining agreements.''

Response: Inclusion of this suggested language in the rule is unnecessary. Under the final rule, the costs of collective bargaining that are not persuader activity under FAR 31.205–21(b) are covered by FAR 31.205–21(a), and would be allowable to the extent that the costs were reasonable, allocable, and not unallowable under another cost principle, and are otherwise lawful. (See response to comment in section II.A.) Neutrality agreements would be handled in similar fashion. These agreements are entered into by contractors and labor organizations and have often been used to establish mutually agreed-to restraints for reducing disputes associated with union representation. Therefore, costs associated with the development, negotiation, and enforcement of neutrality agreements would not normally be expected to involve any persuader activity. So long as that is the case, under the rule, costs associated with agreements of this kind would generally be allowable as part of the maintenance of satisfactory labor relations, provided that they do not represent persuader activity under FAR 31.205–21(b), are reasonable, allocable, not unallowable under another cost principle, and are otherwise lawful.

G. Contractors' Indirect Litigation Costs

Comment: A respondent stated that it is important to clarify that this rule applies to a contractor's indirect litigation costs which are directly associated with the activities described in FAR 31.205–21(b) and suggested that this clarification could be accomplished by adding a fifth example of unallowable costs to the four listed in the proposed rule, which states ''Costs of litigation or other legal proceedings arising on account of any activities described in paragraph (b) where it is determined by National Labor Relations Board, the National Mediation Board, a similar State or local administrative agency or a court of law that such activities were in violation of law or undertaken to persuade employees regarding their exercise of collective bargaining rights.''

Response: This suggested clarification is not necessary since FAR 31.201–6 already disallows costs that are directly associated with unallowable costs, including associated litigation costs under FAR 31.205–47.

H. Additional Examples

Comment: A respondent suggested that two additional examples of unallowable costs be added to the list of examples contained in the proposed rule. The first example would state that the costs of surveillance by video, email, or other means of employee organizing activities are unallowable costs. The second example would state that ''informal polling of employees as to their preferences for or against unionization is unlawful under the NLRA as a means of dissuading employees with respect to union activities, see, *e.g.,* Smithfield Foods, 347 N.L.R.B. 1225 (2006), and therefore, time spent by supervisors and others conducting informal polls during the pendency of a union organizing campaign is unrelated to contract performance and should be listed as an example of unallowable costs under the Executive Order.''

Response: Inclusion of these examples is not necessary. The examples in the rule are not exhaustive, but adequately cover the allowability of costs for a full range of lawful activities. Furthermore, the costs of activities that are unlawful, including unlawful activities under the NLRA, are not allowed under the FAR. FAR 31.201–3(b)(2) makes clear that costs incurred for unlawful activities shall not be reimbursed.

I. Contract Administration Activities

Comment: A respondent suggested that various contract administration activities be addressed in this rule, including that the contractors be required to update their accounting systems to account for the costs made unallowable by this rule; that contractors demonstrate to contracting officers that their accounting systems can effectively account for these unallowable costs; that contracting officers, upon issuance of the final rule, undertake supplemental reviews of the adequacy of the contractors' accounting systems to account properly for unallowable union persuasion costs; that contracting officers undertake an additional review of cost reimbursement claims to ensure that this new rule is being followed and the Government is not overcharged; that contractors certify on each bill or claim whether they have undertaken any activities to persuade employees concerning the manner of exercising their right to organize or bargain collectively and whether those costs have been accounted for and excluded from the reimbursement sought from the Federal Government; and that contracting officer's representatives include in their regular reports whether they know of any union persuasion activities the contractors may have undertaken during the reporting period.

Response: The FAR already contains coverage addressing the negotiation and administration of contracts that would cover these types of activities.

J. Role of Inspector General

Comment: A respondent stated that each agency should designate a member of the agency Inspector General's staff to collect information related to potentially unallowable union persuasion activities from employees or members of the public, some of whom may wish to remain anonymous, and refer that information to the contracting officer to facilitate billing reviews and audits as well as require that the Inspector General from each agency perform a review of the implementation of this rule within one year after the final rule goes into effect.

Response: This recommendation is outside the scope of this case, which was limited to the implementation of E.O. 13494 in the FAR. The FAR does not prescribe activities for Inspectors General.

K. Investigation of Reports of Employer Persuader Activities

Comment: A respondent stated that the final rule should make clear that contracting officers are to receive and investigate instances of employer persuader activities reported by workers or labor union representatives and that FAR 3.903 protects the right of the contractor's employees to report such activities. The respondent believed that the final rule should establish a process by which employees of Federal contractors or others with knowledge of employer persuasion costs can disclose that information to designated officials anonymously. Finally, the respondent believed that the final rule should state that FAR 33.209 applies to any Federal contractor who submits for reimbursement any costs made unallowable by this rule.

Response: These recommendations are outside the scope of this case, which was limited to the implementation of E.O. 13494. To the extent that FAR 3.903 and 33.209 are applicable, there is already adequate FAR coverage. Further, FAR subpart 3.10 also addresses contractor business ethics.

L. Regulatory Flexibility Act

Comment: Two respondents stated that the rule fails to comply with the Regulatory Flexibility Act. Both requested the basis for the stated conclusions and one requested the Councils to conduct an Initial Regulatory Flexibility Analysis.

Response: DoD, GSA, and NASA have certified that the rule will not have a significant economic impact on a substantial number of small entities. The Regulatory Flexibility Act certification is based upon an analysis of the data in the Federal Procurement Data System (FPDS). (See additional discussion in section IV, Regulatory Flexibility Act.) That certification states that most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive fixed-price basis, and thus do not require application of the cost principle contained in this rule. This is supported by the most recent data available from the FPDS. For Fiscal Year 2010, a search of FPDS revealed 1,822,515 awards to small businesses. Of these, 1,814,282 were fixed price (99.5 percent), and 1,220,154 (67 percent) were below the simplified acquisition threshold.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is a significant regulatory action and, therefore, was subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive fixed-price basis, and do not require application of the cost principles contained in this rule.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 31

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 31 as set forth below:

PART 31—CONTRACT COST PRINCIPLES AND PROCEDURES

■ 1. The authority citation for 48 CFR part 31 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

■ 2. Revise section 31.205–21 to read as follows:

31.205–21 Labor relations costs.

(a) Costs incurred in maintaining satisfactory relations between the contractor and its employees (other than those made unallowable in paragraph (b) of this section), including costs of shop stewards, labor management committees, employee publications, and other related activities, are allowable.

(b) As required by Executive Order 13494, Economy in Government Contracting, costs of any activities undertaken to persuade employees, of any entity, to exercise or not to exercise, or concerning the manner of exercising, the right to organize and bargain collectively through representatives of the employees' own choosing are unallowable. Examples of unallowable costs under this paragraph include, but are not limited to, the costs of—

(1) Preparing and distributing materials;

(2) Hiring or consulting legal counsel or consultants;

(3) Meetings (including paying the salaries of the attendees at meetings held for this purpose); and

(4) Planning or conducting activities by managers, supervisors, or union representatives during work hours.

[FR Doc. 2011–27790 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 4, and 8

[FAC 2005–54; Item X; Docket 2011–0078; Sequence 3]

Federal Acquisition Regulation; Technical Amendments

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This document makes amendments to the Federal Acquisition Regulation (FAR) in order to make editorial changes.

DATES: *Effective Date:* November 2, 2011.

FOR FURTHER INFORMATION CONTACT: The Regulatory Secretariat, 1275 First Street, NE., 7th Floor, Washington, DC 20417, (202) 501–4755, for information

pertaining to status or publication schedules. Please cite FAC 2005–54, Technical Amendments.

SUPPLEMENTARY INFORMATION: In order to update certain elements in 48 CFR parts 1, 4, and 8, this document makes editorial changes to the FAR.

List of Subjects in 48 CFR Parts 1, 4, and 8

Government procurement.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 1 and 8 as set forth below:

■ 1. The authority citation for 48 CFR parts 1, 4, and 8 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

PART 1—FEDERAL ACQUISITION REGULATIONS SYSTEM

1.106 [Amended]

■ 2. Amend section 1.106, in the table following the introductory text, by adding FAR segments ''52.215–22'' and ''52.215–23'' and their corresponding OMB Control Number ''9000–0173''.

PART 4—ADMINISTRATIVE MATTERS

4.604 [Amended]

■ 3. Amend section 4.604 in paragraph (c) by removing ''guidance, by January 5,'' and adding ''guidance, within 120 days after the end of each fiscal year,'' in its place.

PART 8—REQUIRED SOURCES OF SUPPLIES AND SERVICES

8.501 [Amended]

■ 4. Amend section 8.501 by removing ''*http://www.nm.blm.gov/www/amfo/amfo_home.html*'' and adding ''*http://blm.gov/8pjd*'' in its place.

[FR Doc. 2011–27791 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket FAR 2011–0077; Sequence 6]

Federal Acquisition Regulation; Federal Acquisition Circular 2005–54; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide.

SUMMARY: This document is issued under the joint authority of DOD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of rules appearing in Federal Acquisition Circular (FAC) 2005–54, which amend the Federal Acquisition Regulation (FAR). Interested parties may obtain further information regarding these rules by referring to FAC 2005–54, which precedes this document. These documents are also available via the Internet at *http://www.regulations.gov.*

DATES: For effective dates see separate documents, which follow.

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below. Please cite FAC 2005–54 and the specific FAR case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755.

LIST OF RULES IN FAC 2005–54

Item	Subject	FAR case	Analyst
I	Notification of Employee Rights Under the National Labor Relations Act	2010–006	McFadden.
II	Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions	2008–025	Robinson.
III	Small Disadvantaged Business Program Self-Certification	2009–019	Morgan.
IV	Certification Requirement and Procurement Prohibition Relating to Iran Sanctions	2010–012	Davis.
V	Representation Regarding Export of Sensitive Technology to Iran (Interim)	2010–018	Davis.
VI	Set-Asides for Small Business (Interim)	2011–024	Morgan.
VII	Sudan Waiver Process	2009–041	Davis.
VIII	Successor Entities to the Netherlands Antilles	2011–014	Davis.
IX	Labor Relations Costs	2009–006	Chambers.
X	Technical Amendments.		

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these FAR cases, refer to the specific item numbers and subject set forth in the documents following these item summaries. FAC 2005–54 amends the FAR as specified below:

Item I—Notification of Employee Rights Under the National Labor Relations Act (FAR Case 2010–006)

This rule adopts as final, without change, the interim rule that published in the **Federal Register** at 75 FR 77723 on December 13, 2010, implementing Executive Order (E.O.) 13496, Notification of Employee Rights Under Federal Labor Laws, as implemented by the Department of Labor (DOL). The E.O. requires contractors to display a notice for employees of their rights under Federal labor laws, and the DOL has determined that the notice shall include employee rights under the National Labor Relations Act.

Item II—Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions (FAR Case 2008–025)

This final rule amends the FAR to address personal conflicts of interest by employees of Government contractors, as required by section 841(a) of the Duncan Hunter National Defense Authorization Act for Fiscal Year 2009 (Pub. L. 110–417) (now codified at 41 U.S.C. 2303). This rule requires the contractor to take the steps necessary to identify and prevent personal conflicts

of interest for employees that perform acquisition functions closely associated with inherently governmental functions. The contracting officer shall consult with agency legal counsel for advice and recommendations on a course of action when the contractor reports a personal conflict of interest violation by a covered employee or when the contractor violates the clause requirements.

Item III—Small Disadvantaged Business Program Self-Certification (FAR Case 2009–019)

This rule adopts as final, without change, an interim rule that implements revisions made by the Small Business Administration (SBA) in its Small Disadvantaged Business (SDB) regulations. The FAR interim rule was published in the **Federal Register** at 75 FR 77737 on December 13, 2010, to allow SDBs to self-represent their SDB status to prime contractors in good faith when seeking Federal subcontracting opportunities. This FAR revision removed an administrative burden for SDB subcontractors to obtain SBA certification, as well as prime contractors, who were required to confirm that SDB subcontractors had obtained SBA certification.

Item IV—Certification Requirement and Procurement Prohibition Relating to Iran Sanctions (FAR Case 2010–012)

This rule adopts as final, with minor changes, an interim rule. The interim rule implemented sections 102 and 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010. Section 102 requires certification that each offeror, and any person owned or controlled by the offeror, does not engage in any activity for which sanctions may be imposed under section 5 of the Iran Sanctions Act of 1996. Section 106 imposes a procurement prohibition relating to contracts with persons that export certain sensitive technology to Iran. This rule will have little effect on domestic small business concerns, because such dealings with Iran are already generally prohibited under U.S. law.

Item V—Representation Regarding Export of Sensitive Technology to Iran (FAR Case 2010–018) (Interim)

This interim rule amends the FAR to include additional requirements to implement section 106 of the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010, Pub. L. 111–195. To enhance enforcement of section 106, the FAR will require each offeror to complete a representation that the offeror does not export certain sensitive technology to the government of Iran or any entities or individuals owned or controlled by or acting on behalf or at the direction of the government of Iran. This rule will have little effect on domestic small business concerns, because such dealings with Iran are already generally prohibited in the United States.

Item VI—Set-Asides for Small Business (FAR Case 2011–024) (Interim)

This interim rule amends the FAR to implement section 1331 of Public Law 111–240, the Small Business Jobs Act of 2010, providing agencies with the legal authority to set aside or reserve multiple-award contracts and orders.

Specifically, section 1331 authorizes agencies to (1) Set aside part or parts of multiple-award contracts; (2) set aside orders placed against multiple-award contracts; and (3) reserve one or more multiple-award contracts for small business concerns that are awarded using full and open competition.

The interim rule gives agencies an additional procurement tool to increase opportunities for small businesses to compete in the Federal marketplace.

Item VII—Sudan Waiver Process (FAR Case 2009–041)

This final rule amends the FAR to revise section 25.702, Prohibition on contracting with entities that conduct restricted business operations in Sudan. The rule adds specific criteria, including foreign policy aspects, that an agency must address when applying to the President or his appointed designee for a waiver of the prohibition on awarding a contract to a contractor that conducts restricted business operations in Sudan, in accordance with the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110–174). The rule also describes the consultation process that will be used by the Office of Federal Procurement Policy in support of the waiver review. The rule does not impose any requirements on small businesses.

Item VIII—Successor Entities to the Netherlands Antilles (FAR Case 2011–014)

This final rule amends FAR parts 25 and 52 to revise the definitions of ''Caribbean Basin country'' and ''designated country'' due to the change in status of the islands that comprised the Netherlands Antilles. On October 10, 2010, the Netherlands Antilles dissolved into five separate successor entities. The rule does not impose any requirements on small businesses.

Item IX—Labor Relations Costs (FAR Case 2009–006)

This final rule amends the FAR to implement Executive Order (E.O.) 13494, Economy in Government Contracting, issued on January 30, 2009, and amended on October 30, 2009. This E.O. treats as unallowable the costs of any activities undertaken to persuade employees, whether employees of the recipient of Federal disbursements or of any other entity, to exercise or not to exercise, or concerning the manner of exercising, the right to organize and bargain collectively through representatives of the employee's own choosing.

Item X—Technical Amendments

Editorial changes are made at FAR 1.106, 4.604, and 8.501.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2011–27794 Filed 11–1–11; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 2011; Docket No. 2011–0091; Sequence 1]

Review of Regulatory Coverage Regarding Prevention of Personal Conflicts of Interest for Contractor Employees (FAR PCI COMMENT)

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Request for information.

SUMMARY: DoD, GSA, and NASA in consultation with the Office of Federal Procurement Policy (OFPP) and the Office of Government Ethics (OGE), are seeking public comment on the question of whether additional guidance is necessary to address personal conflicts of interest by employees of Government contractors.

DATES: Interested parties should submit comments in writing to the Regulatory Secretariat at the address shown below on or before January 3, 2012.

ADDRESSES: Submit comments identified by ''FAR PCI COMMENT'' by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by inputting ''FAR PCI COMMENT'' under the heading ''Comment or Submission.'' Select the link ''Send a Comment or Submission'' that corresponds with FAR PCI COMMENT. Follow the instructions provided to complete the ''Public Comment and Submission Form.'' Please include your name, company name (if any), and ''FAR PCI COMMENT'' on your attached document.
- *Fax:* (202) 501–4067.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Hada Flowers, 1275 First Street, NE., Washington, DC 20417.

Instructions: Please submit comments only and cite ''FAR PCI COMMENT'' in all correspondence related to this case. All comments received will be posted, without change, to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Robinson, Procurement Analyst, at (202) 501–2658, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat division at (202) 501–4755. Please cite FAR PCI COMMENT.

SUPPLEMENTARY INFORMATION: DoD, GSA, and NASA, in close consultation with OFPP and OGE, have issued a final rule to address personal conflicts of interest by contractor employees performing acquisition functions closely associated with inherently governmental functions for, or on behalf of, a Federal agency or department. See FAR Case 2008–025, Preventing Personal Conflicts of Interest by Contractor Employees Performing Acquisition Functions, published concurrently with this notice. The rule implements provisions in section 841(a) of the Duncan Hunter National Defense Authorization Act (NDAA) for Fiscal Year 2009 (Pub. L. 110–417).

Section 841(b) further requires that OFPP conduct a review of the Federal Acquisition Regulation to determine whether coverage of personal conflicts of interest should be expanded beyond contractors whose work supports acquisition functions closely associated with inherently governmental functions. DoD, GSA, and NASA, in consultation with OFPP and OGE, are working together to implement this requirement. As part of their review, they seek public comment on the issue of expanded coverage, taking into account the coverage provided by FAR Case 2008–025, and especially welcome public comment in response to the following questions:

(1) Are there contracting methods, types, and services (other than those covered by FAR Case 2008–025) that raise heightened concerns for potential personal conflicts of interest?

(2) Should regulatory coverage be expanded to address personal conflicts of interest by contractor employees with respect to functions other than those covered by FAR Case 2008–025? If so, what additional functions should be considered to ensure policies for the prevention and mitigation of personal conflicts of interest are sufficiently rigorous, comprehensive, and uniform?

Responses to this notice will be taken into consideration by DoD, GSA, and NASA, in consultation with OFPP and OGE, as they evaluate the need for additional guidance on personal conflicts of interest.

Dated: October 21, 2011.

Laura Auletta,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2011–27795 Filed 11–1–11; 8:45 a.m.]

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FEDERAL REGISTER

Vol. 76 Wednesday,

No. 212 November 2, 2011

Part VI

The President

Memorandum of October 28, 2011—Making It Easier for America's Small Businesses and America's Exporters to Access Government Services to Help Them Grow and Hire

Federal Register
Vol. 76, No. 212
Wednesday, November 2, 2011

Presidential Documents

Title 3—

The President

Memorandum of October 28, 2011

Making It Easier for America's Small Businesses and America's Exporters to Access Government Services to Help Them Grow and Hire

Memorandum for the Heads of Executive Departments and Agencies

As I outlined in my State of the Union address to the Congress on January 25, 2011, winning the future in the global economy will require a Government that wisely allocates its scarce resources to maximize efficiency and effectiveness so that it can best support American competitiveness, innovation, and job growth. If we are to thrive in the global economy, and make America the best place on Earth to do business, we need to equip our Government with the tools necessary to support innovation and job growth in the 21st century.

Accordingly, we must make it easier for businesses to access the full range of Government programs and services without having to waste effort navigating their way through the Federal bureaucracy. At the same time, we must further streamline and coordinate Federal programs to reduce costs and provide customer-oriented service.

Businesses looking for assistance from the Federal Government should feel like they are interacting with one entity, rather than a number of separate, albeit linked, components. This means adopting a ''No Wrong Door'' policy that uses technology to quickly connect businesses to the services and information relevant to them, regardless of which agency's website, call center, or office they go to for help.

In addition, a business's interactions with the Federal Government should be individualized and efficient. If the private sector can allow consumers to customize interactions so that they receive only the information they want, in the form they want it, so can the Federal Government.

Today, I am directing a first wave of changes focused on both small businesses and businesses of all sizes that want to begin or increase exporting (exporters), because those businesses help drive economic growth and have the most to gain from Federal assistance. We plan to use the resulting improvements as a model for future reforms so that, in time, all businesses and all citizens receive the highest level of customer service when they interact with the Federal Government.

Accordingly, I direct the following:

(1) All executive departments and agencies (agencies) shall work with a Steering Committee co-chaired by the Federal Chief Information Officer, Assistant to the President and Chief Technology Officer, and Chief Performance Officer (the Co-Chairs) to carry out the directives in this memorandum within 90 days of the date of this memorandum, unless a provision of this memorandum expressly states otherwise. The Steering Committee shall include senior policy and technical representatives, appointed by the heads of their respective agencies, from the Departments of State, Defense, Agriculture, Commerce, and Veterans Affairs, the Small Business Administration (SBA), the General Services Administration (GSA), the Export-Import Bank,

and other agencies designated by the Co-Chairs. The Co-Chairs and representatives from the Department of Commerce and SBA shall serve as the Executive Committee of the Steering Committee, which shall coordinate the strategy, design, development, launch, and operation of BusinessUSA, a common, open, online platform and web service with dedicated resources that will, as a first step, disseminate core information regarding the Federal Government's programs and services relevant to small businesses and exporters.

(2) Agencies shall work with the Steering Committee to develop and launch an introductory version of BusinessUSA. BusinessUSA shall be designed, tested, and built with the active feedback of U.S. businesses and relevant online communities. To the extent appropriate, practicable, and permitted by law, the BusinessUSA platform shall integrate related State and local government services as well as those of private sector partners.

(3) Agencies shall make information regarding their small business and export programs and services accessible through BusinessUSA. To accomplish this in a uniform fashion, the Steering Committee shall develop a common set of standards for content available through BusinessUSA, which shall identify the types of programs and services to be included initially on BusinessUSA and a structure for organizing and presenting such information. These standards shall be used by all agencies in the creation, presentation, and delivery of information regarding their programs and services, to the extent practicable and permitted by law.

(4) Agencies shall also work with the Steering Committee to develop new content for BusinessUSA that synthesizes information available across agencies to better serve small businesses and exporters. Among other things, agencies shall work together to aggregate on the BusinessUSA platform statistical, demographic, and other raw Government datasets of particular interest to small businesses and exporters, making Government data more easily accessible and spurring innovative uses of the data through business-oriented web or mobile applications.

(5) Agencies shall integrate BusinessUSA, including ready access to the BusinessUSA website, into their current websites, call centers, and field offices to ensure that small businesses and exporters have access to the wide range of Government programs and services at each entry point into the Federal Government. During the year following the date of this memorandum, agencies shall work with GSA and the Office of Management and Budget to enhance the centralized call center for responding to public questions about Federal programs and services (1–800–FED–INFO) to add expertise with Government programs and services for small businesses and exporters.

(6) (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law or Executive Order to an agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) BusinessUSA shall be operated by a single hosting agency under the Executive Committee's coordination. To the extent permitted by law, agencies shall reimburse the hosting agency for the cost of establishing, maintaining, and operating BusinessUSA.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(7) The Director of the Office of Management and Budget is authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, October 28, 2011.

[FR Doc. 2011–28593
Filed 11–1–11; 11:15 am]
Billing code 3110–01–P

FEDERAL REGISTER

Vol. 76 Wednesday,

No. 212 November 2, 2011

Part VII

The President

Notice of November 1, 2011—Continuation of the National Emergency With Respect to Sudan

Federal Register
Vol. 76, No. 212
Wednesday, November 2, 2011

Presidential Documents

Title 3—

The President

Notice of November 1, 2011

Continuation of the National Emergency With Respect to Sudan

On November 3, 1997, by Executive Order 13067, the President declared a national emergency with respect to Sudan, pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706), to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States posed by the actions and policies of the Government of Sudan. On April 26, 2006, in Executive Order 13400, the President determined that the conflict in Sudan's Darfur region posed an unusual and extraordinary threat to the national security and foreign policy of the United States, expanded the scope of the national emergency to deal with that threat, and ordered the blocking of property of certain persons connected to the conflict. On October 13, 2006, the President issued Executive Order 13412 to take additional steps with respect to the national emergency and to implement the Darfur Peace and Accountability Act of 2006 (Public Law 109–344).

Because the actions and policies of the Government of Sudan continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, the national emergency declared on November 3, 1997, as expanded on April 26, 2006, and with respect to which additional steps were taken on October 13, 2006, must continue in effect beyond November 3, 2011. Therefore, consistent with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Sudan.

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

THE WHITE HOUSE,
November 1, 2011.

[FR Doc. 2011–28620
Filed 11–1–11; 2:00 pm]
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To extend the Generalized System of Preferences, and for other purposes. (Oct. 21, 2011; 125 Stat. 401)

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